



Centauri PFA System

Abstract Booklet

April 2026

Tips for Easy Navigation

- 1 Within each topic, publications are sorted by year in descending order
- 2 Each entry is linked to the respective abstract page within this document

1

Table of Contents

Chapter

1. Author. Journal. 20233

2. Author. Journal. 20224

3. Author. Journal. 20215

2

- 3 The journal name is linked to the online publication

Chapter

1

Publication Title

Author Name

3

JOURNAL 2023

- 4 Link to the table of contents

Table of Contents

Foundational Science

1. Neal R., Heart Rhythm Journal, Aug 2021 9
The Influence of Heterogeneous Environments on Pulsed Electric Field Therapy Effects: Implications in Cardiac Ablation
2. Perez J., & Suarez A., Plos One, Nov 2023 10
How Intramyocardial Fat Can Alter the Electric Field Distribution During Pulsed Field Ablation (PFA): Qualitative Findings from Computer Modeling
3. Verma A. Et AL., Jacc, Sep 2023 11
Thermal Profiles for Focal Pulsed Electric Field Ablation

Preclinical Research

4. Nakagawa H., Et AL., Heart Rhythm Journal, Aug 2021 14
Histological Characterization of Reversible and Irreversible Ventricular Lesion Boundaries Produced by Pulsed Field Ablation
5. Jerltorp K., et al., EP Europace, May 2025 16
Stiffness assessment of acute atrial lesions after radiofrequency and pulsed-field ablation using multifrequency magnetic resonance elastography
6. Mohaissen T., et al., EHRA 2026, April 2026 18
Acute monopolar biphasic pulsed field-mediated effects on coronary endothelial function and vascular integrity: the Vasc-PFA study
7. Gil-Ramirez A., et al., EHRA 2026, April 2026 20
Impact of cardiac muscle metabolism and calcium load on lesion formation by pulsed-field electroporation in pig ventricles
8. Nakagawa H., Et AL., Heart Rhythm, May 2022 22
Assessment Of Lesion Durability Produced by Pulsed Electric Field Ablation: Evaluation in a Swine Atrial Linear Lesion Mode
9. Nakagawa H., Et AL., Heart Rhythm, May 2022 23
Temporal And Spatial Evolution of Reversible and Irreversible Ventricular Lesion Boundaries Produced by Pulsed Field Ablation
10. Verma A., Et AL., Journal of Cardiovascular Electrophysiology, Nov 2022 25
Characteristics Of Pulsed Electric Field Cardiac Ablation Porcine Treatment Zones with a Focal Catheter
11. Sandhu U. Et AL., Europace, Apr 2023 26
In Vivo Pulsed-Field Ablation in Healthy Vs. Chronically Infarcted Ventricular Myocardium: Biophysical and Histologic Characterization
12. Nakagawa H. et al., Circulation, Dec 2023 27
Effects of Contact Force on Lesion Size During Pulsed Field Catheter Ablation: Histochemical Characterization of Ventricular Lesion Boundaries
13. Alkukhun L. Et AL., Jice May 2023 28
Multi-Modality Imaging Assessment of Microbubbles and Cerebral Emboli in Left Ventricular Pulsed Field Ablation

14. Evans J. Et AL., Heart Rhythm Journal, Aug 2021 29
The Susceptibility and Recovery of Esophageal Tissue Layers to Pulsed Electric Fields
15. Evans J., Castellvi Q., & Neal R., Heart Rhythm Journal, Aug 2021 30
Biphasic Focal Monopolar Pulsed Electric Field Therapy: Preserved Phrenic Nerve Function and Anatomy

Sponsored Clinical Investigations

16. Verma, A. Et AL., Heartrhythm, May 2022 32
Pulmonary Vein Isolation (PVI) And Posterior Wall Isolation (PWI) For Atrial Fibrillation Using Point-By-Point Pulsed Electric Fields: Space AF Acute Results
17. Anic, A. Et AL., Europace, Jun 2023 33
Pulsed Field Ablation Using Focal Contact Force–Sensing Catheters for Treatment of Atrial Fibrillation: 1-Year Outcomes of the Eclipse AF Study
18. Anic, A, Et AL., Circulation, Dec 2024 34
Pulsed Field Ablation Using Focal Contact Force–Sensing Catheters for Treatment of Atrial Fibrillation: 1-Year Outcomes of the Eclipse AF Study

Investigator-Led Studies

19. Wenzel J. Et AL., Circulation: Arrhythmia And Electrophysiology, Aug 2023 39
Nonthermal Point-By-Point Pulmonary Vein Isolation Using a Novel Pulsed Field Ablation System
20. Starek, Z. Et AL., Europace, May 2025 40
A Prospective Randomized Clinical Comparison of Catheter Ablation of Atrial Fibrillation Using the Centauri PEF System and Standard Radiofrequency Ablation
21. Wenzel J. Et AL., Heart Rhythm, Mar 2024 41
Repeat Pulmonary Vein Isolation and Anterior Line Ablation Using a Novel Point-By-Point Pulsed-Field Ablation System
22. Farnir, F. Et AL., Europace, May 2025 43
A Tailored Substrate-Based Approach Using Focal Pulsed Field Ablation in Patients with Symptomatic Atrial Fibrillation and Advanced Atrial Substrate : Procedural Data and 6-Months Success Rates
23. Sirotic, T., Prolic Kalinsek, T., Jan, M & Stublar, J., Europace, May 2025 45
RFA Vs PFA In Posterior Wall Isolation for PeAf: A Single Center Prospective Study - Preliminary Results
24. Farnir, F. Et AL., Europace, May 2025 46
Cavo-Tricuspid Isthmus Dependent Flutter Ablation Using a Focal Monopolar Pulsed-Field Ablation Catheter
25. Weyand S. Et AL., Journal Of Clinical Medicine, Jan 2024 48
Focal Pulsed Field Ablation for Atrial Arrhythmias: Efficacy and Safety Under Deep Sedation
26. Auf Der Heiden, C., Et AL., Europace, May 2025 49
Hemolysis After Pulsed Field Ablation in Pulmonary Vein Isolation: A Prospective Controlled Trial
27. Farnir F. Et AL, Jice, Mar 2024 51
Impedance Drop During Focal Monopolar Pulsed Field Ablation in the Atrium

28.	Erhard, N., Et AL., Heart Rhythm, Jan 2025 Focal Pulsed Field Ablation in Complex Atrial Tachycardia: First Clinical Experience And 1-Year Outcome	52
29.	Cespon Fernandez, M., Et AL., Ep Europace, May 2024 First Experience of Focal Pulsed Field Ablation for Premature Ventricular Contractions	53
30.	Peichl P. Et AL., Europace, Jul 2024 Efficacy And Safety of Focal Pulsed-Field Ablation for Ventricular Arrhythmias: Two-Centre Experience	55
31.	Della Rocca, D., Et AL., Circ A&E, Sep 2024 Focal Pulsed Field Ablation for Premature Ventricular Contractions: A Multicenter Experience	56
32.	Ruwald, M., Et AL., Heart Rhythm, Feb 2025 Feasibility and Midterm Effectiveness of Focal Pulsed Field Ablation for Ventricular Arrhythmias	58

Case Series

33.	Ruwald M. Et AL., Journal of Interventional Cardiac Electrophysiology, May 2023 Focal Pulsed Field Ablation and Ultrahigh-Density Mapping — Versatile Tools for All Atrial Arrhythmias? Initial Procedural Experiences	60
34.	De Asmundis C. Et AL., Europace, Jan 2024 Redo Procedures After Sinus Node Sparing Hybrid Ablation for Inappropriate Sinus Tachycardia/Postural Orthostatic Sinus Tachycardia	61
35.	Farnir F. Et AL., Heart Rhythm, Jan 2024 Focal point-by-point pulsed field ablation for the treatment of atrial arrhythmias in patients with challenging anatomy where radiofrequency ablation cannot be applied: A case series	62
36.	Chaldoupi, S., Et AL., Heart Rhythm, Oct 2024 Focal Monopolar Pulsed Field Ablation from within the Great Cardiac Vein for Idiopathic Premature Ventricular Contractions after failed Radiofrequency Ablation	63
37.	Breskovic T. Et AL., Heart Rhythm, Aug 2024 Ablation of Accessory Pathways in Different Anatomic Locations Using Focal Pulsed Field Ablation	64
38.	Heart Rhythm, Vol 23, No 4, April 2026 Monopolar biphasic focal pulsed field ablation directly at the atrioventricular junction and from within the noncoronary cusp: The PFA-CONDUCT study	65
39.	Farnir F. Et AL., Europace, Mar 2024 Focal Point-By-Point Biphasic Monopolar Pulsed Field Ablation for Posterior Wall Isolation	66
40.	Sikiric I. Et AL., Jice, Jan 2024 Focal Pulsed Field Ablation for Guiding And Assessing The Acute Effect of Cardioneuroablation	67

Case Reports

- | | | |
|-----|---|----|
| 41. | Weyand S. Et AL., Jice, Mar 2023
First in human focal pulsed field ablation to treat an epicardial VT focus with an endocardial approach in non-ischemic cardiomyopathy | 69 |
| 42. | Worck R. Et AL, Heart Rhythm O2, Jul 2023
A case of safe and durable focal pulsed field electroporation treatment of outflow tract premature ventricular contractions | 70 |
| 43. | Hansen J., Heart Rhythm, Aug 2023
Focal pulsed field electroporation of left ventricular premature contractions after failed radiofrequency ablation | 71 |
| 44. | Mestrovic I. Et AL., Journal of Cardiovascular Electrophysiology, Jan 2024
Ablation of Epicardial Ventricular Focus Through Coronary Sinus Using Pulsed-Field Ablation. A Case Report | 72 |
| 45. | Cespon-Fernandez M. Et AL., Jacc, Jun 2024
Sequential Unipolar Biventricular Pulsed Field Ablation for Refractory Intramural Septal Ventricular Tachycardia | 73 |
| 46. | Spenkelink, D., Et AL., European Heart Journal, Sep 2024
Pulsed field ablation as a feasible option for the treatment of epicardial left ventricular summit premature complex foci near the coronary arteries: A case report | 74 |
| 47. | Santos, R., Et AL., Heartrhythm O2, Nov 2024
Ventricular tachycardia: Focal pulsed field electroporation as a rescue therapy | 75 |
| 48. | Phlips T. Et AL., Heart Rhythm Case Reports, Mar 2023
Pulsed Field Ablation Using a Focal Contact Force Catheter Allowed Successful Ablation of a Focal Right Atrial Tachycardia in the Proximity of The Phrenic Nerve | 76 |

Glossary

77

Keyword Index

Keyword	Reference (Title)	Page
Atrial Fibrillation (AF)	SPACE AF Acute Results (PVI + PWI)	32
Atrial Fibrillation (AF)	Centauri IDE 90-Day Results	33
Atrial Fibrillation (AF)	Centauri IDE 12-Month Results (ECLIPSE AF)	34
Ventricular Tachycardia (VT)	Two-Centre Ventricular Arrhythmia Study	55
Ventricular Tachycardia (VT)	Feasibility and Midterm Effectiveness Study	58
Ventricular Tachycardia (VT)	Epicardial VT Case (Endocardial Approach)	69
Ventricular Tachycardia (VT)	VT Rescue Therapy Case	75
Premature Ventricular Contractions (PVCs)	First Experience PVC Study	53
Premature Ventricular Contractions (PVCs)	Multicenter PVC Study	56
Premature Ventricular Contractions (PVCs)	Outflow Tract PVC Case	70
Atrial Flutter (CTI)	CTI Flutter Ablation Study	46
Accessory Pathways	Accessory Pathway Ablation Study	64
Pulmonary Vein Isolation (PVI)	SPACE AF Acute Results	32
Pulmonary Vein Isolation (PVI)	Acute + 90-Day Remapping Study	33
Pulmonary Vein Isolation (PVI)	ECLIPSE AF 1-Year Outcomes	34
Pulmonary Vein Isolation (PVI)	Nonthermal PVI Study	39
Posterior Wall Isolation (PWI)	SPACE AF Acute Results	32
Posterior Wall Isolation (PWI)	PFA vs RFA Posterior Wall Study	45
Posterior Wall Isolation (PWI)	Biphasic Monopolar PWI Study	67
Redo / Repeat Ablation	Repeat PVI + Anterior Line Study	41
Substrate-Based Ablation	Tailored Substrate Approach Study	43
Esophageal Safety	Esophageal Tissue Recovery Study	29
Phrenic Nerve	Biphasic PEF Phrenic Safety Study	30
Phrenic Nerve	RA Tachycardia Near Phrenic Nerve	76
Coronary / Vascular	Vasc-PFA Study	18
Coronary / Vascular	Great Cardiac Vein PVC Study	63
Coronary / Vascular	LV Summit Case	74
Hemolysis	Hemolysis After PVI Study	49
Cerebral Emboli / Microbubbles	Microbubble Imaging Study	28
Sedation	Deep Sedation Safety Study	48
Lesion Formation	Porcine Treatment Zone Study	25
Lesion Boundaries	Histological Boundary Study	14
Lesion Boundaries	Temporal Evolution Study	23
Lesion Durability	Swine Durability Study	22
Lesion Durability	Remapping Studies (AF)	33,34
Contact Force	Contact Force Lesion Study	27
Impedance	Impedance Drop Study	51
Electric Field Modeling	Heterogeneous Environment Study	9
Electric Field Modeling	Intramyocardial Fat Modeling Study	10
Biphasic / Monopolar PFA	PFA-CONDUCT Study	65
Epicardial Access	Epicardial VT Case	74

Foundational Science

The Influence of Heterogeneous Environments on Pulsed Effects: Implications in Cardiac Ablation

Author

Robert Evans Neal, PhD

HEART RHYTHM JOURNAL, AUG 2021

Background

Pulsed electric field (PEF) therapy kills cells in targeted tissues via mechanisms dependent on local field effects, where different tissue layers will distort this distribution.

Objective

Numerically evaluate the implications of the heterogeneous electrical conductivity tissues surrounding cardiac ablation sites on the spatial distribution of PEF ablation effects.

Methods

A numerical model was created using human CT images and well-established tissue conductivity parameters to estimate the thoracic electric field and current distributions from a focal monopolar electrode delivering PEF to the endocardium.

Results

Electrically heterogeneous environments surrounding cardiac ablation sites affects the spatial distribution of the electric field and current flow during PEF. Discontinuities of conductivity at tissue planes have a dispersive effect on the strength of the field with the most significant diminution of field strength occurring immediately adjacent to the myocardium at the high-impedance fibrous pericardium. These results indicate a protective effect from the heterogeneous tissue layers in the thoracic environment, reducing electric field exposures to extra-cardiac tissues. The pericardial fluid-sac system disperses and insulates the electric current from reaching critical structures in the extra-cardiac environment.

Conclusion

The electrically heterogeneous tissue layers surrounding the heart provide a protective effect to adjacent tissue during the application of PEF. These data support previously described preclinical and clinical findings of spared sensitive tissues, including esophagus, following PEF therapy.

How Intramyocardial Fat Can Alter the Electric Field Distribution During Pulsed Field Ablation (PFA): Qualitative Findings from Computer Modeling

Authors

Juan J. Pérez, Ana González-Suárez

PLOS ONE, NOV 2023

Abstract

Even though the preliminary experimental data suggests that cardiac pulsed field ablation (PFA) could be superior to radiofrequency ablation (RFA) in terms of being able to ablate the viable myocardium separated from the catheter by collagen and fat, as yet there is no formal physical-based analysis that describes the process by which fat can affect the electric field distribution. Our objective was thus to determine the electrical impact of intramyocardial fat during PFA by means of computer modeling. Computer models were built considering a PFA 3.5-mm blunt-tip catheter in contact with a 7-mm ventricular wall (with and without a scar) and a 2-mm epicardial fat layer. High voltage was set to obtain delivered currents of 19, 22 and 25 a. An electric field value of 1000 v/cm was considered as the lethal threshold. We found that the presence of fibrotic tissue in the scar seems to have a similar impact on the electric field distribution and lesion size to that of healthy myocardium only. However, intramyocardial fat considerably alters the electrical field distribution and the resulting lesion shape. The electric field tends to peak in zones with fat, even away from the ablation electrode, so that 'cold points' (i.e. low electric fields) appear around the fat at the current entry and exit points, while 'hot points' (high electric fields) occur in the lateral areas of the fat zones. The results show that intramyocardial fat can alter the electric field distribution and lesion size during PFA due to its much lower electrical conductivity than that of myocardium and fibrotic tissue.

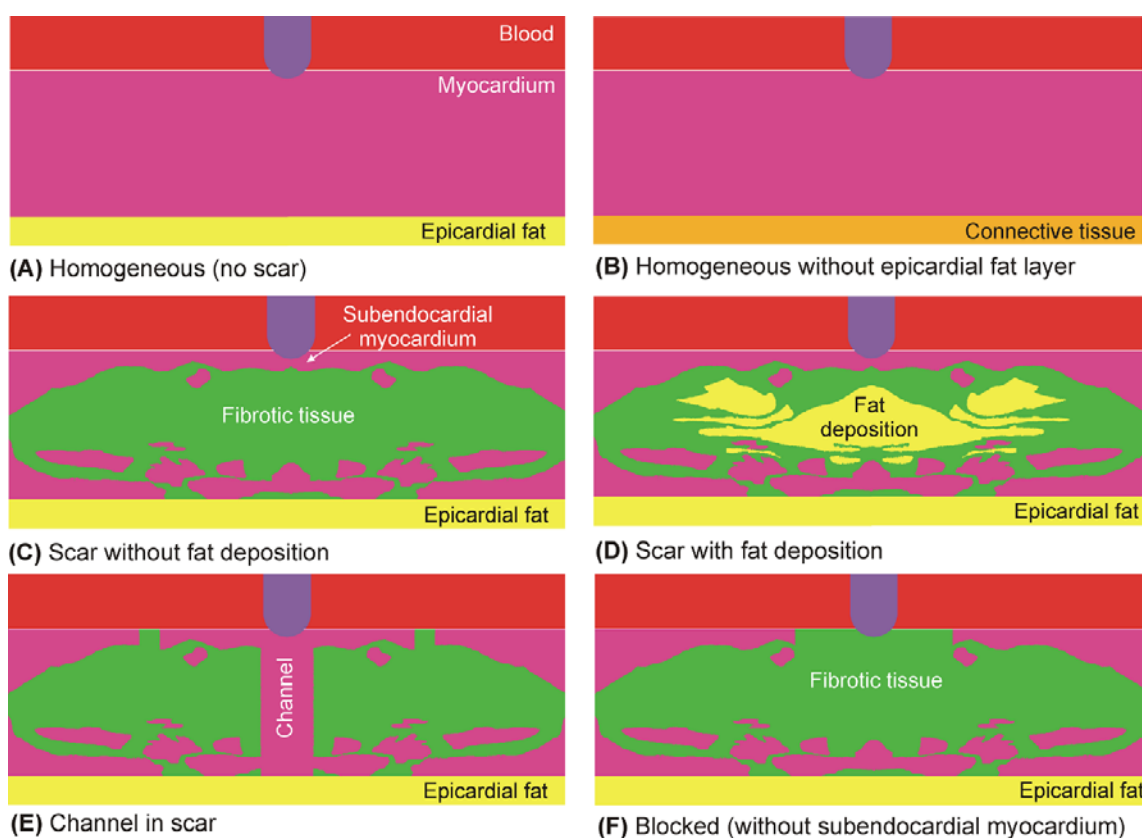


Fig 1. Details of the Modeled Ventricular Walls Consisting of Different Tissues: Myocardium, Fibrotic Tissue and Fat.

Thermal Profiles for Focal Pulsed Electric Field Ablation

Author

Verma A. Et Al

JACC, SEP 2023

Background

Pulsed electrical field (PEF) ablation may cause tissue heating. These changes are reportedly small, but each PEF system and waveform will have a different behavior, and data are lacking.

Objective

This study sought to compare the temperature profile of focal point, monopolar biphasic PEF ablation versus radiofrequency (RF).

Methods

Ablation lesions were performed on perfused thigh muscle of swine. PEF lesions were performed with 3 compatible ablation catheters at the highest (25 amp) energy, and 1 catheter (tacticath se) was also used at the 22- and 19-amp levels. Temperature changes in the tissue were measured using fluoroptic temperature probes inserted at the muscle surface, as well as 3 mm and 7 mm below the surface. Temperatures were recorded continuously at baseline, during delivery, and after ablation. Muscle temperatures were compared with those of RF lesions performed with 1 catheter (tacticath se) at 30 w for 30 seconds.

Results

Electrically heterogeneous environments surrounding cardiac ablation sites affects the spatial distribution of the electric field and current flow during PEF. Discontinuities of conductivity at tissue planes have a dispersive effect on the strength of the field with the most significant diminution of field strength occurring immediately adjacent to the myocardium at the high-impedance fibrous pericardium. These results indicate a protective effect from the heterogeneous tissue layers in the thoracic environment, reducing electric field exposures to extra-cardiac tissues. The pericardial fluid-sac system disperses and insulates the electric current from reaching critical structures in the extra-cardiac environment.

Conclusion

PEF caused detectable temperature changes in muscle tissue, which never exceeded 2.8 °c at the 3-mm depth versus baseline. By contrast, RF produced substantial Temperature Rises. These data support that focal monopolar biphasic energy delivered by this PEF technology retains a favorable thermal safety profile.

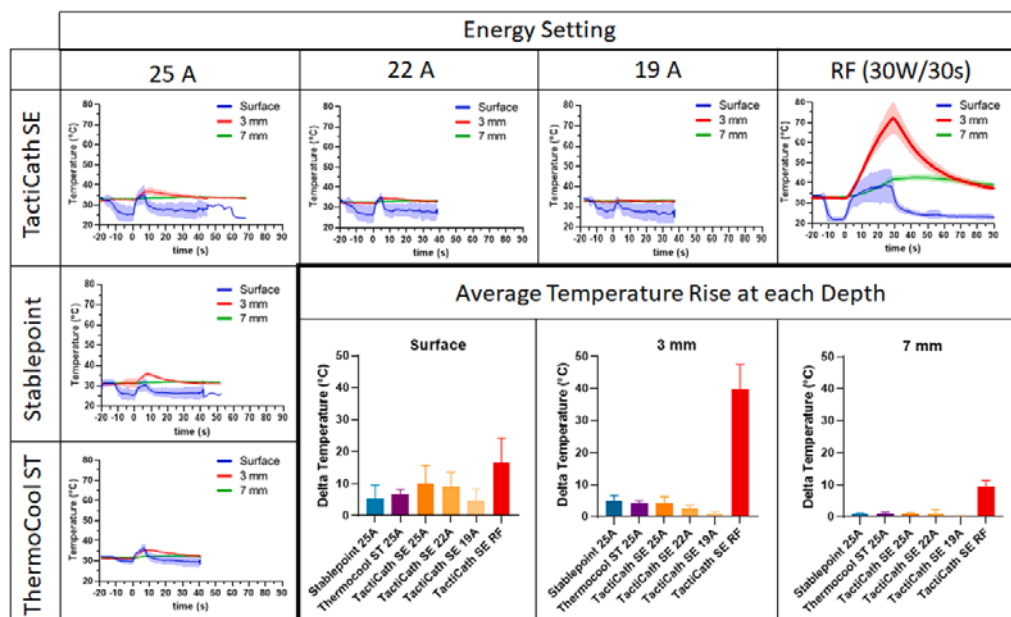


Figure 1 temperature changes observed during pulsed electrical field and radiofrequency ablation. Temporal evolution and average temperature rise at each depth for all tested devices and treatment doses, including the radiofrequency (rf) comparison dose. A = amps.

Ablation Catheter	Energy Setting	Activation Duration	Ablation Duration	Test Ablations
TactiCath SE	RF (30 W/30 s) @ 17 mL/min	30 s	30.0 s	9
TactiCath SE	19 amps @ 4 mL/min	1.4 ms	2.7 s	10
TactiCath SE	22 amps @ 4 mL/min	2.4 ms	4.7 s	10
TactiCath SE	25 amps @ 4 mL/min	3.4 ms	6.7 s	12
Thermocool ST	25 amps @ 4 mL/min	3.4 ms	6.7 s	10
StablePoint	25 amps @ 4 mL/min	3.4 ms	6.7 s	10
Total				61

PEF = pulsed electric field; RF = radiofrequency.

Table 1 PEF And RF Ablation Conditions

Preclinical Research

Histological Characterization of Reversible and Irreversible Ventricular Lesion Boundaries Produced by Pulsed Field Ablation

Authors

Nakagawa H., Et AL.

HEART RHYTHM JOURNAL, AUG 2021

Background

During pulsed field ablation (PFA), electric pulses induce reversible (R) or irreversible (IR) injury on cardiac myocytes.

Objective

To perform histological examination of acute ventricular lesions produced by PFA, determining R and IR injury boundaries in a swine heart model.

Methods

A 7F catheter with a 3.5mm ablation electrode (Tacticath, Abbott) was connected to a pulsed electric field (PEF) generator (Centaury, galaxy medical) and positioned in RV and LV under EnSite guidance in 2 closed chest pigs. Biphasic PEF current was delivered between the ablation electrode and a skin patch at 13 RV sites (28amp, total pulse width of 1.4ms, 4 pulses) and 19 LV sites (35amp, 1.6ms, 7 pulses). Two hours after ablation, triphenyl tetrazolium chloride (TTC) was administered. Pigs were sacrificed and hearts were excised and fixed in formalin. Hearts were sectioned and stained with hematoxylin and eosin (H&E) and masson trichrome. Cytochrome C Oxidase (COX) staining was also performed to examine mitochondrial activity to delineate R and IR lesion boundaries.

Results

Fig. Ablation lesions were well demarcated with TTC staining, showing a dark central zone surrounded by pale boundaries (PB). Histology showed destruction of myocyte architecture within the PB. A hyperstained (dark red) rim beyond the PB indicates R zone. COX staining showed no or low mitochondrial activity within the PB, consistent with IR ablated region. Enhanced activity of COX staining extended to unaffected normal myocardium, consistent with R zone.

Conclusion

Acute ventricular lesions produced by PEF ablation show clear demarcation by TTC staining. COX staining suggests that IR lesions are surrounded by R zone.

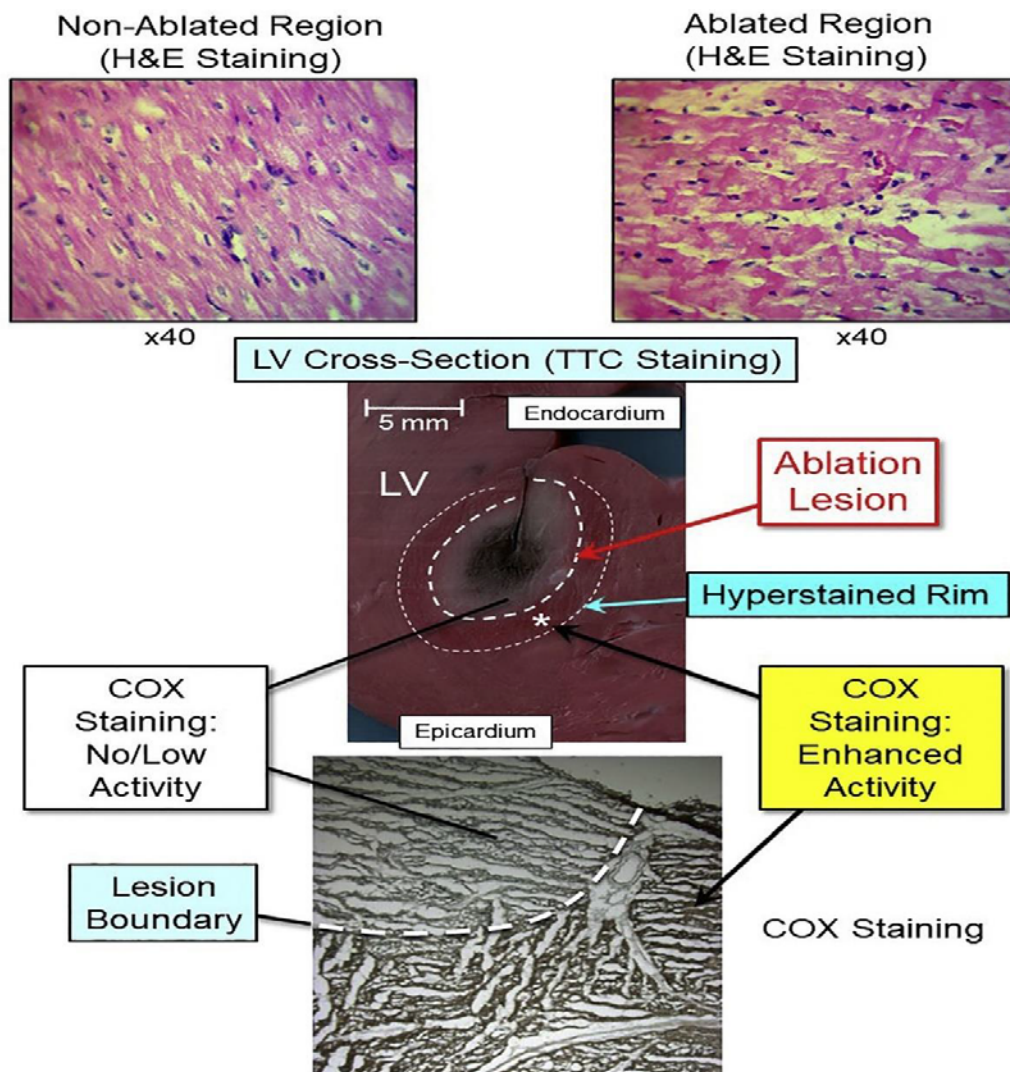


Fig 1 Ablation Lesions Were Well Demarcated with TTC Staining, Showing A Dark Central Zone Surrounded by Pale Boundaries (PB). Histology Showed Destruction of Myocyte Architecture Within the Pb. A Hyperstained (Dark Red) Rim Beyond the Pb Indicates R Zone. COX Staining Showed No or Low Mitochondrial Activity Within the Pb, Consistent with IR Ablated Region. Enhanced Activity of Cox Staining Extended to Unaffected Normal Myocardium, Consistent with R Zone.)

Stiffness assessment of acute atrial lesions after adiofrequency and pulsed-field ablation using multifrequency magnetic resonance elastography

Author

Jerltorp K., et al.

EP EUROPACE, MAY 2025

Background

Extensive catheter ablation beyond pulmonary vein isolation may acutely increase atrial tissue stiffness, however, this may differ between energy sources used.

Objective

This study aimed to compare acute effects of radiofrequency ablation (RFA) and pulsed field ablation (PFA) on atrial tissue stiffness in a porcine model using multifrequency magnetic resonance elastography (MMRE).

Methods

In 17 pigs (50 kg and 16 weeks old) an intercaval line was ablated using only focal RFA (25 W, 30 sec, n=9), only focal monopolar biphasic PFA (CENTAURI PFA generator, 25 A, 10 pulse trains, n=5), or half of the ablation line with PFA and the other half with RFA (n=3) (Figure 1,A). Post-ablation, in vitro MMRE data were acquired with a tabletop MRE scanner (ttMRE) (n=8) (Figure 1,B). In vivo, a novel MMRE protocol utilizing electrocardiography-triggered spin-echo, echo-planar-imaging was established (n=11) (Figure 1,C). Shear wave speed (SWS) was reconstructed as a surrogate for tissue stiffness.

Results

In vitro ttMRE measurements revealed significantly higher SWS for the RFA ablation zone compared to both the PFA ablation zone (p=0.008) and PFA border zone (p=0.003). Consistently, a novel in vivo MMRE protocol showed 1.37-fold higher SWS of the RFA ablation zone than its border zone (p=0.016) and 1.16-fold higher SWS than the PFA ablation zone (p=0.033). Absolute in vivo SWS differences between ablation zones and border zones were significantly higher for RFA compared to PFA (p=0.019).

Conclusion

RFA produces stiffer acute atrial lesions compared to PFA in pigs. A novel MMRE scanning protocol allows RFA and PFA lesion evaluation in vivo with the potential to support the refinement of future catheter approaches by optimizing mechanical properties of ablation lesions and minimizing atrial stiffness.

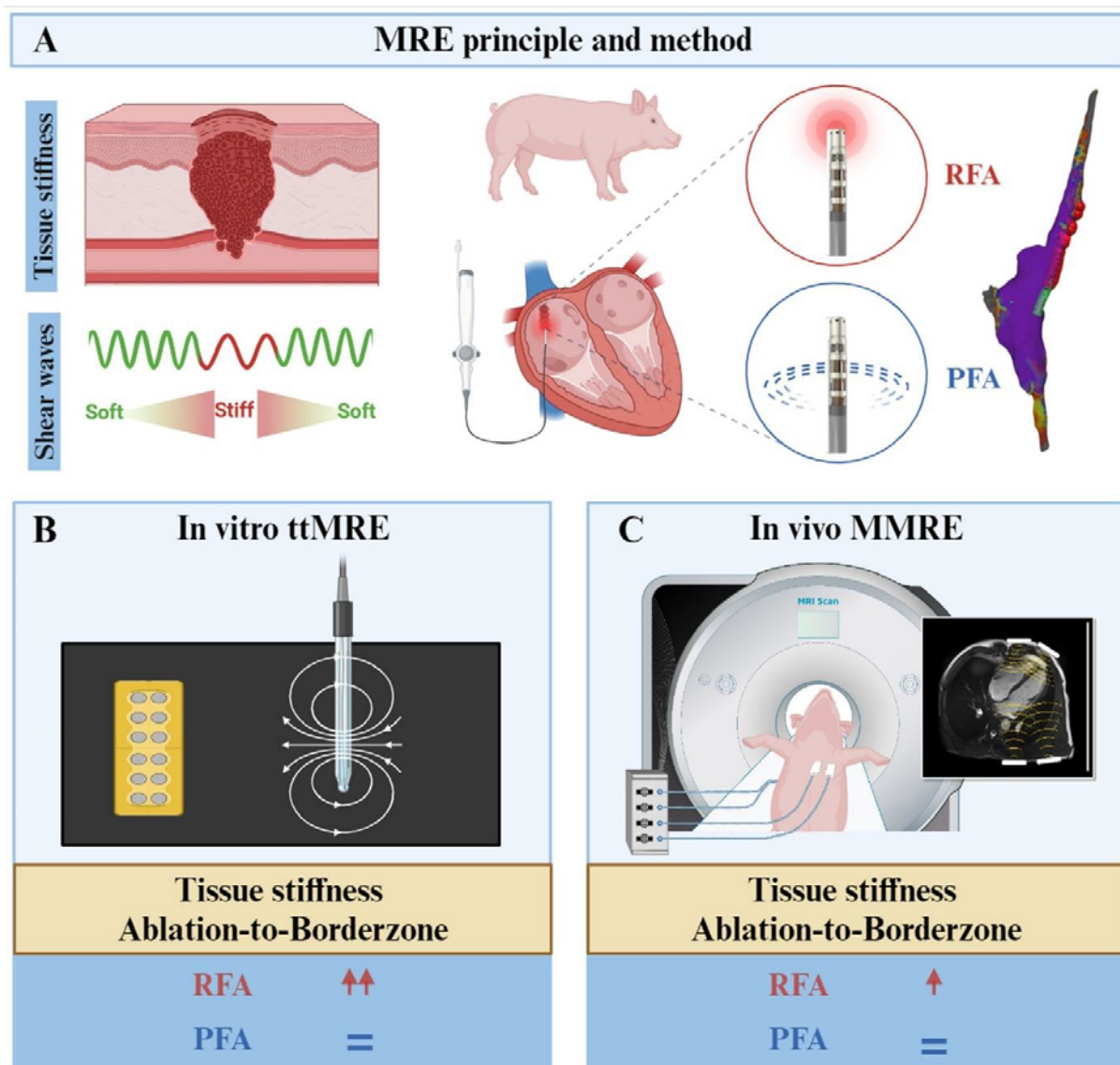


Fig 1 A Post-ablation, in vitro MMRE data were acquired with a tabletop MRE scanner (ttMRE) (n=8) (Figure 1,B). In vivo, a novel MMRE protocol utilizing electrocardiography-triggered spin-echo, echo-planar-imaging was established (n=11) (Figure 1,C). Shear wave speed (SWS) was reconstructed as a surrogate for tissue stiffness

Acute monopolar biphasic pulsed field-mediated effects on coronary endothelial function and vascular integrity: the Vasc-PFA study

Author

Mohaissen T., et al.

EHRA 2026, APRIL 2026

Background

Reports of acute coronary vasospasm and delayed stenosis following pulsed-field ablation (PFA) have raised concerns about its vascular safety. Although coronary spasms are generally transient and responsive to nitroglycerin, the effects of PFA on endothelial function and vascular integrity remain unknown. In this respect, more knowledge is needed, especially when PFA is delivered in close proximity to coronary arteries, such as during cavotricuspid isthmus (CTI) ablation, ablation within the great cardiac vein (GCV), or epicardial PFA applications.

Aim

To evaluate the acute effect of PFA on endothelial and smooth muscle function in clinically relevant scenarios involving PFA application in close proximity to coronary arteries in a porcine model.

Methods

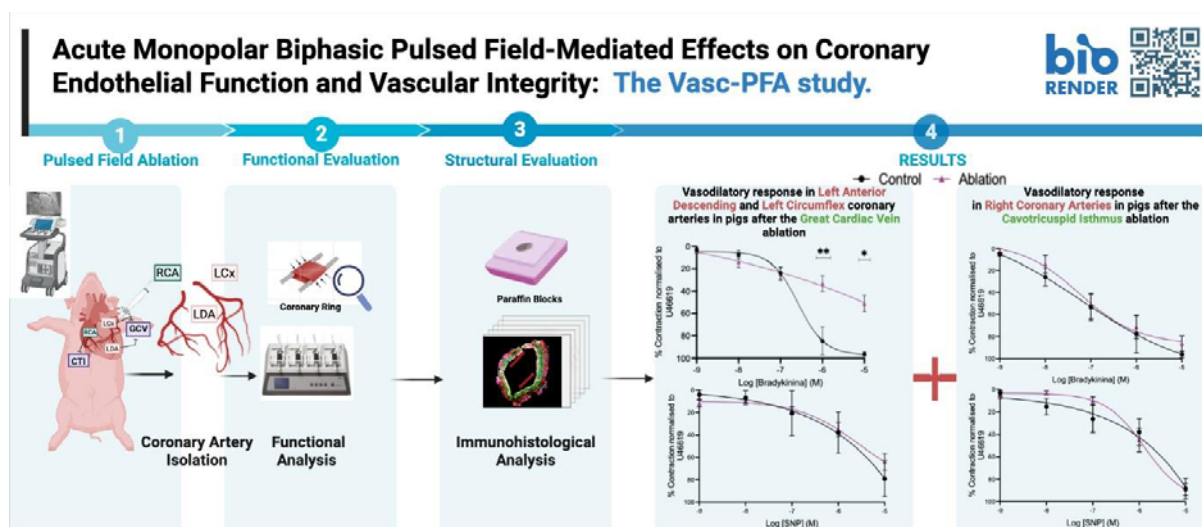
Landrace–Yorkshire–Duroc pigs (~50 kg, ~16 weeks old) underwent PFA using the CENTAURI generator with a focal monopolar biphasic waveform (25 A, 10 pulse trains) targeting the left anterior descending (LAD) and left circumflex (LCx) arteries through the great cardiac vein (GCV) (n = 9) and the right coronary artery (RCA) via the CTI (n = 5). After approximately 30–60 minutes, coronary artery segments were isolated post-ablation and mounted in a wire myograph to assess endothelium-dependent (using the endothelial agonist bradykinin) and endothelium-independent relaxation (using the NO donor nitroprusside). Coronary artery sections were sampled and processed in parallel for immunobiological analysis to assess vascular and endothelial integrity.

Results

In the LAD and LCx, the GCV-delivered PFA significantly reduced endothelium-dependent (bradykinin-induced) vasodilation compared with control ($p < 0.05$), whereas endothelium-independent (nitroprusside-induced) relaxation remained intact. Histological analysis demonstrated endothelial loss in the PFA-treated LAD/LCx segments, whereas the smooth muscle layer was still intact. In contrast, no significant alterations were observed in the structure or function of coronary arteries after CTI ablation in the RCA region. Both bradykinin-induced, endothelium-dependent vasodilation and sodium nitroprusside-induced, endothelium-independent relaxation remained intact.

Conclusion

PFA delivered near the coronary arteries from within the GCV, but not via the CTI, can induce localized endothelial dysfunction in the acute phase after the resolution of the coronary spasm. The preservation of smooth muscle cell function, which remains responsive to NO donors, explains why nitroglycerin effectively alleviates these spasms in the clinic. Further studies are needed to understand the long-term vascular consequences of endothelial damage of PFA when applied in close proximity to major coronary vessels.



Impact of cardiac muscle metabolism and calcium load on lesion formation by pulsed-field electroporation in pig ventricles

Author

Gil-Ramirez A., et al.

EHRA 2026, APRIL 2026

Background

Catheter pulsed field ablation (PFA) is used increasingly to create cardiac muscle specific lesions to treat arrhythmias. While most current research has focused on optimizing catheter design and energy delivery parameters, less attention has been given to tissue determinants of lesion formation. Evidence suggests that calcium overload and changes in metabolism may enhance PFA-induced cellular injury and lesion development; however, this has not yet been systematically studied.

Purpose

To assess whether increased oxidative metabolism or increased calcium load to tissue enhances PFA lesion formation in the ventricle.

Methods

Twelve female Landrace pigs (~50 kg) received focal left ventricular (LV) PFA lesions using the Cardiofocus CENTAURI PFA-generator (25A, 10 pulse-trains) via a contact-force ablation catheter (ThermoCool SmartTouch Catheter, Biosense Webster). The PFA was performed during calcium infusion (n=3), during isoprenaline and rapid pacing (n=5); or without intervention (n=4). After 1.5 hours, the animals were euthanised, and lesions (depth, width, and transmural) were assessed using 1% TTC (2,3,5-triphenyltetrazolium chloride).

Results

71 monopolar biphasic PFA lesions were delivered in the LV (5-7 lesions per pig, Figure 1, left). TTC staining showed ellipsoid lesions with a haemorrhagic core surrounded by a sharp demarcated pale non-viable zone (Figure 1, mid). Mean lesion depth was: 7.3, 8.2, and 7.8mm; width: 10.2, 11.4, and 11.4mm; volume: 212.4, 288.7, and 287.1mm³, and transmural: 53.7%, 57.8%, and 56.2% in the calcium, isoprenaline, and control, respectively (Figure 1, right). None of the interventions changed the size of the lesions significantly (p>0.5).

Conclusion

Application of focal PFA produced reproducible ventricular lesions that were deep relative to wall thickness and within the upper range reported for ventricular focal PFA lesions. The lesions were not modified by augmented metabolic stress or increased calcium delivery to the tissue.

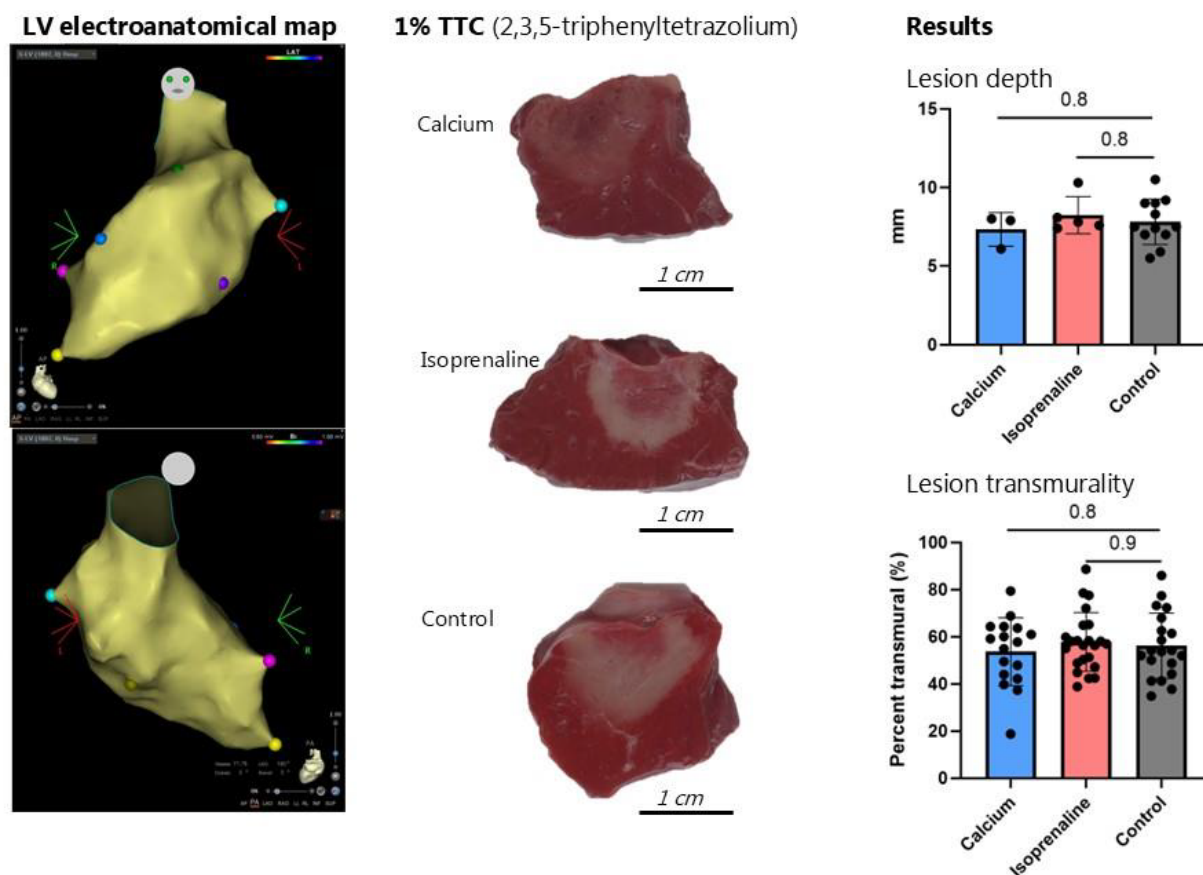


Fig 1 TTC staining showed ellipsoid lesions with a haemorrhagic core surrounded by a sharp demarcated pale non-viable zone (Figure 1, mid). Mean lesion depth was: 7.3, 8.2, and 7.8mm; width: 10.2, 11.4, and 11.4mm; volume: 212.4, 288.7, and 287.1mm³, and transmural: 53.7%, 57.8%, and 56.2% in the calcium, isoprenaline, and control, respectively (Figure 1, right). None of the interventions changed the size of the lesions significantly ($p \geq 0.5$).

Assessment Of Lesion Durability Produced by Pulsed Electric Field Ablation: Evaluation in a Swine Atrial Linear Lesion Model

Author

Nakagawa H., Et AL.

HEART RHYTHM, MAY 2022

Background

Pulsed electric field (PEF) ablation may cause durable or transient injury to cardiac myocytes.

Objective

To examine acute and chronic integrity of the line of conduction block produced by PEF ablation in a swine heart model.

Methods

A 7F catheter with a 3.5 mm ablation electrode (Tacticath, Abbott) was connected to a PEF generator (Centauri, galaxy medical) and positioned in RA and LA under EnSite guidance in 4 closed chest pigs. Using the lowest energy output settings of the PEF system (19 a, 1.4 ms), biphasic PEF current was delivered between the ablation electrode and a skin patch. A total of 10 linear ablations were performed in the SVC (n=3), inter-caval region (n=4) and right superior pulmonary vein (n=3) using point-by-point ablation (average CF: 15 g) with different inter-lesion distances (ILD): 12-15 mm (n=1), 6-8 mm (n=5) and 4 mm (n=4). Conduction block/isolation was assessed acutely (4 pigs) and 14 days (3 pigs) after index procedures.

Results

Complete elimination of electrograms on the ablation catheter was typically observed after the first PEF application. Complete line of block/isolation was obtained acutely in all 10 lines, confirmed by EnSite activation and voltage maps. At 14 days, recovery of conduction was observed in 4/5 (80%) lines with 6-8 mm ILD and 0/4 lines with 4 mm ILD ($p<0.05$). Gaps in linear lesions were confirmed by gross pathology in 4 lines with reconnection using TTC staining.

Conclusion

At the lowest PEF dose, acute conduction block can be consistently achieved with large ILD. While all 4 mm ILD lesions remained durable, recovery of conduction at 14 days was often observed for $ILD \geq 6$ mm, suggesting durable lesion sizes between 4-5 mm surrounded by transiently stunned myocardium.

Temporal And Spatial Evolution of Reversible and Irreversible Ventricular Lesion Boundaries Produced by Pulsed Electric Field Ablation

Author

Nakagawa H., Et AL.

HEART RHYTHM, MAY 2022

Background

During pulsed electric field (PEF) ablation, electric pulses induce reversible (R) or irreversible (IR) injury on cardiac myocytes. Using triphenyl tetrazolium chloride (TTC) staining, we have reported that acute PEF ablation lesions show a dark central zone (DCZ, contraction band necrosis and hemorrhage) surrounded by pale boundary (pb, no mitochondrial activity, consistent with IR zone) and a hyperstained rim (HR, indicating enhanced mitochondrial activity) beyond the PB, indicating R zone.

Objective

To assess histologically the spatial extent and temporal evolution of PEF ablation lesions in a swine model.

Methods

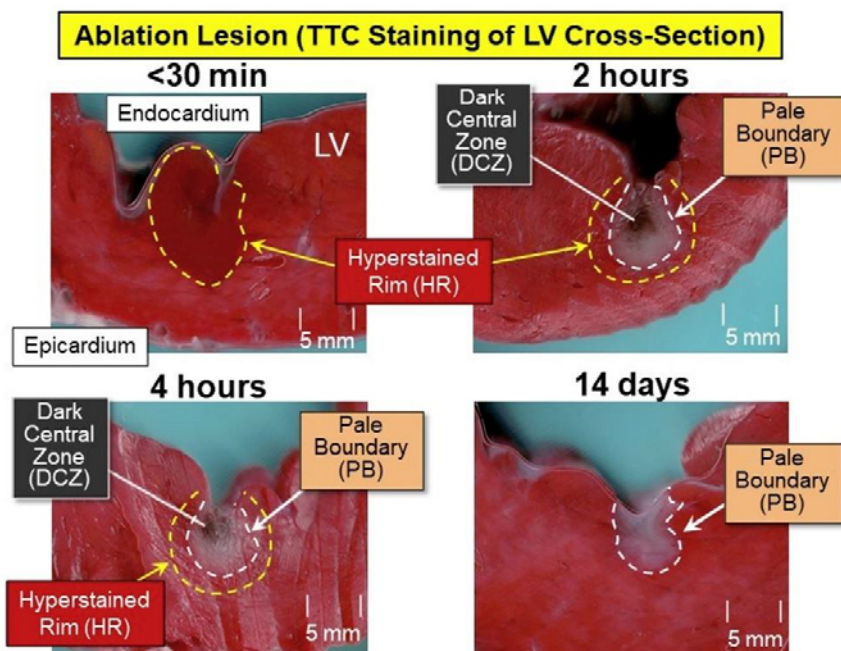
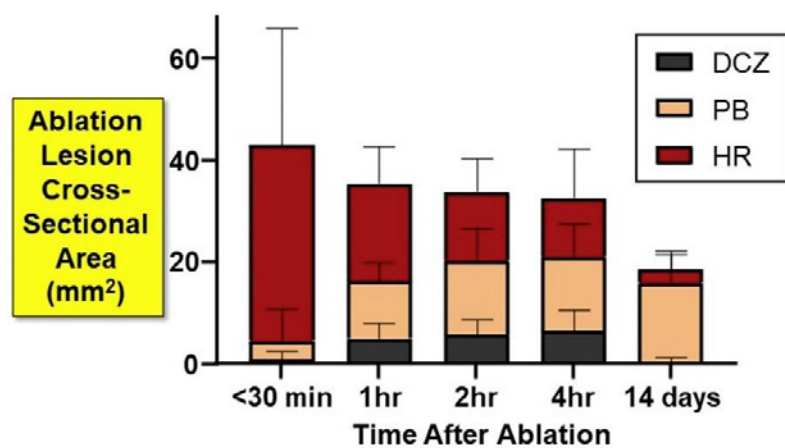
A 7fr catheter with a 3.5 mm ablation electrode (Tacticath, Abbott) was connected to a PEF generator (Centauri, galaxy medical) and positioned in RV and LV under EnSite guidance in 4 closed chest pigs. Biphasic PEF current (19 a, total duration 1.4 ms) was delivered between the ablation electrode and a skin patch at 50 ventricular sites at different target timepoints of <30 min, 1hr, 2hrs, 4hrs and 14 days after ablation. TTC was infused prior to animal sacrifice.

Results

Fig. The HR was initially greatest (<30 min) and gradually decreased over time while pb increased up to 4hr after ablation. The DCZ became evident only after 1hr and increased up to 4hr after ablation. At 14 days, ablation lesions show slightly smaller pb with no or minimal DCZ and hr. Histology showed fibrosis within the pb at 14 days, consistent with IR zone.

Conclusion

TTC staining showed dynamic temporal and spatial evolution of the DCZ, PB and HR. The large initial HR zone indicates IR lesions are surrounded by relatively large r zone even 4hrs after ablation, suggesting the mechanism of transient conduction block during PEF ablation.



Characteristics Of Pulsed Electric Field Cardiac Ablation Porcine Treatment Zones with a Focal Catheter

Author

Verma A., Et Al..

JOURNAL OF CARDIOVASCULAR ELECTROPHYSIOLOGY, NOV 2022

Background

During pulsed electric field (PEF) ablation, electric pulses induce reversible (R) or irreversible (IR) injury on cardiac myocytes. Using triphenyl tetrazolium chloride (TTC) staining, we have reported that acute PEF ablation lesions show a dark central zone (DCZ, contraction band necrosis and hemorrhage) surrounded by pale boundary (pb, no mitochondrial activity, consistent with IR zone) and a hyperstained rim (HR, indicating enhanced mitochondrial activity) beyond the PB, indicating R zone.

Objective

Pulsed electric field (PEF) therapies employ punctuated energy delivery to kill cells in a volume of tissue through mechanisms that are not dependent on thermal processes. A key component to successful cardiac ablation procedures is ensuring the generation of transmural, contiguous ablation zones, which requires in-depth knowledge regarding treatment sizes for a given therapeutic application.

Methods

In this study, a series of acute treatments were delivered to porcine ventricles, where triphenyl tetrazolium chloride (TTC) vitality stain was used to identify treatment effect sizes for the three focal monopolar Centauri PEF cardiac ablation energy settings.

Results

Treatment depths were 5.7, 7.2, and 8.2 mm for the 19, 22, and 25 an energy settings, respectively. Gross pathology indicated umbral zones of hemorrhage surrounded by pale avital TTC-negative-negative tissue, which contrasted significantly from radiofrequency ablation (RF) controls. Histologically, treatment zones are identified by regions of contraction band necrosis and cardiomyocytolysis, which contrasted with RF control lesions composed primarily of coagulation necrosis.

Conclusion

Together, these data indicate the ability for focal monopolar PEF treatments to generate deep treatment zones in cardiac ablation without incurring the gross or histological coagulative characteristics of RF thermal lesions.

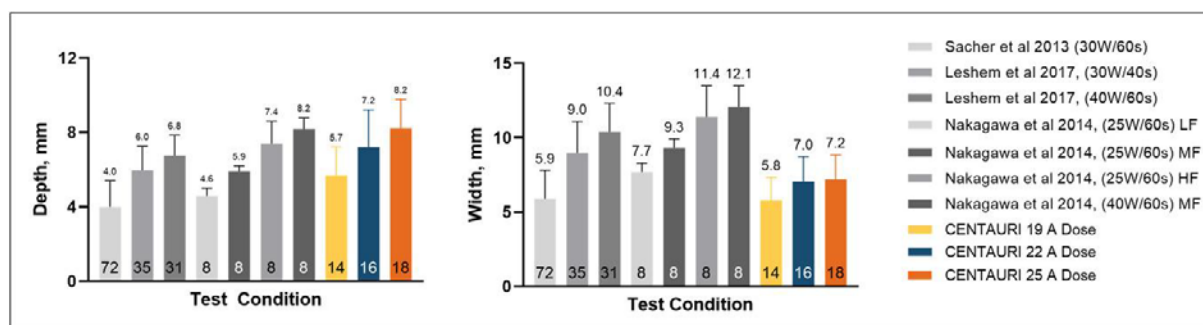


Fig 1 comparing focal monopolar PEF ventricle ablation depths (left) and widths (right) with RF. RF contact forces indicated by low force (LF, 3–8 g), medium force (MF, 18–27 g), and high force (HF, 40–62 g). Trial numbers for each test condition are indicated inside the bars. PEF, pulsed electric field; RF, radiofrequency

In Vivo Pulsed-Field Ablation in Healthy Vs. Chronically Infarcted Ventricular Myocardium: Biophysical and Histologic Characterization

Author

Sandhu U. Et Al.

EUROPACE, APR 2023

Aims

Data on ventricular pulsed-field ablation (PFA) are sparse in the setting of chronic myocardial infarction (MI). The objective of this study was to compare the biophysical and histopathologic characteristics of PFA in healthy and MI swine ventricular myocardium.

Methods and results

Myocardial infarction swine (n = 8) underwent coronary balloon occlusion and survived for 30 days. We then performed endocardial unipolar, biphasic PFA of the MI border zone and a dense scar with electroanatomic mapping and using an irrigated contact force (CF)-sensing catheter with the Centauri system (galaxy medical). Lesion and biophysical characteristics were compared with three controls: MI swine undergoing thermal ablation, MI swine undergoing no ablation, and healthy swine undergoing similar PFA applications that included linear lesion sets. Tissues were systematically assessed by gross pathology utilizing 2,3,5-triphenyl-2h-tetrazolium chloride staining and histologically with haematoxylin and eosin and trichrome. Pulsed-field ablation in healthy myocardium generated well-demarcated ellipsoid lesions (7.2 ± 2.1 mm depth) with contraction band necrosis and myocytolysis. Pulsed-field ablation in MI demonstrated slightly smaller lesions (depth 5.3 ± 1.9 mm, $p = 0.0002$), and lesions infiltrated into the irregular scar border, resulting in contraction band necrosis and myocytolysis of surviving myocytes and extending to the epicardial border of the scar. Coagulative necrosis was present in 75% of thermal ablation controls but only in 16% of PFA lesions. Linear PFA resulted in contiguous linear lesions with no gaps in gross pathology. Neither CF nor local r-wave amplitude reduction correlated with lesion size.

Conclusion

Pulsed-field ablation of a heterogeneous chronic MI scar effectively ablates surviving myocytes within and beyond the scar, demonstrating promise for the clinical ablation of scar-mediated ventricular arrhythmias.

Table 1. PFA lesions in healthy versus chronically infarcted tissue

	Healthy LV myocardium (46 applications, 44 lesions)	Chronic MI (89 applications, 49 lesions)	P-value
Contact force (g)	13.3 ± 4.9	13.1 ± 5.6	0.864
R-wave pre-ablation (mV)	4.5 ± 2.4	1.1 ± 0.6	<0.0001
R-wave post-ablation (mV)	2.1 ± 1.2	0.7 ± 0.4	<0.0001
R-wave reduction (%)	53 ± 23	34 ± 22	0.0002
Depth (mm)	7.2 ± 2.1	5.3 ± 1.9	0.0002
Width (mm)	5.5 ± 1.2	5.1 ± 1.4	0.344
Volume (mm ³)	470 ± 244	310 ± 166	0.002

LV, left ventricular; MI, myocardial infarction.

Effects of Contact Force on Lesion Size During Pulsed Field Catheter Ablation: Histochemical Characterization of Ventricular Lesion Boundaries

Author

Nakagawa H. et al.

CIRCULATION, DEC 2023

Background

Effects of contact force (CF) on lesion formation during pulsed field ablation (PFA) have not been well validated. The purpose of this study was to determine the relationship between average CF and lesion size during PFA using a swine-beating heart model.

Methods

A 7F catheter with a 3.5-mm ablation electrode and CF sensor (TactiCath SE, Abbott) was connected to a PFA system (CENTAURI, Galvanize Therapeutics). In 5 closed-chest swine, biphasic PFA current was delivered between the ablation electrode and a skin patch at 40 separate sites in right ventricle (28 Amp) and 55 separate sites in left ventricle (35 Amp) with 4 different levels of CF: (1) low (CF range of 4–13 g; median, 9.5 g); (2) moderate (15–30 g; median, 21.5 g); (3) high (34–55 g; median, 40 g); and (4) no electrode contact, 2 mm away from the endocardium. Swine were sacrificed at 2 hours after ablation, and lesion size was measured using triphenyl tetrazolium chloride staining. In 1 additional swine, COX (cytochrome c oxidase) staining was performed to examine mitochondrial activity to delineate reversible and irreversible lesion boundaries. Histological examination was performed with hematoxylin and eosin and Masson trichrome staining.

Results

Ablation lesions were well demarcated with triphenyl tetrazolium chloride staining, showing (1) a dark central zone (contraction band necrosis and hemorrhage); (2) a pale zone (no mitochondrial activity and nuclear pyknosis, indicating apoptosis zone); and a hyperstained zone by triphenyl tetrazolium chloride and COX staining (unaffected normal myocardium with preserved mitochondrial activity, consistent with reversible zone). At constant PFA current intensity, lesion depth increased significantly with increasing CF. There were no detectable lesions resulting from ablation without electrode contact.

Conclusion

Acute PFA ventricular lesions show irreversible and reversible lesion boundaries by triphenyl tetrazolium chloride staining. Electrode-tissue contact is required for effective lesion formation during PFA. At the same PFA dose, lesion depth increases significantly with increasing CF.

Multi-Modality Imaging Assessment of Microbubbles and Cerebral Emboli in Left Ventricular Pulsed Field Ablation

Author

Alkukhun L. Et Al.

JICE MAY 2023

Background

Pulsed field ablation (PFA) may have a superior safety profile compared to other technologies, but it has the potential to cause gaseous microbubbles (MB), which may be associated with cerebral emboli. Limited relative safety data has been published regarding PFA in the left ventricle (LV).

Methods

Healthy and chronic myocardial infarction (mi) swine underwent PFA (monopolar, biphasic, 25 amps) in the lv using an irrigated focal catheter under intra-cardiac echocardiography (ICE) guidance for mb monitoring. Two control swine received air MBs through the lumen of the ablation catheter. Swine underwent brain MRI before and after PFA (or control air mb injection). Gross pathology and histology of brains with abnormal MRI findings were performed.

Results

Four healthy and 5 chronic MI swine underwent 124 left ventricular PFA applications. No PFA-related MB formation was noted on ICE. Both control swine developed multiple acute emboli in the thalamus and caudate on DWI, ADC, and flair brain MRI images in response to air MB injection. Of the 9 PFA swine, there were no abnormalities on ADC or flair images. There was one hyperintense focus in the left putamen on the DWI trace image, but the absence of ADC or flair affirmation suggested it was artifact. Gross pathology and histopathology of this region did not detect any abnormalities.

Conclusion

Focal monopolar biphasic PFA of both healthy and chronically infarcted left ventricular myocardium does not generate any MB or cerebral emboli observable on ICE and brain MRI.

The Susceptibility and Recovery of Esophageal Tissue Layers to Pulsed Electric Fields

Author

Evans J. Et Al.

HEART RHYTHM JOURNAL, AUG 2021

Background

Thermal cardiac ablation can cause collateral esophageal injury that may degenerate to an atrio-esophageal fistula. Pulsed electric fields (PEFs) induce cell death independently from thermal processes, potentially preventing esophageal damage. However, the implications of worst-case treatment effects to the esophagus must be characterized.

Objective

This preclinical animal study evaluates the acute and chronic effects of PEFs to esophageal tissue.

Methods

Monopolar, biphasic PEF therapy was applied directly to the esophageal mucosa in 3 swine using a commercial focal ablation catheter and clinically applicable treatment parameters (n=6 per pig). Irrigation (10-17ml/min) was provided during treatment to compensate for blood flow. Survivals were acute (n=1) and 28-day (n=2). The esophagus was removed, gross examination was performed, and regions of interest were submitted for histology.

Results

Acute PEF grossly resulted in focal pale regions in the mucosa which extended transmurally through the serosa. Histology indicated affected regions presenting submucosal edema, with intact vasculature, and avital epithelial tissue and smooth muscle cells remaining in situ. Conversely, the 28-day esophagi were unremarkable grossly. Serial sections were collected and further histology did not indicate any appreciable signs of PEF treatment.

Conclusion

Clinically relevant PEF therapy can generate treatment effects when directly applied to the esophageal mucosa. However, preservation of the extracellular matrix, a hallmark of properly titrated PEF therapy, facilitates complete recovery of the tissue by 28 days post-treatment.

Biphasic Focal Monopolar Pulsed Electric Field Therapy: Preserved Phrenic Nerve Function and Anatomy

Author

Evans J., Castellvi Q., & Neal R.

HEART RHYTHM JOURNAL, AUG 2021

Background

Thermal cardiac ablation may cause phrenic nerve (PHN) palsy. Pulsed electric fields (PEF) induce cell death independently from thermal processes, potentially enabling cardiac ablation underlying the PHN without disrupting its function or morphology.

Objective

This preclinical study evaluates cardiac-based PEF treatments on the morphology and function of the PHN.

Methods

In the right atrium of 4 pigs a focal ablation catheter was maneuvered with pacing until the location and minimum PHN stimulation threshold was established, as determined by monitoring diaphragmatic movement while decreasing pacing amplitude until capture was lost. Biphasic monopolar PEF therapy was then delivered with the focal catheter either directly over, or in proximity to the PHN when electrically isolating the SVC and RSPV. Following treatment, the PHN stimulation threshold was re-evaluated. Pigs were survived acutely (n=1) and at 28 days (n=3), after which the PHN was examined grossly and histologically.

Results

The PHN stimulation threshold did not change following treatment. No clinical signs of PHN palsy nor diaphragmatic paralysis were observed during the 28-day recovery period. Gross and histological examination of the PHN did not indicate signs of macroscopic nor microscopic morphology, while svc and RSPV electrical isolation was retained.

Conclusion

The mechanisms underlying PEF ablation enable treatment to tissue adjacent to the PHN without adversely affecting its form or function. This suggests the ability to perform PEF-based cardiac ablation in regions typically associated with high risk for PHN injury without appreciable risk of PHN-associated morbidity.

Sponsored Clinical Investigations

Pulmonary Vein Isolation (PVI) And Posterior Wall Isolation (PWI) For Atrial Fibrillation Using Point-By-Point Pulsed Electric Fields: Space AF Acute

Author

Verma, A. Et Al.

HEARTRHYTHM, MAY 2022

Background

Pulsed electrical field (PEF) has been used for pulmonary vein isolation (PVI). The Centauri system enables PEF ablation via standard contact force ablation catheters. The point-by-point clinical workflow may enable treatment beyond PVI, including posterior wall isolation (PWI).

Objective

Space AF study is evaluating feasibility and safety of PVI with PWI using PEF in patients with high burden paroxysmal and persistent AF.

Methods

Centuari PEF system (galaxy medical) and a focal contact force sensing catheter (thermocool st, Biosense webster) were used for PEF ablation for wide antral PVI with PWI. Operators chose one of three doses (19a, 22a, 25a) with contact force of >5g. Primary efficacy outcome was entrance/exit block of all pulmonary veins (PVS) after a 20-minute wait. Composite safety endpoint comprised of pre-specified adverse events including microbubble formation on intracardiac echo (ICE), st-segment changes, phrenic nerve palsy, esophageal temperature rises, nih stroke scale (nihss) changes, PV stenosis, and silent cerebral lesions after PEF ablation. Ct of the PVS will be done at 3 months. Cranial MRI was done at 24 hours in a subset of patients. Secondary endpoint includes recurrence of AF post-ablation at 6 and 12 months with serial holter monitoring. Space AF will report on 30 patients.

Results

Thus far, 12 patients (58% male, age 55.8 ± 10.5 years) have been treated. Acute PVI and PWI was achieved in all 12 patients (100%). An average of 113.8 ± 12.1 applications were delivered per patient. Energy settings were 32% at 22a and 68% at 25a. There were no st-segment changes, microbubble formations, phrenic nerve injuries, or esophageal temperature rises during PEF ablation. There were no changes to NIHSS pre- vs. Post-procedure. Three (3) patients have participated in the cranial MRI sub-study, and all had negative DWI and flair post-procedure. No patients experienced procedure- or device-related AES at 30 days. PV anatomy will be assessed at 90 days. Long-term AF recurrence outcomes will be assessed at 6-month and 12-month follow-up via 48-hour holter.

Conclusion

Cardiac ablation using PEF delivered through standard focal catheters is safe and acutely successful when performing PWI after PVI. Further results on additional patients and AF recurrence will be presented.

Pulsed Field Ablation Using Focal Contact Force-Sensing Catheters for Treatment of Atrial Fibrillation: Acute and 90-Day Invasive Remapping

Author

Anic, A. Et AL.

EUROPACE, JUN 2023

Objective

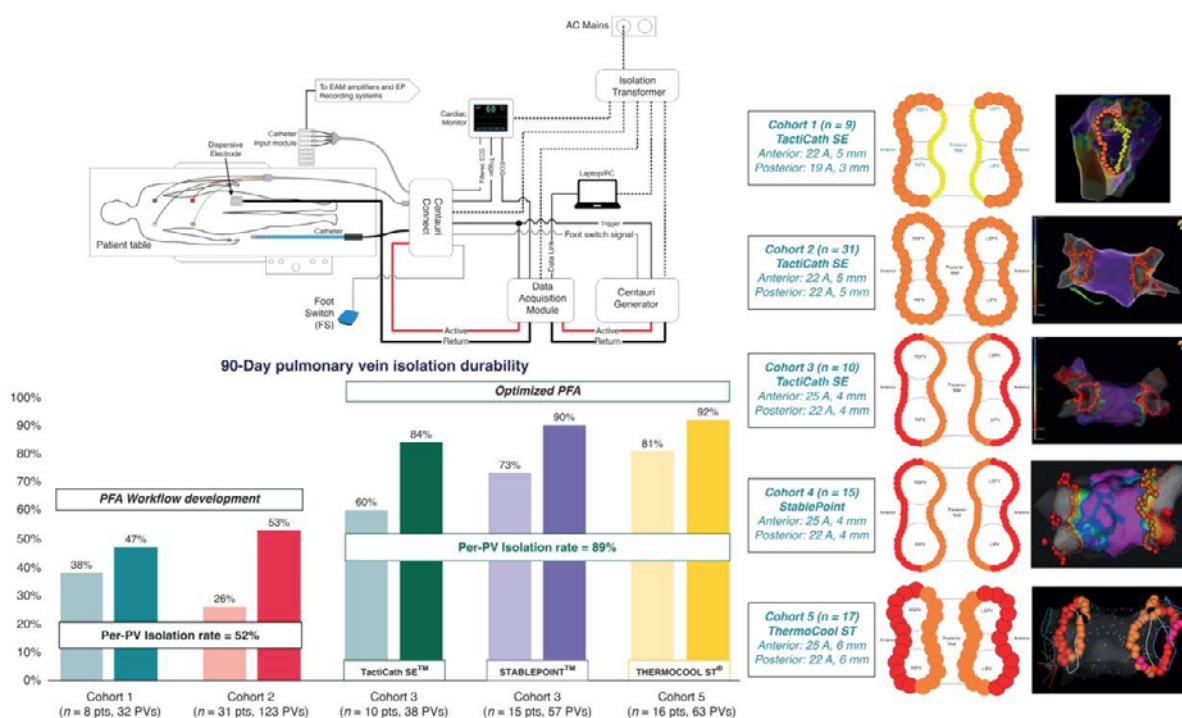
Pulsed field ablation (PFA) has emerged as a promising alternative to thermal ablation for treatment of atrial fibrillation (AF). We report performance and safety using the Centauri™ system (galvanize therapeutics) with three commercial, focal ablation catheters.

Methods and results

Eclipse AF (nct04523545) was a prospective, single-arm, multi-centre study evaluating safety and acute and chronic pulmonary vein isolation (PVI) durability using the Centauri system in conjunction with the TactiCath se, Stablepoint, and ThermoCool st ablation catheters. Patients with paroxysmal or persistent AF were treated at two centres. Patients were analysed in five cohorts based upon ablation settings, catheter, and mapping system. Pulsed field ablation was performed in 82 patients (74% male, 42 paroxysmal AF). Pulmonary vein isolation was achieved in 100% of pulmonary veins (322/322) with first-pass isolation in 92.2% (297/322). There were four serious adverse events of interest (three vascular access complications and one lacunar stroke). Eighty patients (98%) underwent invasive remapping. Pulsed field ablation development cohorts 1 and 2 showed a per-patient isolation rate of 38% and 26% and a per-PV isolation rate of 47% and 53%, respectively. Optimized PFA cohorts 3–5 showed a per-patient isolation rate of 60%, 73%, and 81% and a per-PV isolation rate of 84%, 90%, and 92%, respectively.

Conclusion

Eclipse AF demonstrated that optimized PFA using the Centauri system with three commercial, contact force-sensing, solid-tip focal ablation catheters resulted in transmural lesion formation and high proportion of durable PVI with a favorable safety profile, thus providing a viable treatment option for AF that integrates with contemporary focal ablation workflows.



Pulsed Field Ablation Using Focal Contact Force-Sensing Catheters for Treatment of Atrial Fibrillation: 1-Year Outcomes of the Eclipse AF Study

Author

Anic, A, Et Al.

CIRCULATION, DEC 2024

Background

Pulsed field ablation (PFA) is a promising treatment for atrial fibrillation. We report 1-year freedom from atrial arrhythmia outcomes using monopolar PFA delivered through 3 commercial, contact force-sensing focal catheters.

Methods

Eclipse AF (safety & clinical performance study of catheter ablation with the Centauri system for patients with atrial fibrillation; nct04523545) was a prospective, single-arm, multicenter study evaluating acute and chronic safety and performance using the Centauri system to deliver focal PFA with tacticath se, stablepoint, and thermocool st. Patients with paroxysmal or persistent atrial fibrillation underwent pulmonary vein (PV) isolation under deep sedation or general anesthesia and returned for remapping at 90 days to evaluate chronic durability. Freedom from atrial arrhythmia was evaluated continuously through 12 months using standard rhythm monitoring for symptomatic episodes and 24-hour holter at 6 and 12 months.

Results

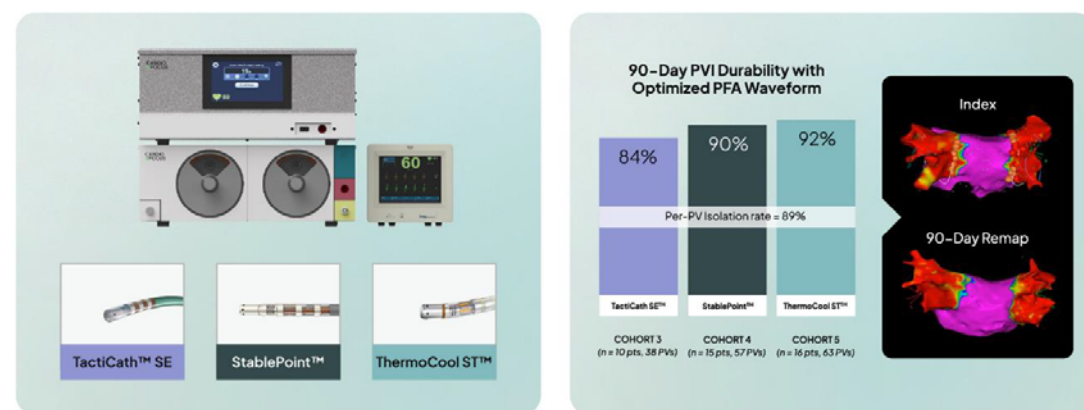
Eighty-two patients (74% male, 51.2% paroxysmal, and 58.5% deep sedation) were treated. PV isolation was achieved in 100% of targeted veins (322/322) with first-pass isolation in 92.2% (297/322). There were 4 primary safety events in 4 patients (4.9%, 4/82); 1 nonembolic stroke due to exacerbated cardiac tamponade secondary to catheter perforation and 3 hemorrhagic vascular access complications. There were no incidences of adverse event fistula, diaphragmatic paralysis, myocardial infarction, pericarditis, thromboembolism, PV stenosis, transient ischemic attack, or death. Eighty patients (98%) underwent remapping. Optimized PFA cohorts 3, 4, and 5 showed per-patient isolation rates of 60%, 73%, and 81% and per-PV isolation rates of 84%, 90%, and 92%, respectively. One-year freedom from atrial arrhythmia was 80.2% (95% ci, 69.7%–87.4%) for the entire patient sample, including 41 patients who underwent repeat focal PFA with the Centauri system at remapping.

Conclusion

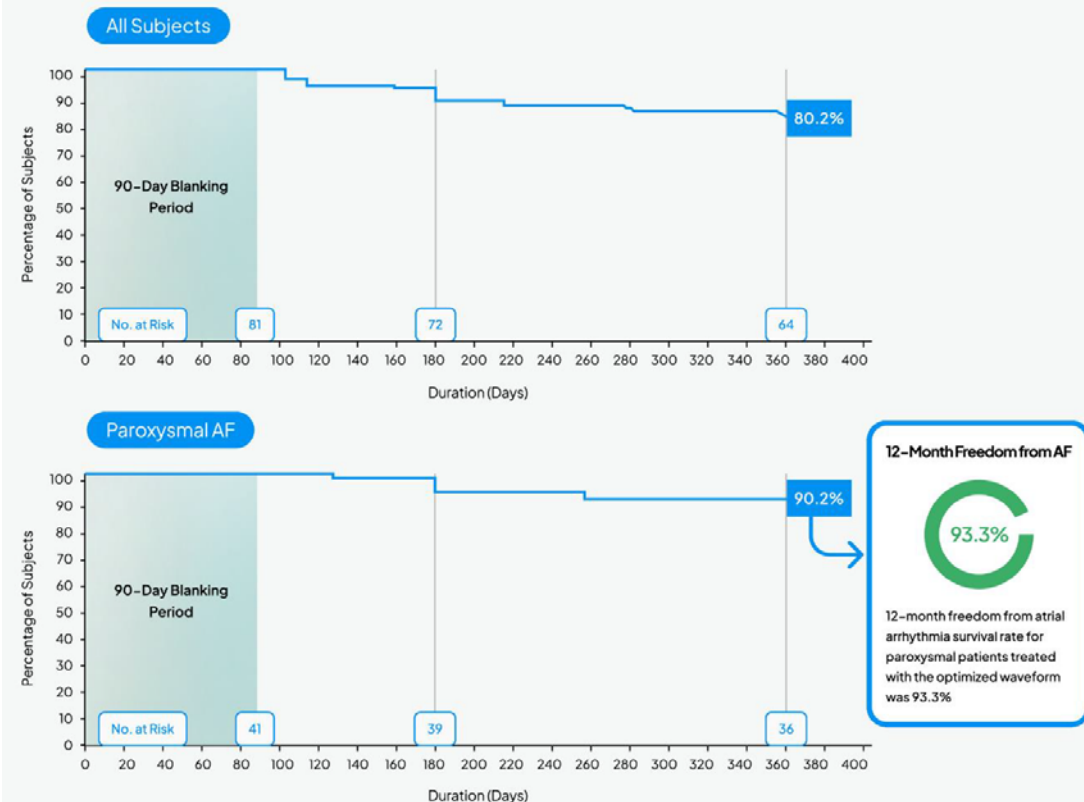
This study demonstrated that optimization of focal PFA with 3 contact force-sensing, solid-tip ablation catheters resulted in the progressive improvement of PV isolation durability at 3-month remapping and high freedom from atrial arrhythmia survival rates, providing a promising focal PFA treatment option integrated with current ablation workflows.

1-Year Results of Focal PFA in ECLIPSE AF

Patients underwent PVI using the Centauri PFA System with three focal, contact-force sensing ablation catheters. The PFA waveform was optimized with 90-day remapping, resulting in improved 12-month patient outcomes.



Clinically Significant Freedom from AF/AFL/AT



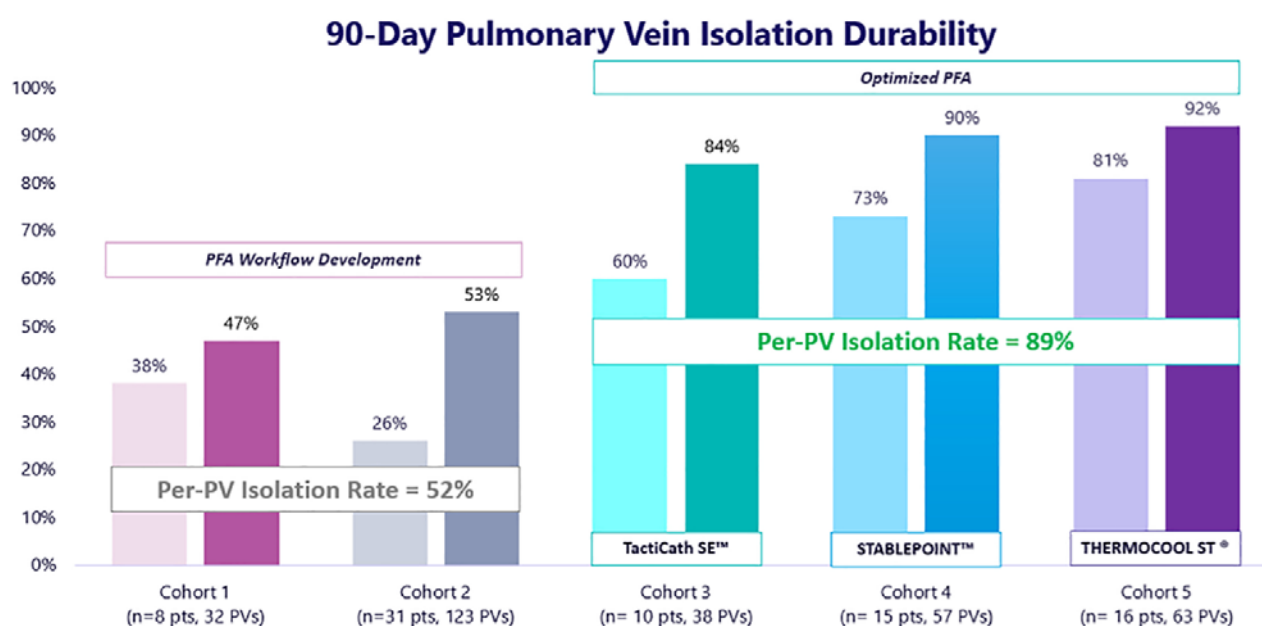


Fig 3 Chronic pulsed field ablation (PFA) lesion durability was measured per-patient and per-pulmonary vein (PV), at 90 days, for each cohort.

Patients in the PFA workflow development cohorts 1 and 2 showed a per-patient isolation rate of 38% and 26% and a per-pulmonary vein isolation rate of 47% and 53%, respectively. Patients in the optimized PFA cohorts 3, 4, and 5 showed a per-patient isolation rate of 60%, 73%, and 81% and a per-pv isolation rate of 84%, 90%, and 92%, respectively. There were no adverse events associated with the optimization in energy settings and clinical workflows.

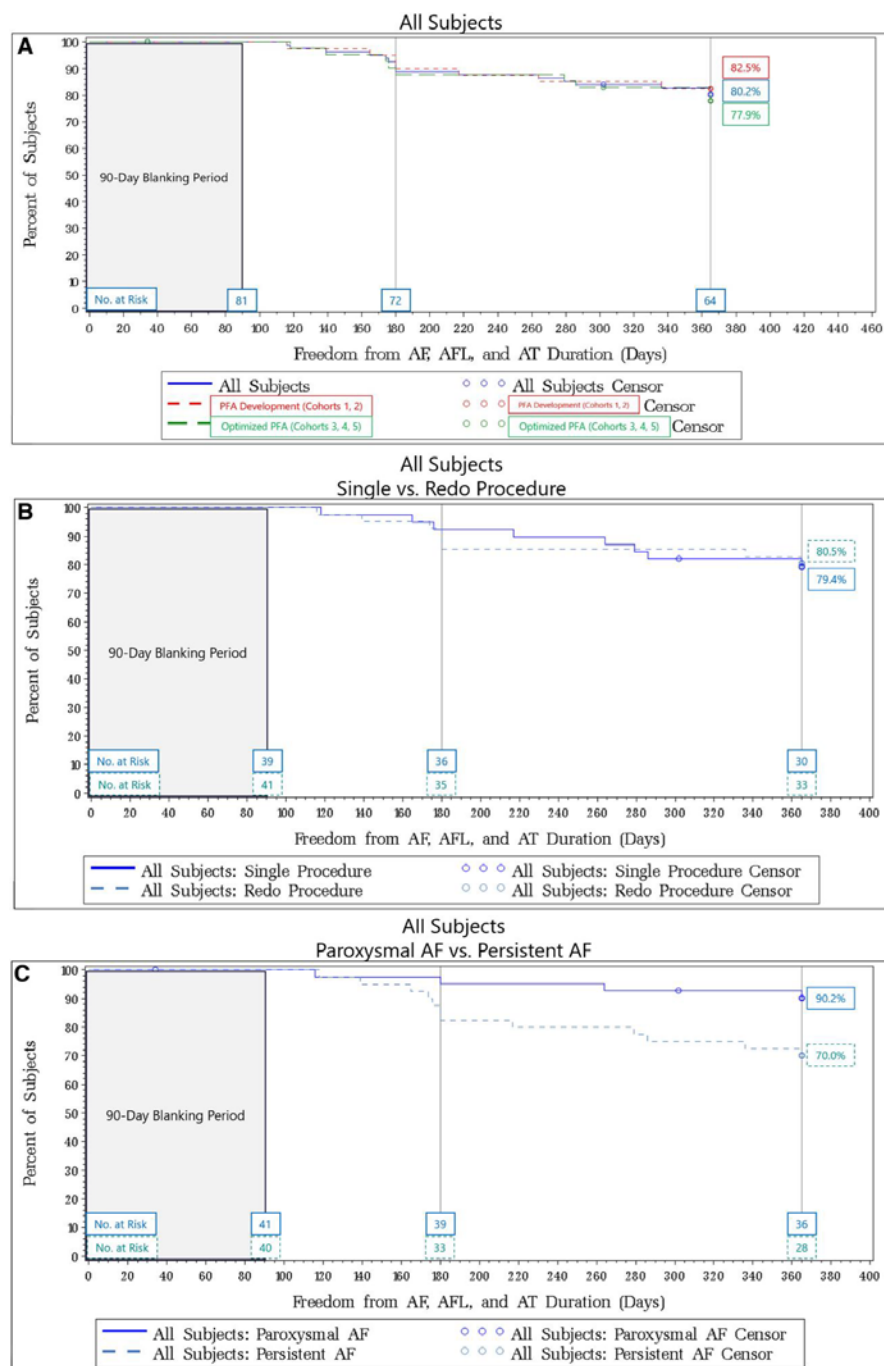


Fig 4 Kaplan-meier curve estimates for freedom of atrial fibrillation (AF)/atrial flutter (AFL)/atrial tachycardia (at) for all subjects treated in the study.

Survival estimates were broken further down by cohort

(a), single vs redo procedure (b), and patients with paroxysmal atrial fibrillation (PAF) vs persistent atrial fibrillation (peraf) (c).

Investigator-Led Studies

Nonthermal Point-By-Point Pulmonary Vein Isolation Using a Novel Pulsed Field Ablation System

Author

Wenzel J. Et Al.

CIRCULATION: ARRHYTHMIA AND
ELECTROPHYSIOLOGY, AUG 2023

Summary

In this prospective observational study, researchers evaluated the feasibility and safety of the novel Centauri point-by-point pulsed-field ablation (PFA) system for pulmonary vein isolation (PVI) in patients with paroxysmal and persistent atrial fibrillation, demonstrating effective treatment of diverse vein anatomies, and with no reported complications.

Thirty consecutive patients (40% women, 37% paroxysmal AF) were treated with wide area circumferential PVI using the Centauri point-by-point PFA system, a ThermoCool contact-force-sensing catheter, and Carto 3D mapping. Energy was delivered to the posterior wall at 22A, with 25A lesions elsewhere. Lesion tags were placed with a 6mm diameter and 20% overlap of lesions with a 10-25g force were targeted.

All veins (117/117) were successfully isolated, with 60/60 of the right and 56/57 left veins isolated at the first pass. Three patients had a common left vein that was isolated on the first pass as well. There were no adverse events reported.

Patients were followed for six months, with any preexisting AADs discontinued for three months. Overall freedom from atrial arrhythmia recurrence was 73% (82% for PAF, 68% for PeAF).

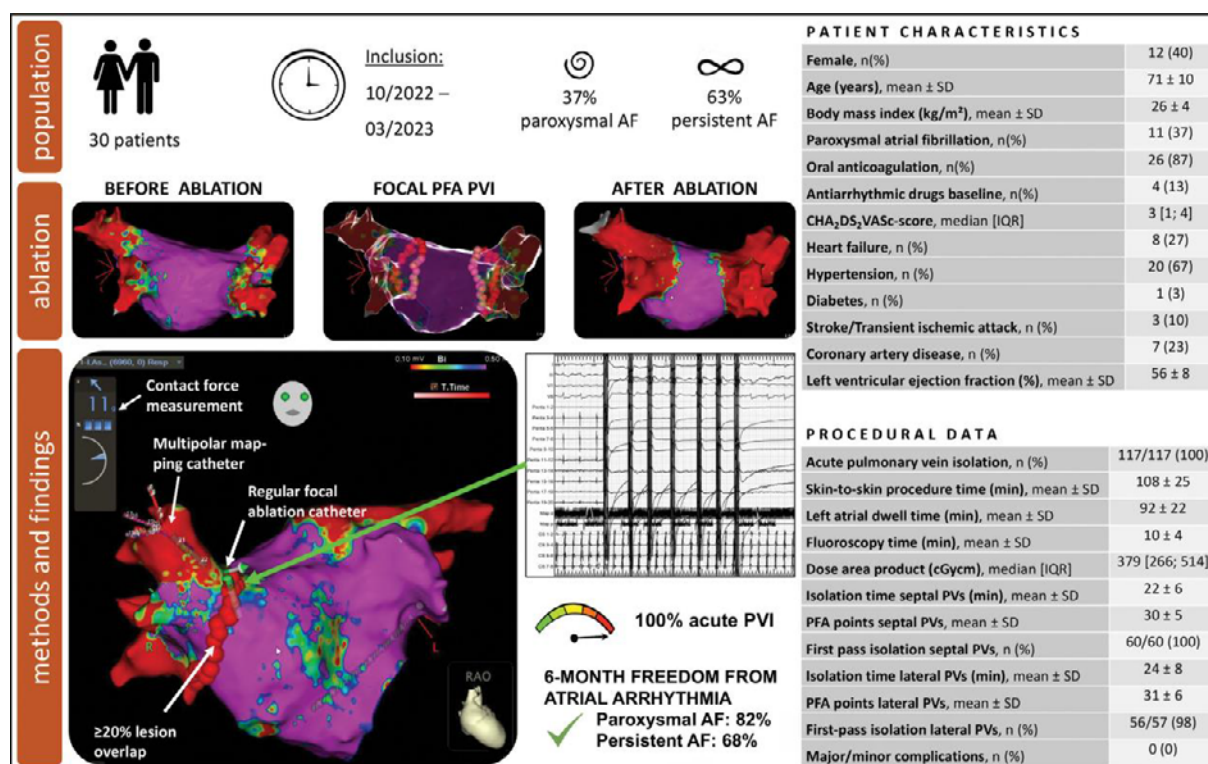


Fig 1 Nonthermal point-by-point pulmonary vein isolation (PVI) using a novel pulsed field ablation (PFA) system. Continuous data are described as mean±sd if normally distributed; otherwise, the median and interquartile distance as first and third quartile (q1–q3) are reported; categorical data are described with absolute and relative frequencies (%). AF indicates atrial fibrillation; IQR, interquartile range; LA, left atrium; PV, pulmonary vein; and RAO, right anterior oblique.

A Prospective Randomized Clinical Comparison of Catheter Ablation of Atrial Fibrillation Using the Centauri PEF System and Standard Radiofrequency Ablation

Author

Starek, Z. Et AL..

EUROPACE, MAY 2025

Introduction

Radiofrequency (RF) catheter ablation has been the standard treatment for atrial fibrillation (AF) in recent years. However, irreversible electroporation (pulse field ablation, PFA) is emerging as a promising alternative. The aim of this study was to present one-year results comparing the efficacy and safety of catheter ablation for AF using the point-to-point Centauri PEF system (Cardiofocus inc.) And the single-shot Farapulse system (Boston scientific).

Methods

Patients referred for ablation of paroxysmal and persistent AF were enrolled in this study and randomly assigned to one of two groups. The Centauri PEF group underwent ablation with the EnSite precision 3d mapping system (Abbott) for left atrial mapping and a Tactiath CF ablation catheter (Abbott) for point-to-point ablation using PFA generated by the Centauri generator. The Farapulse group underwent ablation with a specialized single-shot multipolar basket catheter under fluoroscopy and intracardiac ultrasound guidance. All procedures were performed under general anesthesia. Periprocedural parameters and follow-up results were compared between the two groups.

Results

Between May 3, 2023, and November 1, 2024, a total of 201 patients underwent catheter ablation for AF (127 with paroxysmal AF and 74 with persistent AF). Of these, 106 patients were treated with the Centauri system (Centauri group - cent) and 95 with the Farapulse system (Farapulse group - Fara). The baseline characteristics of the two groups were similar: 27% of patients were women, the mean age was 61 years, and the mean left atrial size was 45 mm. The average total procedure time was 110 min for the cent and 70 min for the Fara. The x-ray dose was 1500 mgy·cm² for the cent and 2550 mgy·cm² for the Fara. The isolation time of the left pulmonary veins (LPVS) was 17 min for the cent and 8 min for the Fara. The isolation time of the right pulmonary veins (RPVS) was 19 min for the cent and 8 min for the Fara. Acute or subacute complications were not recorded in the cent, while in the Fara was one stroke and one pericardial effusion requiring pericardiocentesis. A total of 29 patients from the cent attended a follow-up visit at 12 months, 72% of patients maintained sinus rhythm. No patients in the Fara underwent a 12-month follow-up visit yet. The results for ablation of both paroxysmal and persistent AF were similar for the two groups.

Conclusion

Catheter ablation with both PFA systems appears to be comparably effective and safe. The complications observed in the Farapulse group are typical of those associated with catheter ablation of arrhythmias and may be attributed to the learning curve. Procedure times were longer with the Centauri system, primarily due to 3d mapping and point-by-point ablation, while the Farapulse system resulted in a shorter procedure time but a significantly higher x-ray dose. The assessment of long-term effectiveness is limited by the small number of patients with follow-up data.

Repeat Pulmonary Vein Isolation and Anterior Line Ablation Using a Novel Point-By-Point Pulsed-Field Ablation System

Author

Wenzel J. Et Al.

HEART RHYTHM, MAR 2024

Background

Pulsed-field ablation (PFA) is a nonthermal energy source for ablation of cardiac arrhythmias. This study investigated the prospective outcomes of a novel PFA generator in conjunction with a commercially available, contact force-sensing, focal ablation catheter.

Objective

The purpose of this study was to assess the feasibility, safety, and lesion characteristics of point-by-point PFA in consecutive patients undergoing repeat ablation of atrial fibrillation (AF).

Methods

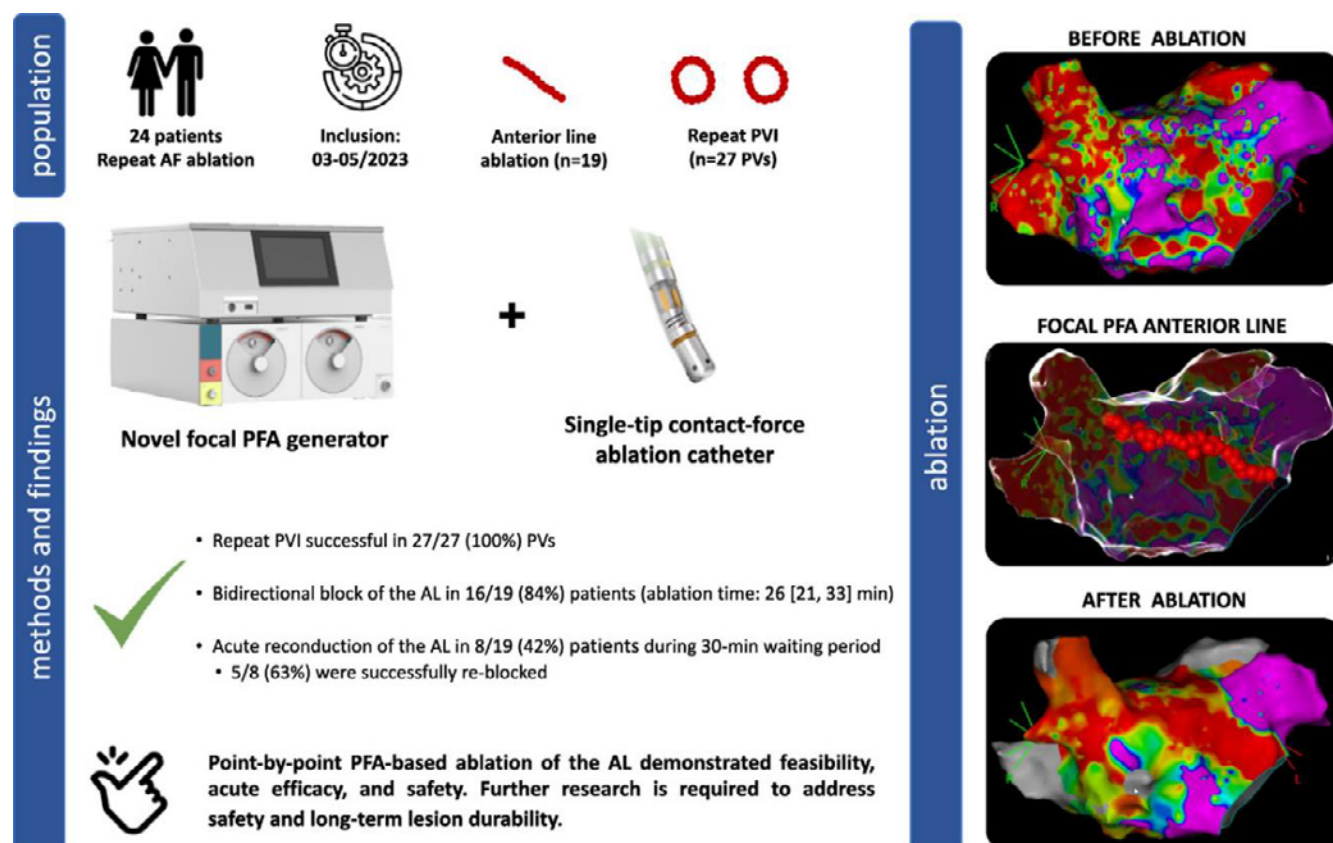
The study involved reisolation of pulmonary veins (PVS) with electrical reconnection and the creation of an anterior line (al) in patients with anterior substrate or durable pulmonary vein isolation (PVI).

Results

In 24 patients (46% female; mean age 67 ± 10 years; 67% persistent AF), successful reisolation of 27 of 27 reconnected PVS (100%) was performed. In 19 patients, all ablation was performed, with bidirectional block in 16 (84%), median ablation time 26 minutes, and first-pass bidirectional block in 13 patients (68%). Acute all reconduction occurred in 8 of 19 patients (42%). Among these 8 patients, a subsequent sustained block of the al was achieved in 5 (63%). Ultra-high-density electroanatomic mapping revealed homogeneous but relatively large low-voltage areas in the ablated regions. Median procedural, left atrial dwell, and fluoroscopy times were 100 [90, 109] minutes, 83 minutes, and 10 minutes, respectively. No major or minor complications occurred.

Conclusion

This study demonstrated feasibility, acute efficacy, and safety of point-by-point PFA for repeat PVI and AL ablation. Further studies are warranted to assess the long-term durability and comparison with established ablation methods.



A Tailored Substrate-Based Approach Using Focal Pulsed Field Ablation in Patients with Symptomatic Atrial Fibrillation and Advanced Atrial Substrate: Procedural Data and 6-Months Success Rates

Author

Farnir, F. Et AL.

EUROPACE, MAY 2025

Background

Focal pulsed-field ablation (f-PFA) integrated in electroanatomical mapping (EAM) systems allows tailored lesion sets in patients with atrial fibrillation (AF) and advanced atrial cardiomyopathy.

Purpose

To determine feasibility, safety and efficacy outcome of F-PFA for a tailored substrate-based catheter ablation (CA) approach in patients with AF and advanced atrial substrate.

Methods

We prospectively enrolled consecutive patients with AF and advanced atrial substrate treated by a F-PFA system (Cardiofocus) through contact-force sensing catheters integrated in EAM systems.

For substrate assessment, a high density mapping catheter was used. We defined an advanced substrate as the presence of prior AF ablation, presence of persistent AF and/or presence of significant left atrial scar (bipolar voltage $<0,15\text{mv}$).

The substrate-based tailored catheter ablation approach included isolation of all pulmonary veins (PVI) with wide area circumferential ablation (complete, partial or antralisation), posterior wall isolation (PWI), mitral anterior line (MAL) and cavo-tricuspid isthmus (CTI) ablation. Beyond this standard lesion set, ablation could be targeted on areas of focal fibrosis. The proposed workflow is presented in figure 1.

We evaluated feasibility of these lesion sets as well as arrhythmia recurrence and safety at 6 months, respecting 2 months blanking period.

Results

83 patients were included (33% female, mean age 66 years, 80% persistent AF or atrial flutter (AFL), 57% re-do procedures, $\text{cha}^2\text{ds}^2\text{va}$ 2.1 ± 1.3 , lavi $44\pm15\text{ml/m}^2$, time since first diagnosis 69 [32,107] months). 36 patients were first-do ablation and 47 patients re-do ablation.

Successful de-novo PVIS were performed in all 36 first-do patients and re-PVI in

30/47 re-do patients. Mitral anterior line was performed in 19 patients presenting atypical AFL and/or AF with anterior low voltage areas; PWI was performed in 38 patients with AF and low voltage areas or evoked delayed electrograms of posterior wall during premature atrial extrastimuli; CTI was performed in 24 patients for AF with associated typical AFL. Median procedural and fluoroscopy times were 115 and 7 minutes, respectively.

Lesion set feasibility is presented in figure 2a.

No major or minor complications occurred.

At 6 months, arrhythmia recurrence occurred in 30/83 patients (21 AF; 9 AFL), respecting a 2 months blanking period (figure 2b). 8/9 patients with a recurrence during blanking had a late recurrence within 6 months of follow-up.

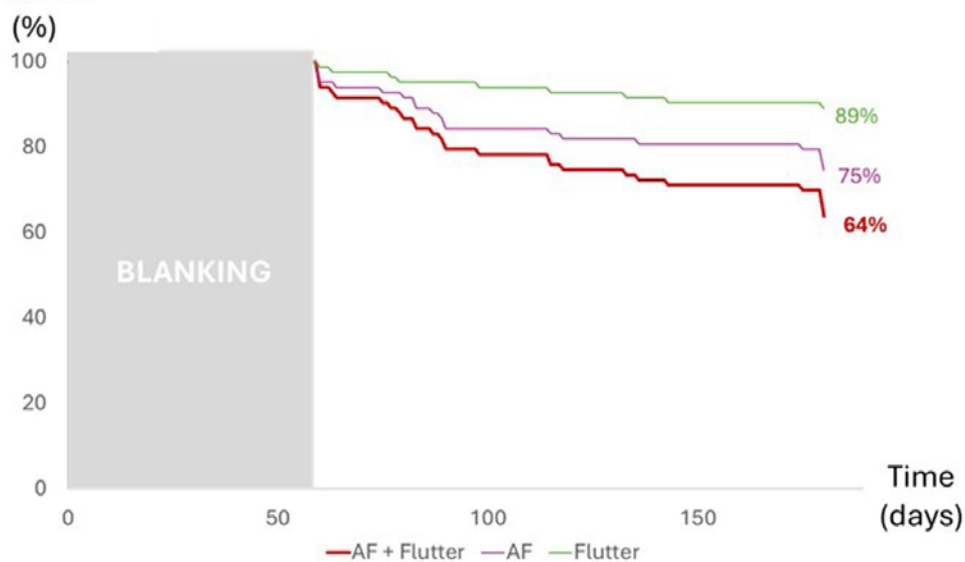
Conclusion

Tailored substrate-based f-PFA in patients with AF and atrial cardiomyopathy is safe and effective. Acute procedural success was 100% with 64% freedom from arrhythmias after 6 months.

(A)

Secondary efficacy endpoints, total procedure	Total procedure		
Procedure time, min	115 [94,132]		
Irradiation time, min	7 [5,12]		
dosis, mGy	23 [10,55]		
Secondary efficacy endpoints by lesion set	PVI N=45	PWI N=38	MAL N=19
Bidirectional block, n (%)	45 (100)	38 (100)	19 (100)
First pass isolation, n (%)	42 (93)/44 (98)	38 (100)	17 (89)
Reconnection, n (%)	3 (7)/4 (9)	0 (0)	0 (0)
Time, minutes	24/22	12 [9,16]	12 [8,15]
Line length, mm	/	30 [22,37] / 34 [25,40]	56 [37,62]
Ablation points, n	/	9 [7,12] / 10 [8,13]	22 [12,23]
Ablation points/cm	/	3.2±0.7 / 3.1±0.4	2.8±0.4
Remap procedure	N=4	N=1	N=1
Persistent isolation/block	3 (75) / 1(25%)	1 (100)	1 (100)

(B) Patients



RFA Vs PFA In Posterior Wall Isolation for PeAf: A Single Center Prospective Study – Preliminary Results

Authors

Sirotic, T., Prolic Kalinsek, T., Jan, M & Stublar, J.

EUROPACE, MAY 2025

Introduction

Despite advancements in mapping and ablation techniques, durable posterior wall isolation remains a challenge with conventional radiofrequency ablation, mainly due to anatomical difficulties in safely achieving transmural lesion due to the close proximity of the esophagus. Pulsed field ablation offers a promising new approach to ablation of the posterior wall, without the dangers to surrounding structures classically associated with RFA.

Purpose

To compare the long term posterior wall isolation (PWI) durability with two ablation methods - RFA vs PFA.

Methods

We performed a randomized trial including patients with PeAF assigned 1:1 to either PVI + PWI with RFA or to PVI + PWI with PFA. In the RFA group, PVI was achieved according to the close protocol and PEI was achieved with box-lesion set. In the PFA group, the PVI was performed with point-by-point PFA Cardiofocus Centauri system and PWI was achieved with contiguous area of ablations with interlesions distance of less than 6 mm. PVI and PPWI were confirmed after a 20-minute waiting period with HD mapping. Follow-up procedure with HD re-mapping was performed 3 months after the index procedure to test durability of PVI and PWI.

Results

There were 10 patients in the RFA group and 11 patients in the PFA. Baseline characteristics did not significantly differ between the 2 groups (male gender (90% vs 73%, $p=0.15$), mean age ($62 \pm 12,5$ vs $59 \pm 8,4$ years, $p=0.57$), mean BMI ($34,5 \pm 10,5$ vs $30,4 \pm 4,6$ kg/m², $p=0.40$). Mean procedural duration was similar in RFA and PAF groups ($212 \pm 38,7$ vs $198 \pm 25,0$ minutes, $p=0.18$). Both first pass PVI (RFA 7/10 vs PFA 11/11, $p=0.03$) and first pass PWI (RFA 4/10 vs PFA 11/11, $p<0,05$) during the index procedure differed significantly in both groups in favor of PFA. Follow-up reassessment was done in 7 patients in the RFA group and in 8 patients in the PFA group. Entrance block in all pulmonary veins per patient (5/7 vs 4/8, $p=0.34$) and per vein (25/28 vs 26/32, $p=0,20$) did not significantly differ between the groups. In contrast, PWI was significantly higher in the PFA group compared with RFA group ($10/7$, $p<0,05$).

Conclusion

PFA results in higher rate of PWI compared to RFA.

Cavo-Tricuspid Isthmus Dependent Flutter Ablation Using a Focal Monopolar Pulsed-Field Ablation Catheter

Author

Farnir, F. Et AL.

EUROPACE, MAY 2025

Background

Radiofrequency catheter ablation of the cavo-tricuspid isthmus (CTI) has demonstrated excellent feasibility and a high success rate in obtaining bidirectional block (BIB). However, anatomical particularities (pouch, trabeculations and prominent ridge) can make the procedure challenging and increase the risk of thermal complications (steam pop). Conversely, the use of pulsed-field ablation (PFA) for CTI ablation has been associated with the presence of coronary spasm (CS) and conductive disorders (CD).

Purpose

To assess the feasibility of CTI ablation using a focal monopolar PFA catheter (F-PFA), and to assess the risk of CS and CD.

Methods

We prospectively enrolled consecutive patients with CTI dependent flutter treated by a F-PFA system (cardiofocus) through contact-force sensing catheters integrated in electroanatomical mapping systems. Intravenous nitroglycerine was administered prior to ablation. The ablation targeted mid CTI and a current of 25a was used for the caval part and 22a for the annular part of CTI. We evaluated feasibility (ablation time, number of ablation points needed, first pass block, bidirectional block) and safety (including occurrence of cs or cd). In cardiac CT-scans, we evaluated the course of the right coronary artery (RCA) and the distance to the hypothetical ablation zone. We marked the HIS position on the electro-anatomical mapping system and measured the distance between the ablation line and the HIS at the end of the procedure.

Results

83 patients were included (18% female, mean age 66 years, cha2ds2va 1.6 ± 1.3). Short procedure times 7 [5,11] and a high proportion of first pass block (93%) and further procedural data are presented in figure 1. Regarding safety, 4 patients presented transient ST elevation and 2 patients showed a transient total av block during ablation (figure 2a). The patients with ST elevation were effectively treated with titrated iv nitroglycerin. 17 patients had preprocedural cardiac CT, including 1 patient with ST elevation. The distance between RCA and the target ablation zone was 18 [18,38] mm and was not significantly shorter in the patient presenting ST elevation (26mm, $p=0.76$) (figure 2b). The patients with av block had spontaneous resolution of their cd during the procedure. 17 patients had a HIS-CTI measurement, including 1 patient with av block. The distance between his and the ablation zone was 37 [35,42] mm and was not significantly shorter in the patient with av block (31mm, $p=0.35$) (figure 2c).

Conclusion

CTI ablation using F-PFA is feasible. Transient cs and cd are rare and not solely related to the anatomical proximity of the CTI line to the HIS region and the RCS.

Procedure data	PFA N=83
General informations	
Anesthesia	
General anesthesia	71 (86)
Deep sedation	12 (14)
Local anesthesia	0 (0)
Navigation system	
Carto	81 (98)
EnsiteX	2 (2)
Ablation set	
CTI alone, n (%)	14 (17)
CTI +, n (%)	69 (83)
PVI, n (%)	62 (75)
Other, n (%)	12 (14)
CTI data	
Duration, min	7 [5,11]
Line length, mm	29 [24,34]
Ablation points, n	11 [9,14]
First pass block, n (%)	77 (93)
Bidirectional block, n (%)	83 (100)
DP duration, ms	130 [117,140]

Tab 1 Procedure Information and Feasibility

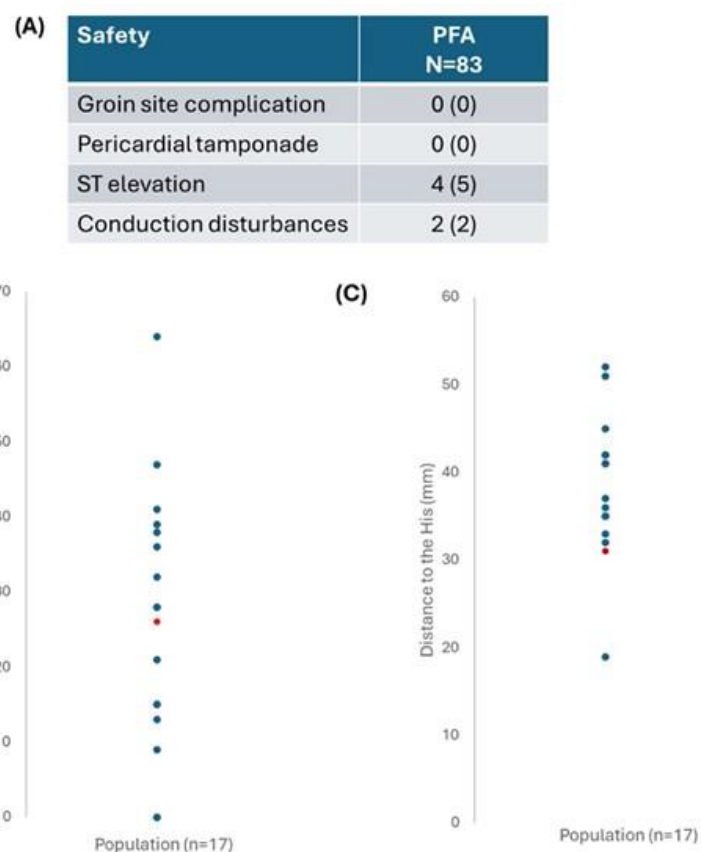


Fig 1 (A) Safety, (B) ST Elevation, (C) CD

Focal Pulsed Field Ablation for Atrial Arrhythmias: Efficacy and Safety Under Deep Sedation

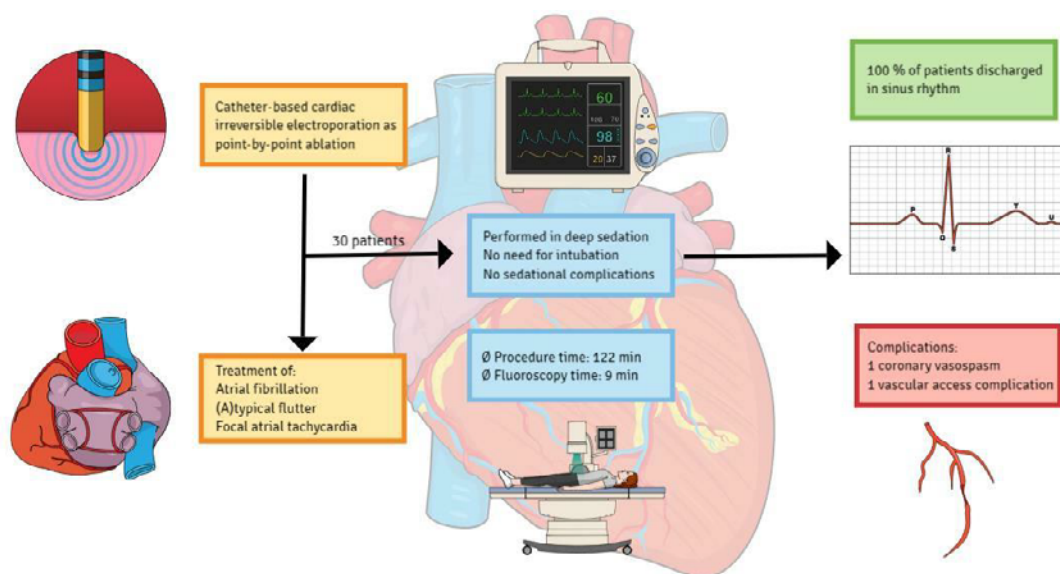
Author

Weyand S. Et Al.

JOURNAL OF CLINICAL MEDICINE, JAN 2024

Abstract

Focal pulsed field ablation (PFA) is a novel technique for treating cardiac arrhythmias. It has demonstrated positive results in initial studies and has a good safety profile. In recent studies, PFA was often utilized for first-time pulmonary vein isolation (PVI) and was performed under general anesthesia. In our study, we assessed the feasibility, safety, acute procedural efficacy, and efficiency of focal PFA under deep sedation in patients, 80% of whom had undergone at least one left atrial ablation previously. We treated 30 patients (71 ± 7 , 46% male) using the Centauri system for various atrial arrhythmias, including atrial fibrillation, typical and atypical atrial flutter, and focal atrial tachycardia. The average procedure and fluoroscopy times were 122 ± 43 min and 9 ± 7 min, respectively. A total of 83.33% of patients received additional line ablations beyond PVI, specifically targeting the posterior box and anterior mitral line. All ablations were successfully performed in deep sedation with only one major and one minor complication observed. The major complication was a vasospasm of the right coronary artery during ablation of the cavotricuspid isthmus, which was treated successfully with intracoronary nitroglycerin. All patients could be discharged in sinus rhythm. Moreover, adenosine appears effective in identifying dormant conduction in some patients after focal PFA. In conclusion, focal PFA is an effective approach for complex left atrial ablations under deep sedation, offering both high efficacy and efficiency with a reliable safety profile. Studies on long-term outcomes are needed.



Hemolysis After Pulsed Field Ablation in Pulmonary Vein Isolation: A Prospective Controlled Trial

Author

Auf Der Heiden, C., Et Al.

EUROPACE, MAY 2025

Introduction and Aim

Intravascular hemolysis with consecutive acute kidney injury (AKI) has been described after pulsed field ablation (PFA) in atrial fibrillation (AF). The aim of this study was to evaluate the risk of intravascular hemolysis and AKI after PFA with different numbers and forms of applications.

Methods

During may 2022 to august 2024 consecutive patients undergoing AF ablation were prospectively enrolled in four groups, including equally distributed numbers of patients undergoing PFA (pentaspline) with eight applications (PFA-8), with 16 applications (PFA-16), Cardiofocus focal PFA (PFA-FOC) and radiofrequency ablation (RFA). Blood samples were collected immediately before and after the ablation, as well as on the following day to analyze hemolysis markers (total bilirubin, lactate dehydrogenase (LDH) and potassium) and indicators for AKI (serum creatinine, estimated glomerular filtration rate and serum urea).

Results

A total of 200 patients (68.4 ± 10.8 years) could be included in the final analysis. The blood samples revealed a significant increase in total bilirubin and LDH across all PFA modalities and RFA 24 hours after ablation compared to baseline levels. Potassium levels increased significantly in all PFA modalities immediately post-ablation as compared to baseline, followed by a return to approximately baseline after 24 hours. No significant potassium fluctuations were observed in RFA. Serum creatinine levels showed no significant increase in any PFA modality or RFA within the 24-hour assessment period.

Conclusion

PFA with a specified number of applications for AF treatment appears safe showing no significant risk of AKI despite the significant increase of hemolysis markers. In addition, no dose-dependent increase in hemolysis markers was observed across the different PFA modalities in our study setup. Further research involving a larger patient cohort and varying PFA application forms and doses is needed to confirm these findings and to assess their implications for the safety and efficacy of AF treatment.

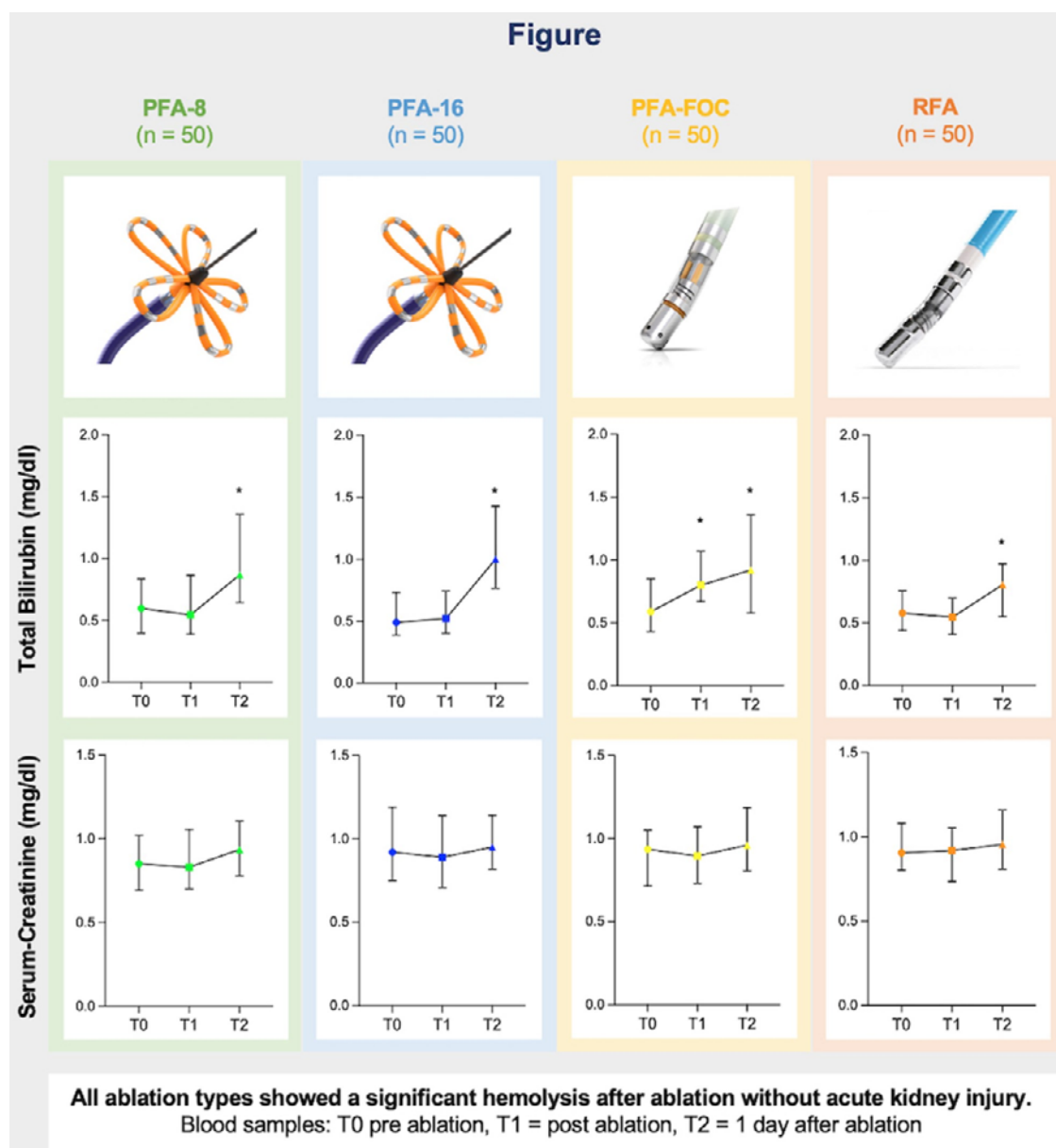


Fig 1 Hemolysis And Kidney Function After PVI

Impedance Drop During Focal Monopolar Pulsed Field Ablation in the Atrium

Author

Farnir F. Et Al

JICE, MAR 2024

Summary

In this analysis, Farnir et al. explored the utility of local impedance drop (id) as a real-time biomarker during focal monopolar PFA in the atrium. They showed a significant id during PFA, which was related to the PFA current applied, the contact force, and baseline impedance. The study builds upon prior findings that id correlates with lesion formation in radiofrequency ablation, suggesting that monitoring id during PFA could provide immediate feedback on lesion efficacy. The authors propose that incorporating id measurements into PFA procedures may enhance the precision and effectiveness of atrial fibrillation ablation strategies. Twenty-one patients with 1178 PFA applications were analyzed. The average id was $7.7\Omega \pm 4.3\Omega$ and contact force averaged 12.6g. Of note, the average id for 25a lesions was more pronounced than for 22a lesions (7.8Ω vs. 7.3Ω). It increased as more contact force was applied and was higher in the context of higher initial impedance. The id was lower for the posterior portions of the RPVS than for the posterior box lower lines or posterior LPV areas. For 25a lesions, id was lower for anterior lines than for anterior portions of the RPVS, LPVS, and roof line portion of the posterior box. The regional differences in id may be related to variable wall thickness and differences in anatomical epicardial (epicardial fat, ganglionated plexi, etc.) and extracardiac (vessels, nerves, esophagus, etc.) structures in the direct proximity to the site of PFA application.

Focal Pulsed Field Ablation in Complex Atrial Tachycardia: First Clinical Experience And 1-Year Outcome

Author

Erhard, N., Et Al.

HEART RHYTHM, JAN 2025

Background

Pulsed field ablation (PFA) has become increasingly important in the treatment of cardiac arrhythmias. In addition to single-shot devices mainly used for pulmonary vein isolation, focal PFA may provide a treatment option that increases the versatility of the technique.

Objective

The purpose of this study was to provide data on feasibility, safety, and long-term outcome of focal PFA for ablation of complex atrial tachycardia (AT).

Methods

All consecutive patients (n = 34) with complex AT treated at our department between 2022 and 2023 with a focal PFA system (CENTAURI™, Galvanize Therapeutics) were included. The majority of patients (32/34) previously had undergone at least 1 radiofrequency ablation. Established contact force-sensing catheters were used for PFA application in combination with a PFA generator. Pulsed electric field trains were conducted in a R-wave triggered manner.

Results

Acute procedural success was accomplished in all patients. PFA included creation of 51 linear lesions and (re) isolation of 12 pulmonary veins. Mean procedural duration was 102.7 ± 30.3 minutes, with left atrial dwell time of 75.0 ± 24.7 minutes. Mean fluoroscopy duration was 8.7 ± 5.3 minutes. No complications occurred. After mean follow-up of 340.9 ± 130.1 days, recurrence of any AT occurred in 15 patients (44.1%). During 9 reablations, 3 gaps in previously created linear lesions were detected; the majority of recurrences (n = 6) were not related to previous PFA lesion creation.

Conclusion

Focal PFA of complex AT substrates was safe and efficient. Acute procedural success was 100%. After 1 year, the majority of patients were in sinus rhythm. A minority of recurrences was caused by insufficient PFA lesion creation.

First Experience of Focal Pulsed Field Ablation for Premature Ventricular Contractions

Author

Cespon Fernandez, M., Et Al.

EP EUROPACE, MAY 2024

Introduction

Pulsed field ablation (PFA) has emerged as a novel strategy to achieve ablation of cardiac tissue. Clinical evidence suggests a remarkable lesion durability and safety profile for AF ablation. Nonetheless, a growing interest exists in broadening its field of application for catheter ablation of ventricular arrhythmias (VA). The Centauri system arises as a promising PFA system for targeting VA as it allows pulsed electric field (PEF) delivery via standard, commercially available focal ablation catheters and concomitant coupling with their mapping systems.

Purpose

To assess, for the first time, the feasibility of focal PFA via the Centauri system for premature ventricular complex (PVC) ablation.

Methods

We conducted a prospective analysis of patients with either high burden (>10%) or symptomatic idiopathic PVC undergoing focal PFA using Centauri system at our institution. Procedures were performed between December 2022 and august 2023. Acute and long-term success were defined as no PVC recurrence during a 24h in-hospital monitoring period, and ≥80% burden reduction with absence of symptoms after at least 30 days post-ablation, respectively. PVC monitoring was performed by implantable loop recorder (ILR) or surface ECG holter monitoring.

Results

Fourteen patients (age range: 16-87 years; 10 females) were included. Procedures were performed via the Centauri system in combination with carto 3 system and EnSite x ep system in 4 (28.6%) and 10 cases (71.4%) respectively. Targeted ablation sites were the right ventricular outflow tract (6 cases), right moderator band (2 cases), left postero-medial papillary muscle -pm- (2 cases), and right posterior pm, tricuspid annulus, left posterior fascicle and aortomitral continuity (AMC) in one case. On average, 6.5 applications were delivered to the site of origin with a mean contact force of 11g. Procedural duration and fluoroscopy time were 102 and 8.9 minutes. Two minor complications were observed: one transitory ST depression (solved after i.v. nitrate administration) after repeated applications to AMC, and a femoral pseudoaneurysm. The remaining 12 procedures were uneventful. Although most of the procedures were performed under general anesthesia due to concerns about potential significant muscular contraction, 3 cases (21.4%) were successfully managed with light sedation, without significant muscular contraction nor map shift. Incomplete abolishment of PVC during first 24 h was observed in 2 patients (14.3%). After a median follow-up of 113 days (iqr: 83-188), recurrences were detected in one patient (7.14%).

Conclusion

Focal PFA of complex AT substrates was safe and efficient. Acute procedural success was 100%. After 1 year, the majority of patients were in sinus rhythm. A minority of recurrences was caused by insufficient PFA lesion creation.

		Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Patient 6	Patient 7	Patient 8	Patient 9	Patient 10	Patient 11	Patient 12	Patient 13	Patient 14
Baseline	Age, Gender	43, F	60, M	42, F	60, F	58, F	38, F	49, F	63, F	87, F	67, M	43, M	77, F	16, M	58, F
	Comorbidities	None	None	None	HT, OSAS	HT	None	HT	None	HT, DLP, PVI and CTI block	HT, OSAS, PVI	DM, DLP	HT, DLP, BrS	None	Poly-arthritis
	Previous Ablation(s)	1	2	No	No	No	No	No	1	No	No	No	No	No	No
Procedural data	PVC Origin	PM-PPM	PL-TA	AL-RVOT	MB	S-RVOT	LPF	RP-PPM	A-RVOT	PM-PPM	AL-RVOT	AS-RVOT	AMC	MB	PS-RVOT
	Earliest Activation, ms	-	-	-35	-31	-25	-32	-32	-28	-17	-35	-24	-25	-29	-28
	Pacemapping Match, %	99	96	97	98	97	96	96	96	-	99	-	95	95	-
	PFA Applications, n	16	7	3+4*	5	2	6	9	5	6	19	8	20	4	1
	Mean Contact Force, gr	18	6	20	4	11	13	14	10	11	7	12	10	12	11
	RF consolidation	No	No	No	No	No	No	No	No	No	No	No	No	No	No
	Fluoroscopy Time, min	11.1	5.4	7.4	6.5	24.9	12.4	5.7	17.7	8.5	6.6	9.3	17.9	0	20.4
	Procedural Time, min	75	63	103	86	118	92	137	72	68	94	97	147	158	115
	Sedation/Anesthesia	General	General	General	Sedation	General ¹	General	General	Sedation	General	General	General	General	General	Sedation
	Peak Current, A	22	22	22	22	25	22	22	25	25	22	22	25	22	22
	Muscle Contraction	No	No	No	No	No	Yes	No	No	No	No	No	No	No	Yes
Outcomes	Total FU Outcome	Success	Success	Success	Success	Success	Success	Recurrence	Success	Success	Success	Success	Success	Success	Success
	FU Strategy	ILR	ILR	Holter ECG	Holter ECG	ILR	Holter ECG	Holter ECG	Holter ECG	Holter ECG	ILR	Holter ECG	Holter ECG	Holter ECG	Holter ECG
	Total FU Time (days)	294	288	204	79	202	145	92	106	80	124	48	120	99	71

Tab 1 Characteristics

Efficacy And Safety of Focal Pulsed-Field Ablation for Ventricular Arrhythmias: Two-Centre Experience

Author

Peichl P. Et Al

EUROPACE, JUL 2024

Aim

A pulsed electric field (pf) energy source is a novel potential option for catheter ablation of ventricular arrhythmias (vas) as it can create deeper lesions, particularly in scarred tissue. However, very limited data exist on its efficacy and safety. This prospective observational study reports the initial experience with VA ablation using focal pf.

Methods and results

The study population consisted of 44 patients (16 women, aged 61 ± 14 years) with either frequent ventricular premature complexes (VPCS, 48%) or scar-related ventricular tachycardia (VT, 52%). Ablation was performed using an irrigated 4 mm tip catheter and a commercially available pf generator. On average, 16 ± 15 pf applications (25 a) were delivered per patient. Acute success was achieved in 84% of patients as assessed by elimination of VPC or reaching non-inducibility of VT. In three cases (7%), a transient conduction system block was observed during pf applications remotely from the septum. Root analysis revealed that this event was caused by current leakage from the proximal shaft electrodes in contact with the basal interventricular septum. Acute elimination of VPC was achieved in 81% patients and non-inducibility of VT in 83% patients. At the 3-month follow-up, persistent suppression of the VPC was confirmed on holter monitoring in 81% patients. In the VT group, the mean follow-up was 116 ± 75 days and a total of 52% patients remained free of any VA.

Conclusion

Pulsed electric field catheter ablation of a broad spectrum of VA is feasible with acute high efficacy; however, the short-term follow-up is less satisfactory for patients with scar-related VT.

Efficacy and safety of focal pulsed-field ablation for ventricular arrhythmia: two-centre experience

Study design



2 centre study

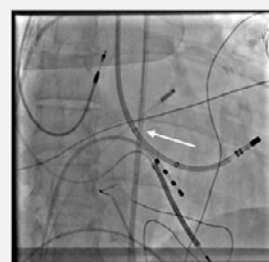


44 patients with VAs
- 21 with VPCs
- 23 with scar-related VTs

Safety issues

In 3 patients (7%) transient conduction system damage occurred during PF applications due to current leakage from the shaft-visualizing ring electrode in contact with the septum (arrow)

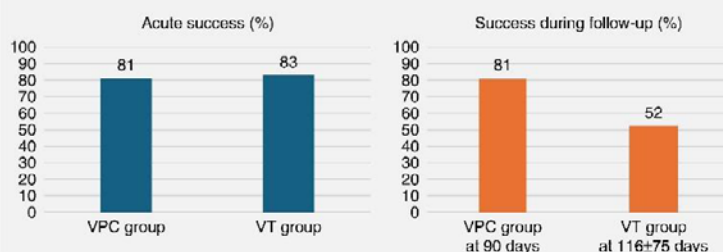
No spasms of coronary noted artery despite PF application in the distal coronary sinus in 11 patients



Methods



Outcome



Focal Pulsed Field Ablation for Premature Ventricular Contractions: A Multicenter Experience

Author

Della Rocca, D., Et Al..

CIRC A&E, SEP 2024

Background

Pulsed field ablation (PFA) is a novel technology for catheter-based atrial arrhythmia treatment. Evidence of its application for ventricular arrhythmia ablation is still limited. In this study, we describe the feasibility and efficacy of focal PFA for premature ventricular contraction (PVC) ablation.

Methods

A prospective cohort of 20 patients referred for PVC ablation at 2 centers was enrolled, regardless of the presence of structural heart disease, PVC morphology, or previous ablation attempts. All procedures were performed using the Centauri system in combination with contact force sensing catheters and 3-dimensional electroanatomical mapping systems. Energy output and the number of applications were left to the operator's discretion.

Results

Eleven (55%) procedures were conducted under general anesthesia, 6 (30%) under deep sedation, and 3 (15%) under light sedation. Muscular contraction was observed in one case (5%). Median procedural and fluoroscopy times were 95.5 and 6.55 minutes, respectively. The median number of PFA applications was 8 with a median contact force of 10g. A statistically significant (76%) reduction was observed in mean peak-to-peak bipolar electrogram voltage before and after ablation (0.707 versus 0.098 mv; $p=0.008$). Ventricular irritative firing was observed in 11 (55%) patients after PFA. The median follow-up was 120 days. Acute procedural success was achieved in 17 of 20 (85% [95% ci, 0.70–1]) patients. Two of the patients with procedural failure had late success with >80% clinical PVC burden suppression during follow-up, and 2 of 17 patients with acute success had late PVC recurrence, which accounts for a total of 17 of 20 (85% [95% ci, 0.70–1]) patients with chronic success. Transient ST-segment depression occurred in 1 patient, and the right bundle branch block was induced in 2 others (permanently only in one case).

Conclusion

PVC ablation using a focal PFA is feasible, effective, and safe, with promising acute and long-term results in several ventricular locations. Irritative firing is frequently observed. Coronary evaluation should be considered when targeting the outflow tract.

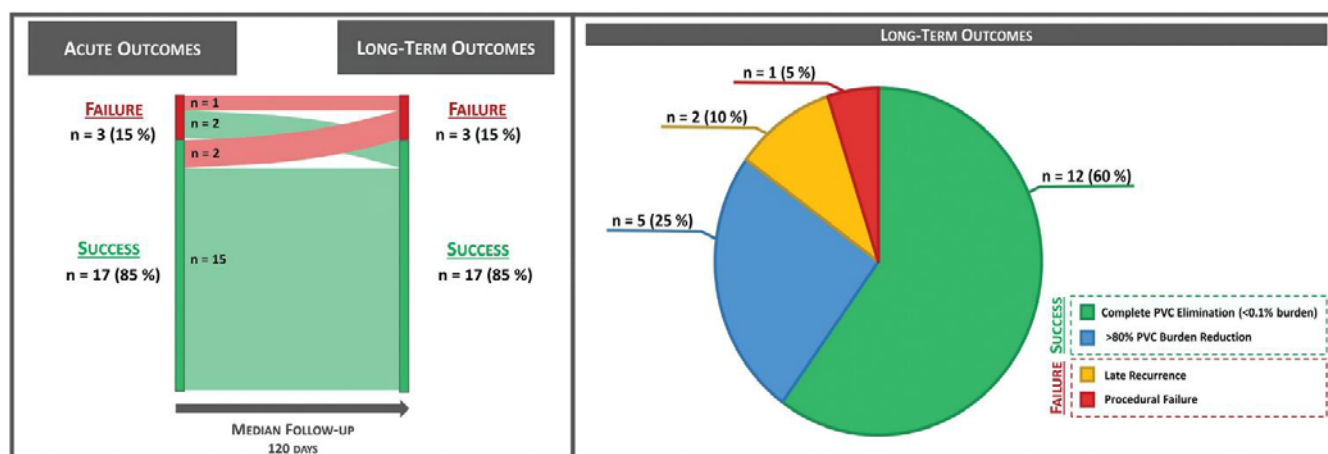
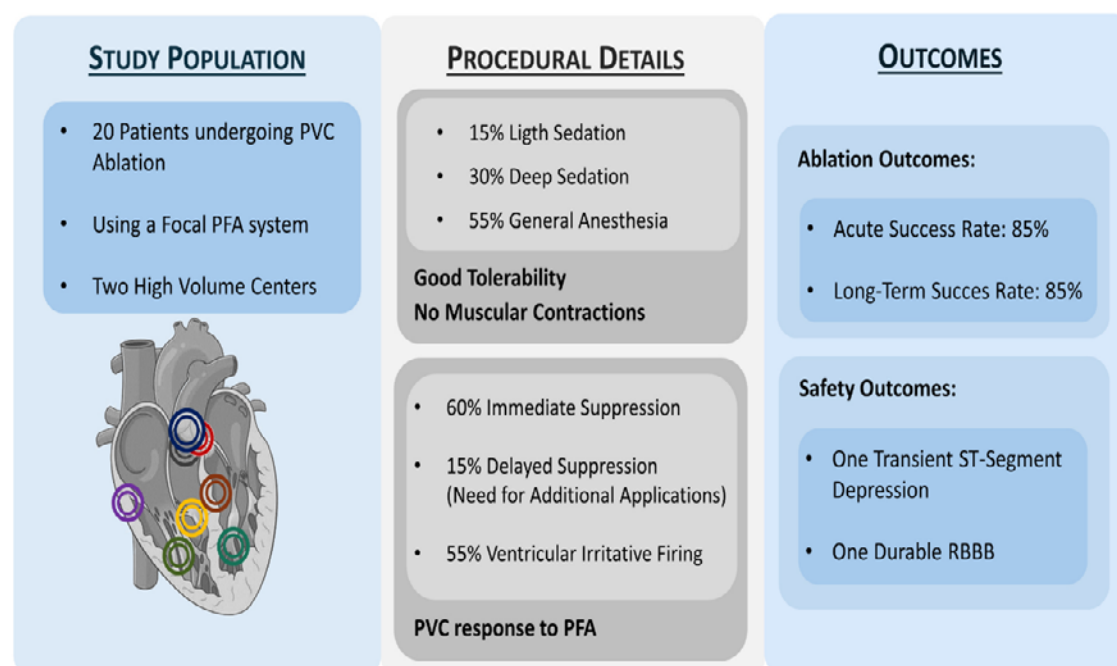


Fig 1 Acute And Long-Term Outcomes. Premature Ventricular Contraction (PVC) Ablation Outcomes Acutely (Considered Successful Those in Which Complete PVC Abolishment Was Achieved) And After a Median Follow-Up Of 120 Days (Considered Successful Those With >80% PVC Burden Decrease with Absence of Symptoms).



Feasibility and Midterm Effectiveness of Focal Pulsed Field Ablation for Ventricular Arrhythmias

Author

Ruwald, M., Et Al.

HEART RHYTHM, FEB 2025

Background

Pulsed field ablation (PFA) is a promising novel method of atrial ablation, with preclinical data suggesting it to be a viable option for ventricular arrhythmias.

Objective

The objective was to report the feasibility, safety, and clinical efficacy of PFA for ventricular arrhythmias.

Methods

All patients (n = 35) scheduled for ablation of premature ventricular complexes (PVCS; n = 24) or ventricular tachycardia (VT; n = 11) underwent focal PFA by use of a pulsed field generator and irrigated ablation catheters. Procedural and clinical outcomes were evaluated by 3-month holter monitoring, implantable cardioverter-defibrillator home monitoring, and chart review.

Results

A total of 11 (31%) patients had experienced previously failed radiofrequency ablation. Most PVCS (58%) originated from the outflow tracts, and most VTs were caused by ischemic cardiomyopathy (55%). Average procedure time was 187 ± 59 minutes. Acute procedural success was achieved in 91% of the patients. PFA was delivered combined endocardially and through the cardiac venous system in 25% of the PVC patients. During a mean follow-up of 288 ± 149 days, the success was 75% for PVCs and 45% for VTs. A total of 5 patients were reablated during follow-up (4 VT, 1 PVC). We observed 7 (20%) minor and 2 (6%) major complications including 2 transient conduction system blocks related to pulsed field delivery and 1 stroke and 1 minor stroke.

Conclusion

Focal PFA exhibited satisfactory acute effectiveness for PVC and VT, but favorable clinical effectiveness was retained only in PVC patients. More data are needed to establish lesion durability, safety, and limitations of PFA in ventricular tissue.

Case Series

Focal Pulsed Field Ablation and Ultrahigh-Density Mapping — Versatile Tools for All Atrial Arrhythmias? Initial Procedural Experiences

Author

Ruwald M. Et AL.

JOURNAL OF INTERVENTIONAL CARDIAC
ELECTROPHYSIOLOGY, MAY 2023

Background

Focal pulsed field ablation (FPFA) is a novel and promising method of cardiac ablation. The aim of this study was to report the feasibility, short-term safety, and procedural findings for a broad spectrum of ablated atrial arrhythmias.

Methods

Patients (n=51) scheduled for ablation of atrial arrhythmias were prospectively included and underwent FPFA using the Galvanize Centauri generator with energy delivery through commercially available ablation catheters with ultrahigh-density (UHDX) 3d electroanatomic voltage/local activation time map evaluations. Workflow, procedural data, and peri-procedural technical errors and complications are described.

Results

Planned ablation strategy was achieved with FPFA-only in 48/51 (94%) of the cases. Ablation strategy was first-time pulmonary vein isolation (PVI) in 17/51 (36%), repeat ablation in 18/51 (38%), PVI+ in 13/51 (28%), and cavotricuspid isthmus block (CTI)-only in 3/51 (6%). The mean procedure time was 104 ± 31 min (first-time PVI), 114 ± 26 min (repeat procedure), 152 ± 36 min (PVI+), and 62 ± 17 min (CTI). Mean UHDX mapping time to assess lesion formation and block after ablation was 7 ± 4 min with 5485 ± 4809 points. First pass acute (linear) isolation with bidirectional block for anatomical lesion sets was 120/124 (97%) for all PVS, 17/17 (100%) for (any) isthmus, and 14/17 (82%) for left atrium posterior wall (LAPW). We observed several time-consuming integration errors with the used ablation system (mean 3.4 ± 3.7 errors/procedure), one transient inferior ST elevation when ablating CTI resolved by intravenous nitroglycerine and one transient av block requiring temporary pacing for > 24 h.

Conclusion

FPFA was a highly versatile method to treat atrial arrhythmias with high first-pass efficiency. UHDX revealed acute homogenous low-voltage lesions in ablated areas. More data is needed to establish lesion durability and limitations of F-PFA.

Redo Procedures After Sinus Node Sparing Hybrid Ablation for Inappropriate Sinus Tachycardia/Postural Orthostatic Sinus Tachycardia

Author

De Asmundis C. Et Al.

EUROPACE, JAN 2024

Aims

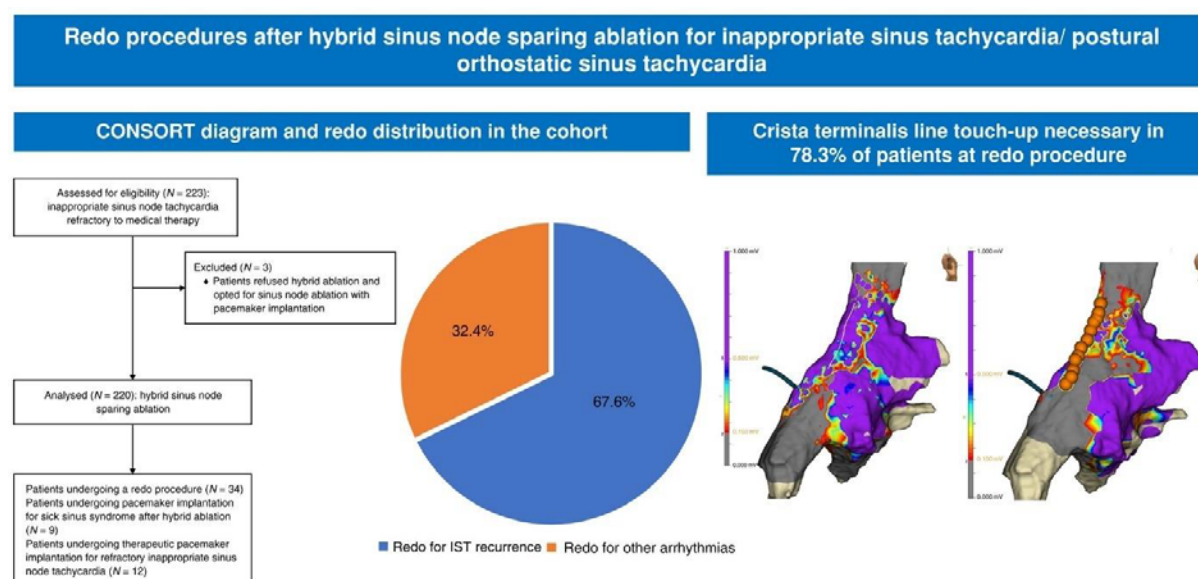
A novel sinus node (SN) sparing hybrid ablation for inappropriate sinus node tachycardia (IST)/postural orthostatic tachycardia syndrome (POTS) has been demonstrated to be an effective and safe therapeutic option in patients with symptomatic drug-resistant IST/POTS. The aim of this study was to evaluate the long-term rate of redo procedures after hybrid IST ablation and procedural strategy, outcomes and safety of redo procedures.

Methods and Results

Patients (n=51) scheduled for ablation of atrial arrhythmias were prospectively included and underwent FPFA. All consecutive patients from 2015 to 2023 were prospectively enrolled in the UZ Brussel monocentric IST/POTS registry. They were analysed if the following inclusion criteria were fulfilled: 1) diagnosis of IST or pots, 2) symptomatic IST/POTS refractory or intolerant to drugs, and 3) hybrid SN sparing ablation performed. The primary endpoint was redo procedure. The primary safety endpoint was pacemaker (PM) implantation. A total of 220 patients undergone to hybrid IST ablation were included, 185 patients (84.1%) were treated for IST and 61 patients (27.7%) for pots. After a follow-up of 73.3 ± 16.2 months, 34 patients (15.4%) underwent a redo. A total of 23 patients (67.6%) had a redo for IST recurrence and 11 patients (32.4%) for other arrhythmias. Pacemaker implantation was performed in 21 patients (9.5%). Nine patients (4.1%) had no redo procedure and experienced sick sinus syndrome requiring a pm. Twelve patients (5.4%) received a pm as a shared therapeutic choice combined with SN ablation procedure.

Conclusion

In a large cohort of patients the long-term free survival from redo procedure after hybrid IST ablation was 84.6% with a low pm implantation rate.



Graphical abstract at long-term follow-up of 6 years, after hybrid inappropriate sinus node tachycardia (IST) ablation 15.4% of patients underwent to a redo procedure. A total 67.6% of patients had a redo procedure for IST recurrence and 32.4% of patients for other arrhythmias. In most patients undergoing a redo procedure a gap in at least one previous line, was found and the most common gap was in the crista terminalis line.

Focal point-by-point pulsed field ablation for the treatment of atrial arrhythmias in patients with challenging anatomy where radiofrequency ablation cannot be applied: A case series

Author

Farnir F. Et AL.

HEART RHYTHM, OCT 2024

Summary

This case series explores the application of focal point-by-point pulsed field ablation (PFA) as an alternative to radiofrequency ablation (RFA) in patients with atrial arrhythmias and complex anatomical considerations that preclude the use of RFA. The authors present a series of cases where PFA was successfully employed to achieve durable arrhythmia control, demonstrating its potential as a safe and effective treatment modality in anatomically challenging scenarios. The study highlights the feasibility of PFA in patients who are not suitable candidates for conventional RFA due to factors such as prior cardiac surgery, vascular anomalies, or other structural abnormalities. While the results are promising, the authors call for further research to validate these findings and establish comprehensive guidelines for the use of PFA in this patient population.

The three cases described are: 1) a 64-year-old woman with significant comorbidities who was found to have a saccular aneurysm on the anterior descending AO, intimately involved with the wall of the Ia; 2) a 63-year-old man with a hiatal hernia with partial stomach incursion into the thoracic cavity, and 3) a 39-year-old woman with a focal atrial tachycardia with origin directly over the phrenic nerve.

All were successfully treated with PFA without sequelae.

Focal Monopolar Pulsed Field Ablation from within the Great Cardiac Vein for Idiopathic Premature Ventricular Contractions after failed Radiofrequency Ablation

Author

Chaldoupi, S., Et Al.

HEART RHYTHM, OCT 2024

Background

Idiopathic epicardial premature ventricular contractions (PVC) originating from the left ventricular summit are difficult to eliminate.

Objective

The purpose of this study was to describe the feasibility and procedural safety of monopolar biphasic focal pulsed field ablation (F-PFA) from within the great cardiac vein (GCV) for treatment of idiopathic epicardial PVCS.

Methods

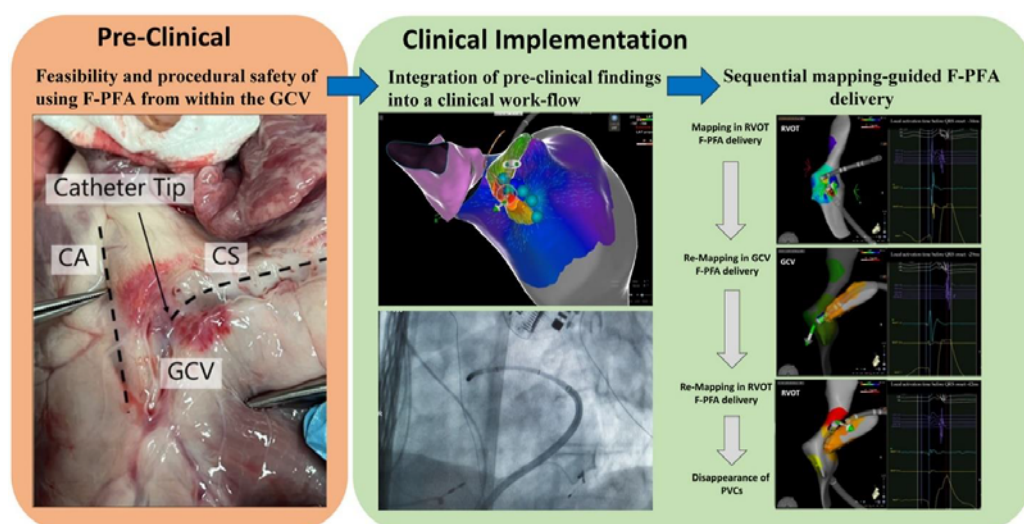
In 4 pigs, F-PFA (Centauri, Cardiofocus) was applied from within the GCV followed by macroscopic gross analysis. In 4 patients with previously failed radiofrequency ablation, electroanatomic mapping was used to guide f-pfa from within the GCV and the ventricular outflow tracts. Coronary angiography and optical coherence tomography (oct) were performed in 2 patients.

Results

In pigs, F-PFA from within the GCV (5 mm away from the coronary arteries) resulted in myocardial lesions with a maximal depth of 4 mm, which was associated with nonobstructive transient coronary spasms. In patients, sequential delivery of f-pfa in the ventricular outflow tracts and from within the GCV eliminated the PVC. During f-pfa delivery from within the GCV with prophylactic nitroglycerin application, coronary angiography showed no coronary spasm when f-pfa was delivered >5 mm away from the coronary artery and a transient coronary spasm without changes in a subsequent oct, when F-PFA was delivered directly on the coronary artery. Intracardiac echocardiography and computed tomography integration was used to monitor F-PFA delivery from within the GCV. There were no immediate or short-term complications.

Conclusion

Sequential mapping-guided f-pfa from endocardial ventricular outflow tracts and from within the GCV is feasible with a favorable procedural safety profile for treatment of epicardial PVCS.



Ablation of Accessory Pathways in Different Anatomic Locations Using Focal Pulsed Field Ablation

Author

Breskovic T. Et Al.

HEART RHYTHM, AUG 2024

Background

Ablation of accessory pathways (APS) is the cornerstone for treatment of patients with Wolff-Parkinson-white syndrome and manifestation of atrioventricular reentrant tachycardia. Pulsed field ablation (PFA) is a new type of nonthermal energy source delivered to the underlying tissue via the ablation catheter and used for ablation of arrhythmic substrates.

Objective

The purpose of this study was to determine the efficiency and long-term outcome of ablation of aps of different localizations using a focal pulsed electrical field.

Methods

Electrophysiological study was performed in patients with indication for ap ablation. An ablation catheter was used to map the position of ap insertion. Pulsed electric field was delivered through a standard ablation catheter. In left-sided APS, the first ablation attempt was within the coronary sinus (CS). Patient follow-up was scheduled 1–3 months after the ablation. Additional check-up was performed after 6 and 12 months.

Results

Fourteen 14 patients (3 pediatric) were treated. Termination of ap conduction was achieved in all procedures. The cohort consisted of 3 right free wall, 3 posteroseptal, and 8 left-sided APS. Ablation through cs was successfully used in 7 of 8 patients with left-sided APS. No complications were reported. Median follow-up was 5.5 months. Conduction recurrence through ap was documented in 1 patient.

Conclusion

Focal PFA for ap shows promising results in terms of efficacy and safety. A high rate of successful termination of left-sided APS by ablation within cs may represent a new standard approach. The safety and efficacy profile of PFA seems to be transferable to the pediatric population.

Monopolar biphasic focal pulsed field ablation directly at the atrioventricular junction and from within the noncoronary cusp: The PFA-CONDUCT study

Author

Dominik Linz, MD, PhD Et AL.

HEART RHYTHM, VOL 23, NO 4, APRIL 2026

Background

The efficacy and safety of monopolar biphasic focal pulsed field ablation (F-PFA) in close proximity to the atrioventricular (AV) node remain unknown.

Objective

This study aimed to describe the effect of direct or indirect F-PFA application at the AV junction.

Methods

In pigs, F-PFA (Centaury, CardioFocus) was applied directly at the AV junction (n 5 3) and indirectly from within the aortic noncoronary cusp (NCC) (n 5 5), followed by macroscopic gross and histologic analysis. In 5 patients planned for a pace-and-ablate strategy, F-PFA was applied at the AV junction. In 1 patient with recurrent para-Hisian atrial tachycardia and previously failed ablation, F-PFA was applied from within the NCC.

Results

In pigs, direct F-PFA applications at the AV junction were associated with junctional beats and resulted in complete AV block after 2–3 F-PFA applications. Tissue histology revealed a lesion depth of approximately 8 mm with minor hemorrhage and leukocyte infiltration. F-PFA from within the NCC resulted in a transient increase in the AV node's Wenckebach cycle length and 1 pig had transient AV block, which recovered within 10 minutes. In 5 patients undergoing pace-and-ablate strategy, F-PFA applications at the AV junction resulted in sustained AV block. In 1 patient, application of F-PFA from within the NCC resulted in termination and noninducibility of a recurrent incessant para-Hisian atrial tachycardia without AV block. There were no immediate or long-term complications.

Conclusion

F-PFA directly at the AV junction results in nonreversible AV block. F-PFA from within the NCC may represent a promising strategy for treating para-Hisian arrhythmias while preserving AV conduction.

Focal Pulsed Field Ablation for Guiding And Assessing The Acute Effect of Cardioneuroablation

Author

Farnir F. Et AL.

EUROPACE, MAR 2024

Summary

This prospective series evaluated the use of focal, point-by-point biphasic monopolar pulsed field ablation (F-PFA) for posterior wall isolation (PWI) in patients with persistent atrial fibrillation. Unlike prior studies that used specialized multi-electrode catheters, this approach employed standard contact-force catheters with the Centauri system. It achieved acute PWI in all patients, with 83% durable isolation at 3 months and no major complications. These results highlight F-PFA as a safe, effective, and versatile strategy for durable PWI using conventional ablation tools.

The cohort comprised 38 patients with PEAf, nine for de novo ablation and 29 for complex re-do procedures. In de novo cases, WACA was performed; for re-dos, focal re-isolation was performed if warranted before applying a posterior box ablation with floor and roof lines. Entrance and exit block were confirmed after mapping with a high-density catheter, and validation was repeated after a 15-minute waiting period.

Focal Point-By-Point Biphasic Monopolar Pulsed Field Ablation for Posterior Wall Isolation study

Author

Sikiric I. Et AL.

JICE, JAN 2024

Summary

This series explores the use of focal pulsed field ablation (PFA) to guide and assess the acute effects of cardioneuroablation (CNA) in patients with cardioinhibitory vasovagal syncope (CI-VVS) and symptomatic sinus bradycardia. Three patients underwent CNA procedures where focal PFA was initially applied to the anterosuperior aspect of the right superior pulmonary vein ostium to provoke a transient vagal response, indicating proximity to the right superior ganglionated plexus (RSGP). Subsequently, radiofrequency ablation (RFA) was performed at the same sites, leading to increased sinus rates and suppression of premature ventricular contractions. Post-ablation, repeat PFA applications failed to elicit vagal responses, suggesting successful denervation.

This approach demonstrates that focal PFA can serve as a valuable tool for both identifying autonomic targets and confirming the immediate efficacy of CNA, potentially enhancing procedural precision and outcomes.

Case Reports

First in human focal pulsed field ablation to treat an epicardial VT focus with an endocardial approach in non-ischemic cardiomyopathy

Author

Weyand S. Et AL.

JICE, MAR 2023

Summary

This case report presents the first known use of focal pulsed field ablation (PFA) to treat an epicardial ventricular tachycardia (VT) focus via an endocardial approach in a patient with non-ischemic cardiomyopathy. The 61-year-old had experienced electrical storm prior, but despite amiodarone and beta blockers he had had increased episodes of VT requiring ICD therapy.

After failed attempts with rf, it was thought that the origin was likely epicardial although the space was difficult to access. The decision was then made to utilize focal PFA via the Centauri system and a Thermocool Smarttouch catheter to deliver energy endocardially, targeting the endocardial origin at the basal anterolateral zone of the lv.

The intervention was successful with no reported complications and no re-inducability even with triple extrastimuli, and the patient remained free of ventricular arrhythmias during follow-up.

This case underscores the potential of focal PFA as a safe and effective modality for managing challenging epicardial arrhythmias through less invasive endocardial access, offering an alternative to traditional epicardial ablation techniques.

A case of safe and durable focal pulsed field electroporation treatment of outflow tract premature ventricular contractions

Author

Worck R. Et AL.

HEART RHYTHM 02, JUL 2023

Summary

This case report documents the first known instance of successful and durable elimination of premature ventricular contractions (PVCs) originating from the outflow tract using focal pulsed-field electroporation (F-PFE). After receiving 0.2mg nitroglycerin iv to prevent coronary spasm, the patient underwent F-PFE targeting the PVC focus, resulting in immediate suppression of ectopic activity without complications. Follow-up assessments confirmed the sustained absence of PVCs, with the PVX burden falling from 11% prior to the procedure to <0.01% at two months post, none of which resembled the ablated PVC morphology.

This case highlights the potential of F-PFE as a safe and effective alternative to traditional ablation techniques for treating ventricular arrhythmias, particularly in anatomically sensitive regions.

Focal pulsed field electroporation of left ventricular premature contractions after failed radiofrequency ablation

Author

Hansen J. Et Al.

HEART RHYTHM, AUG 2023

Summary

This case report details the use of focal pulsed field electroporation (PFE) to successfully eliminate left ventricular premature contractions (LVPCS) that persisted after conventional radiofrequency (RF) ablation. The patient, a 60-year-old male with idiopathic LVPCS, initially underwent rf ablation, which failed to suppress the arrhythmia. Intraprocedure testing led the authors to believe that the source of these PVCS was a deep intramyocardial/epicardial focus that could not be penetrated with RF lesions.

After 0.4mg iv nitroglycerin, subsequent PFE targeting the same region resulted in immediate cessation of the ectopic beats. They highlight that there may have been potential contribution of the RFA pretreatment but note that preclinical work suggests that PFA penetration in mature scar is not different from normal myocardium. Follow-up evaluations confirmed the sustained absence of LVPCS, with no adverse events reported. There were no PVCS on continuous monitoring until discharge, and no palpitations reported AT the one-week follow-up. Several weeks later he experienced palpitations, but these were from a different focus than those treated as well as PACS and atrial tach. There was no recurrence of the ablated PVC.

This case underscores the potential of PFE as an effective alternative to RF ablation for treating refractory ventricular arrhythmias, particularly in anatomically challenging areas.

Ablation of Epicardial Ventricular Focus Through Coronary Sinus Using Pulsed-Field Ablation. A Case Report

Author

Mestrovic I. Et AL.

JOURNAL OF CARDIOVASCULAR
ELECTROPHYSIOLOGY, JAN 2024

Introduction

With the entry of pulsed-field ablation (PFA) into electrophysiology, new possibilities for ablation of different substrates such as epicardial foci of premature ventricular contractions (PVCs) from coronary venous system (CVS) have been opened.

Methods

This article focuses on a case of a 27-year-old patient with frequent monomorphic PVCs of epicardial origin, treated by radiofrequency ablation, followed by PFA.

Results

After unsuccessful focus ablation through CVS with RFA, successful ablations from the same region with PEF were achieved.

Conclusion

This is the first described case of successful ablation of epicardial PVCs using PFA, which we hope will help in defining indications for this novel technology and enhance quality of treatment for patients with different arrhythmias.

Sequential Unipolar Biventricular Pulsed Field Ablation for Refractory Intramural Septal Ventricular Tachycardia

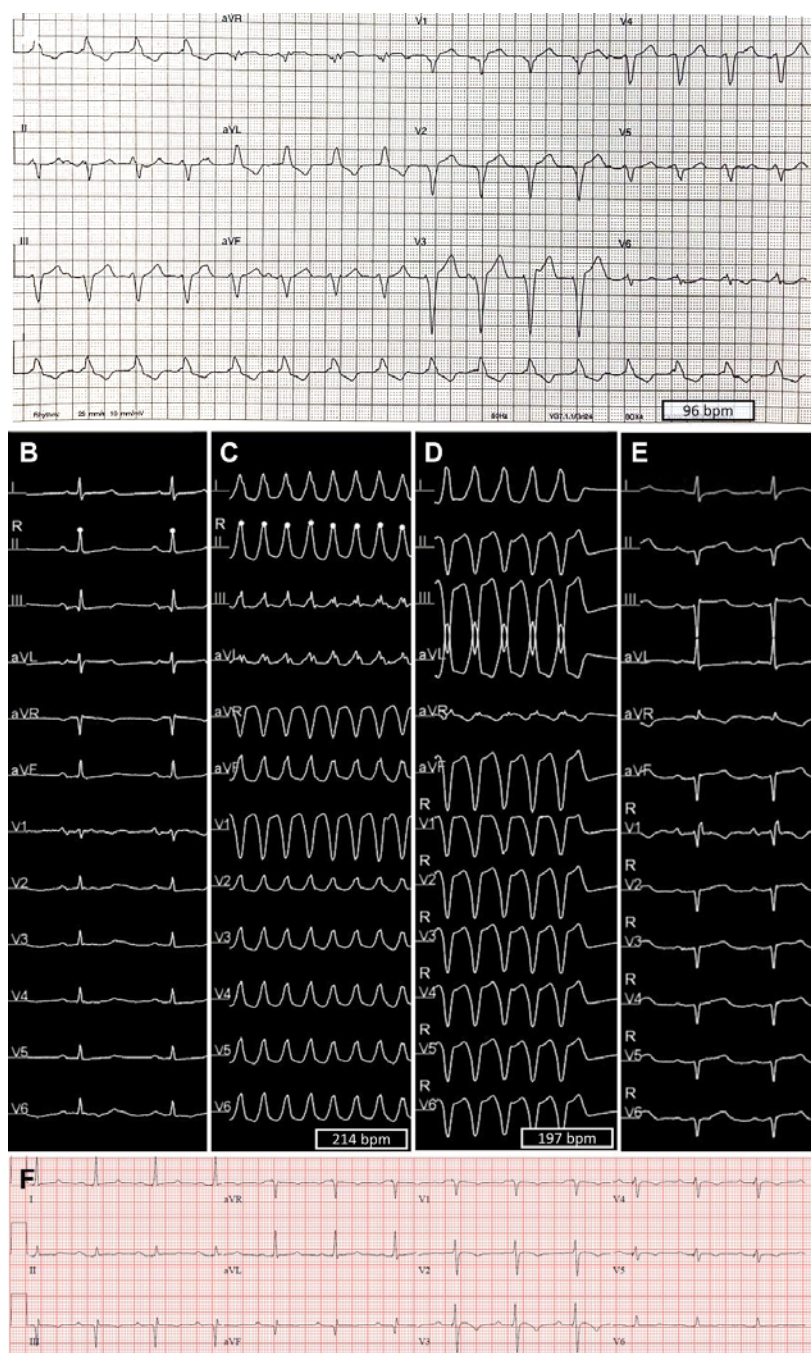
Author

Cespon-Fernandez M. Et Al.

JACC, JUN 2024

Abstract

Catheter ablation of septal ventricular tachycardia (VT) is challenging. Pulsed field ablation is a promising technology, potentially reaching deep substrates. We report the first sequential unipolar biventricular pulsed field ablation targeting refractory septal VT. Besides, we illustrate the importance of searching underlying cardiomyopathy in patients with recurrent multiple morphology VTS and normal magnetic resonance imaging.



(A) VT1 (spontaneous tachycardia).
 (B) Baseline ECG.
 (C) Intraoperative VT2.
 (D) Nonsustained VT3.
 (E) End of the procedure (note incomplete right bundle-branch block and left anterior fascicular block, QRS: 110 ms).
 (F) Twenty-four hours after the procedure (recovered)

Pulsed field ablation as a feasible option for the treatment of epicardial left ventricular summit premature complex foci near the coronary arteries: A case report

Author

Spenkelink, D., Et Al.

EUROPEAN HEART JOURNAL, SEP 2024

Background

Radiofrequency catheter ablation in the left ventricular summit region is a challenging procedure due to proximity to the coronary arteries. Pulsed field ablation, a novel non-thermal ablation modality, does not cause damage to coronary arteries and may be used in the left ventricular summit region.

Case summary

We describe a 45-year-old symptomatic patient with epicardial left ventricular summit premature ventricular complexes. Successful ablation of the focus was achieved by pulsed field ablation via a subxiphoid epicardial approach. Radiofrequency ablation would most likely have been ineffective due to the epicardial fat layer and potentially unsafe due to the proximity to the coronary arteries. Six months after ablation, the patient was asymptomatic and without ventricular ectopy.

Discussion

For the first time, epicardial pulsed field ablation was successfully used for ablation of left ventricular summit extrasystole, where radiofrequency ablation could not be used because of the proximity of the coronary arteries. We conclude that pulsed field ablation might be a feasible option for this indication.

Ventricular tachycardia: Focal pulsed field electroporation as a rescue therapy

Author

Santos, R., Et Al.

HEARTRHYTHM 02, NOV 2024

Summary

This case report details the use of focal pulsed field electroporation (PFE) as a rescue therapy for a patient with structural heart disease and recurrent ventricular tachycardia (VT) refractory to conventional treatments. The patient had a complex history, including ischemic cardiomyopathy, had percutaneous revascularization in 1986, LVEF of 30%, ICD implantation in 2008, multiple failed radiofrequency ablation procedures, and ongoing VT episodes/VT storm despite antiarrhythmic medication.

Electroanatomic mapping revealed an anterior and apical scar in the left ventricle, with substrate maps identifying regions associated with VT termination. Focal PFA at 25a was applied to these arrhythmogenic substrates, resulting in immediate and sustained elimination of VT without complications.

This case underscores the potential of focal PFE as an effective and safe alternative for treating refractory VT, particularly in patients with structural heart disease where conventional ablation techniques have failed.

Pulsed Field Ablation Using a Focal Contact Force Catheter Allowed Successful Ablation of a Focal Right Atrial Tachycardia in the Proximity of The Phrenic Nerve

Author

Phlips T. Et AL.

HEART RHYTHM CASE REPORTS, MAR 2023

Summary

This case report describes the successful use of pulsed field ablation (PFA) to treat focal right atrial tachycardia (at) located near the phrenic nerve. A 33-year-old patient with symptomatic AT, who had failed previous rf ablation due to phrenic proximity, underwent subsequent PFA ablation to minimize the risk of phrenic injury. Electroanatomic mapping identified the earliest activation site in the right atrium, adjacent to the phrenic nerve.

PFA was applied at this site, resulting in phrenic stimulation and transient firing of the focal tachycardia. A relatively broad region of ablation was necessary before the tachycardia eventually stopped, and some additional lesions were placed to consolidate the region of fragmented potentials. In total, 14 lesions were delivered. After the procedure, phrenic nerve capture was confirmed, and the patient remained free from AT during follow-up.

This case highlights the potential of PFA as a safe and effective alternative to conventional thermal ablation techniques, particularly in anatomically challenging regions near critical structures like the phrenic nerve.

Glossary

AF	Atrial Fibrillation
AFL	Atrial flutter
AKI	Acute kidney injury
AMC	Aortomitral continuity
Amp	Amplitude
APS	Accessory pathways
AT	Atrial tachycardia
BIB	Bidirectional block
CD	Conductive disorders
CI-VVS	Cardioinhibitory vasovagal syncope
CNA	Cardioneuroablation
CS	Coronary spasm
CT	Computed Tomography
CTI	Cavo-tricuspid isthmus
COX	Cytochrome C Oxidase
CVS	Coronary venous system
DCZ	Dark central zone
DWI	Diffusion-weighted imaging
EAM	Electroanatomical mapping
F-PFA	Focal pulsed field ablation
F-PFE	Focal pulsed-field electroporation
GCV	Great cardiac vein
H&E	Hematoxylin and eosin
HR	Hyperstained rim
ICE	Intra-cardiac echocardiography
ILD	Inter-lesion distances
ILR	Implantable loop recorder
IST	Inappropriate sinus node tachycardia
IR	Irreversible
LA	Left Atrium
LAPW	Left atrium posterior wall
LCx	left circumflex

LDH	Lactate dehydrogenase
LV	Left Ventricle
LVPSCS	Left ventricular premature contractions
MB	Microbubbles
MI	Myocardial infarction
MRI	Magnetic resonance imaging
NIHSS	Nih stroke scale
OCT	Optical coherence tomography
PEF	Pulsed electric field
PFA	Pulsed Field Ablation
PHN	Phrenic nerve
PB	Pale Boundaries
POTS	Postural orthostatic tachycardia syndrome
PVC	Premature ventricular contractions
PVI	Pulmonary vein isolation
PWI	Posterior wall isolation
R	Reversible
RA	Right Atrium
RCA	Right coronary artery
RF	Radiofrequency
RFA	Radiofrequency Ablation
RSGP	Right superior ganglionated plexus
RSPV	Right Superior Pulmonary Vein
RV	Right Ventricle
SN	Sinus node
SVC	Superior vena cava
SWS	Shear wave speed
TTMRE	Tabletop MRE
TTC	Triphenyl tetrazolium chloride
UHDX	Ultrahigh-density
VA	Ventricular arrhythmias
VPC	Ventricular premature complexes

The Cardiofocus Centauri System Is Ce-Marked. The Centauri System Is An Electrosurgical System Used In Conjunction With Commercially Available Cardiac Ablation Catheters To Deliver Radiofrequency Pulsed Electric Field Energy To Cardiac Tissue. The Centauri System Is Intended To Treat Adult Patients Undergoing Intracardiac Ablation Procedures For The Treatment Of Paroxysmal Atrial Fibrillation.

For Further Information, Please Consult The Cardiofocus Website At www.Cardiofocus.Com/Centauri-System/.

Device Is Not Approved For Sale In The United States

Manufacturer: CardioFocus, Inc.

500 Nickerson Road
Marlborough, Massachusetts 01752

Revision: A (2026-04-30)



532819--A

© BIOTRONIK SE & Co. KG
All rights reserved. Specifications
are subject to modification,
revision and improvement.

BIOTRONIK SE & Co. KG
Woermannkehe 1
12359 Berlin / Germany

Tel +49 (0) 30 68905-0
Fax +49 (0) 30 6852804
sales@biotronik.com
www.biotronik.com

 **BIOTRONIK**
excellence for life