עדכונים על PFA לפרפור פרוזדורים: סקירת מחקרים וטכנולוגיות – מה קיים היום, ומה מחכה לנו בעתיד?

איברהים מרעי
מרכז רפואי צפון- פוריה
28.06.2024

Introduction

- PFA is a novel nonthermal ablation modality: preferentially ablate myocardial tissue.
- During PFA, ultrarapid (micro-to nanosecond) electrical pulses are applied to destabilize cell membranes by forming irreversible nanoscale pores, culminating in cell death, a phenomenon called electroporation.
- Tissue selectivity: the threshold field strength for tissue necrosis appears to be lower for some tissues such as the myocardium than for other tissues such as blood vessels or nerve fibers.
- PFA spares the extracellular matrix
- Preclinical experiments have confirmed the relative tissue selectivity of PFA

Clinical efficacy: 1 year outcome

JACC: CLINICAL ELECTROPHYSIOLOGY VOL. 7, NO. 5, 2021
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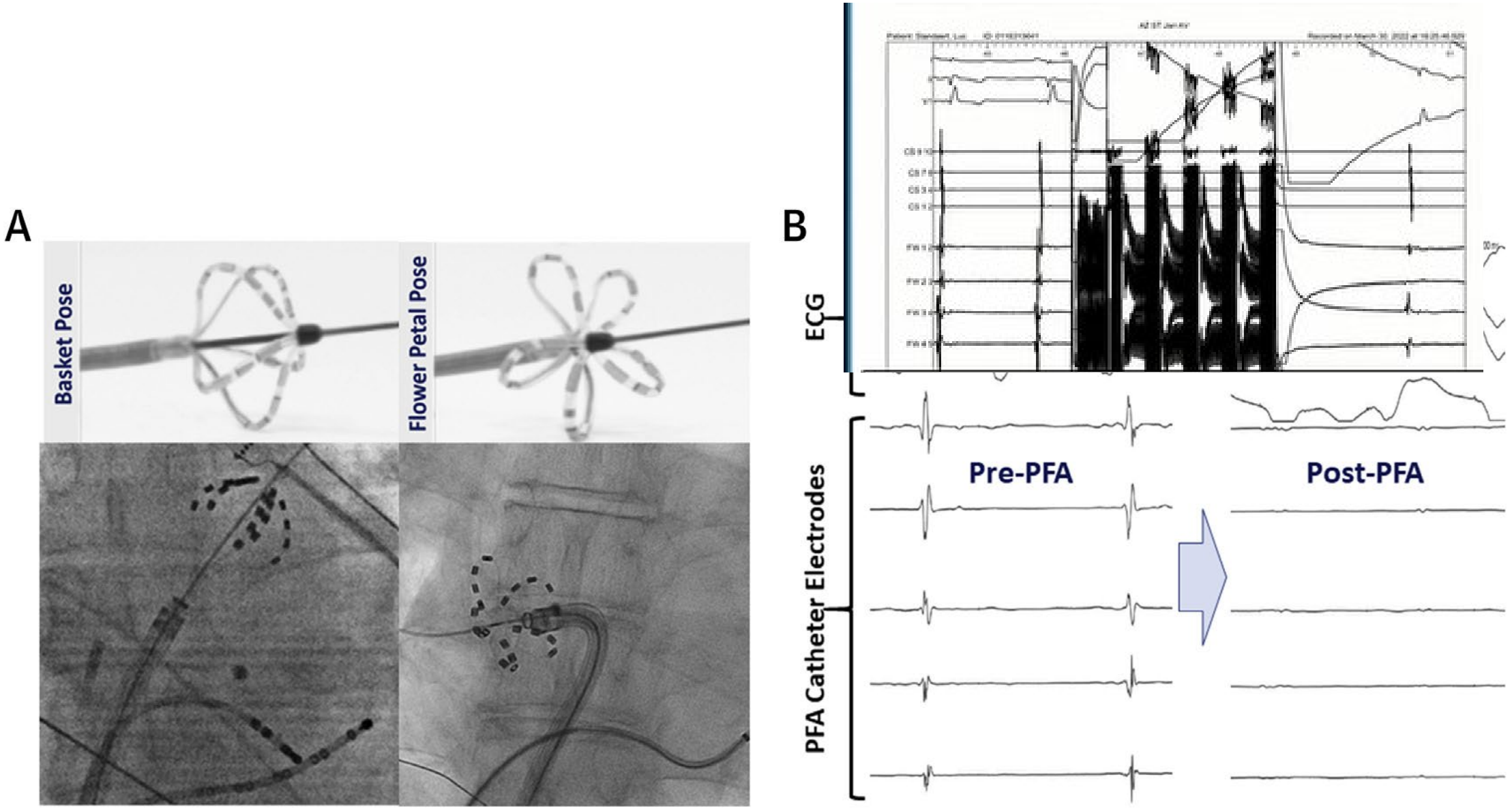
Pulsed Field Ablation of Paroxysmal Atrial Fibrillation

1-Year Outcomes of IMPULSE, PEFCAT, and PEFCAT II

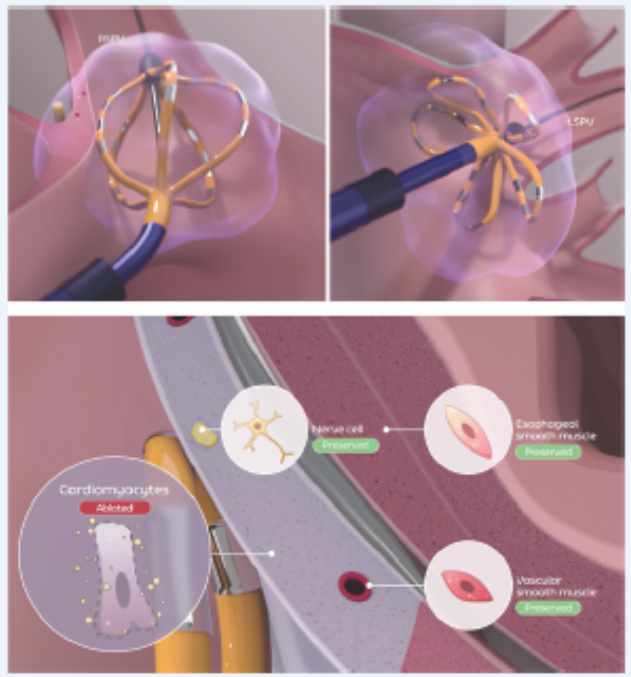
Vivek Y. Reddy, MD,[a,b] Srinivas R. Dukkipati, MD,[b] Petr Neuzil, MD, PhD,[a] Ante Anic, MD,[c] Jan Petru, MD,[a] Moritoshi Funasako, MD,[a] Hubert Cochet, MD, PhD,[b] Kentaro Minami, MD,[a] Toni Breskovic, MD, PhD,[c] Ivan Sikiric, MD,[c] Lucie Sediva, MD,[a] Milan Chovanec, MD,[a] Jacob Koruth, MD,[b] Pierre Jais, MD[d]

Farapulse: basket and flower configuration



CENTRAL ILLUSTRATION PFA for Paroxysmal AF

PFA Catheter & Mechanism of Ablation



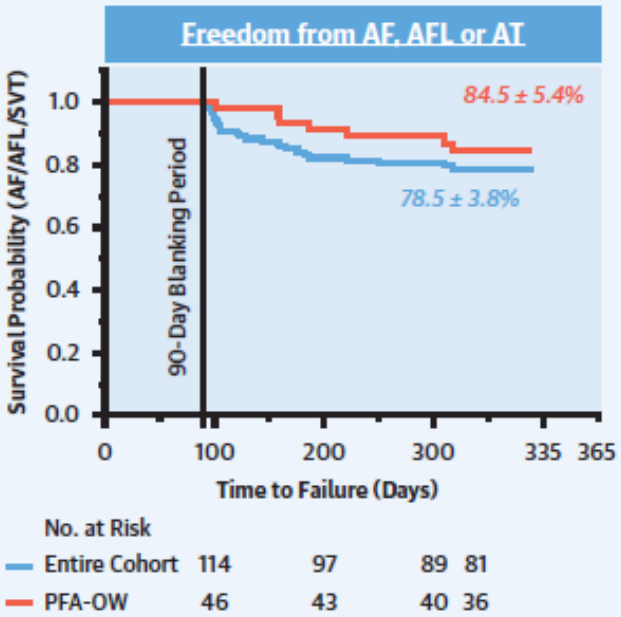
Safety

• *Esophageal Damage*	*0%*
◦ *Esophageal Dysmotility*	*0%*
◦ *Atrioesophageal Fistula*	*0%*
• *Pulmonary Vein Stenosis*	*0%*
• *Phrenic Nerve Injury*	*0%*
• *Stroke*	*0%*
◦ *Transient Ischemic Attack*	*0.9%*
• *Pericardial Effusion*	*0.8%*
• *Vascular injury*	*1.7%*
• *Death*	*0%*

Efficacy

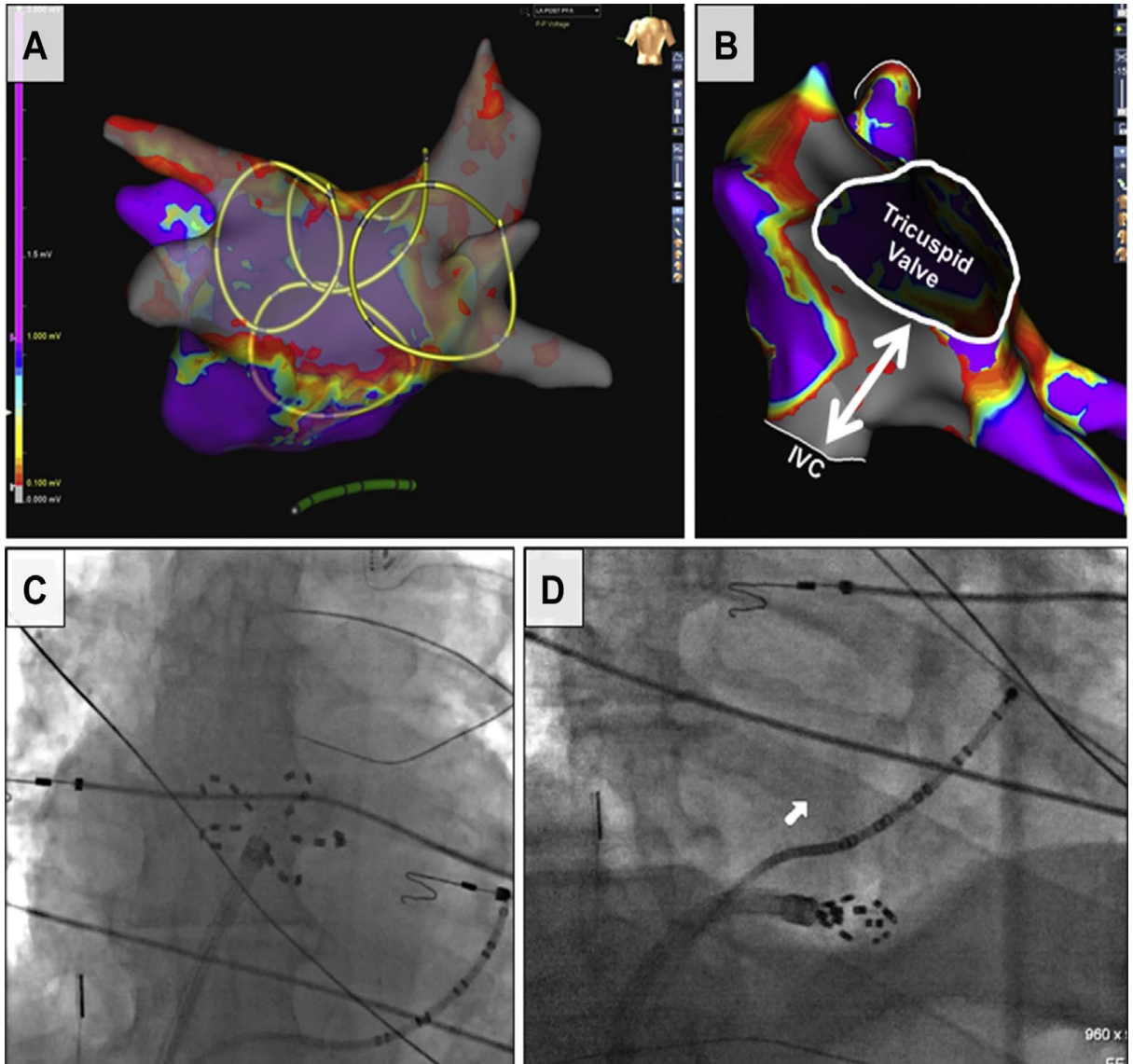
Durability of PV Isolation (Invasive Remapping)

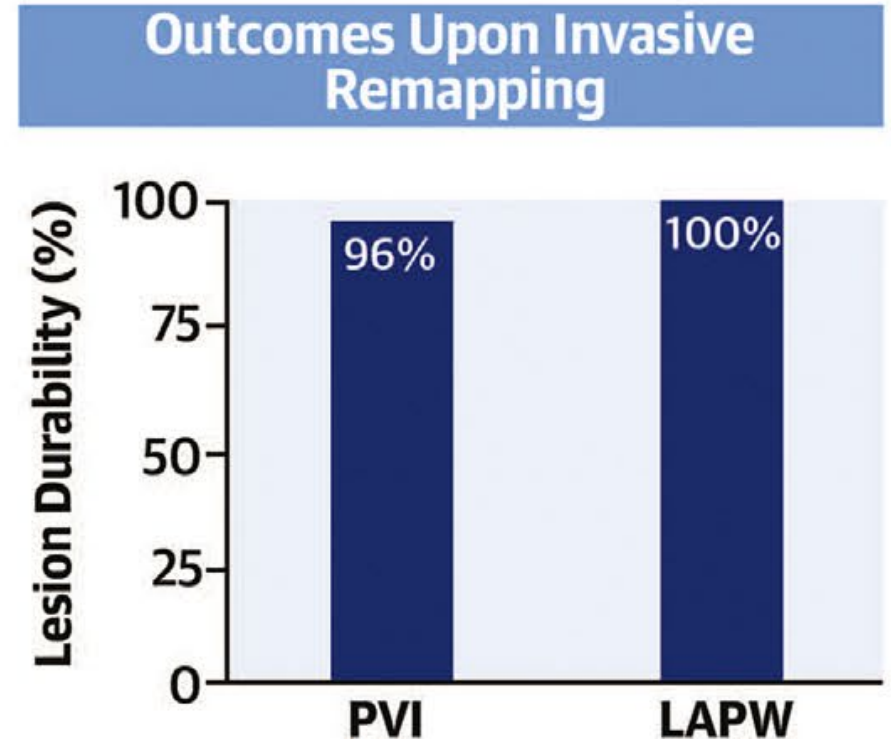
PFA Waveform	Per PV Basis		Per Pt Basis	
	No.%	Durable	No.%	Durable
All	429	84.8%	110	64.5%
PFA-OW	173	96.0%	44	84.1%



Reddy, V.Y. et al. J Am Coll Cardiol EP. 2021;7(5):614-27.

PFA for Persistent AFIB





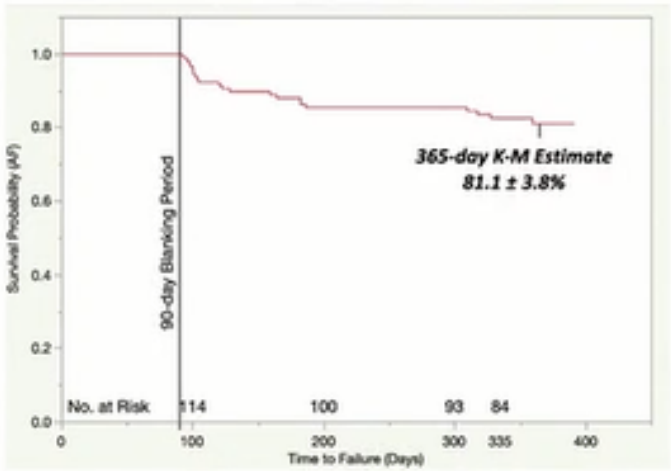
(J Am Coll Cardiol 2020;76:1068–80)

INITIAL 12 MONTHS F/U Data

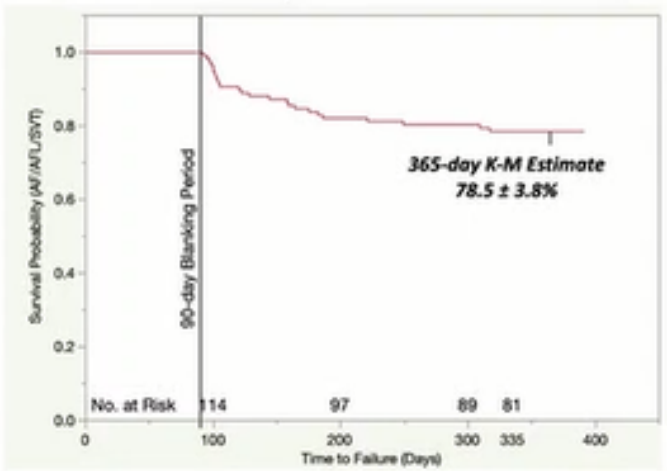
Pulsed Field Ablation of Paroxysmal Atrial Fibrillation

1-Year Outcomes of IMPULSE, PEFCAT, and PEFCAT II

Freedom from AF: Entire Cohort

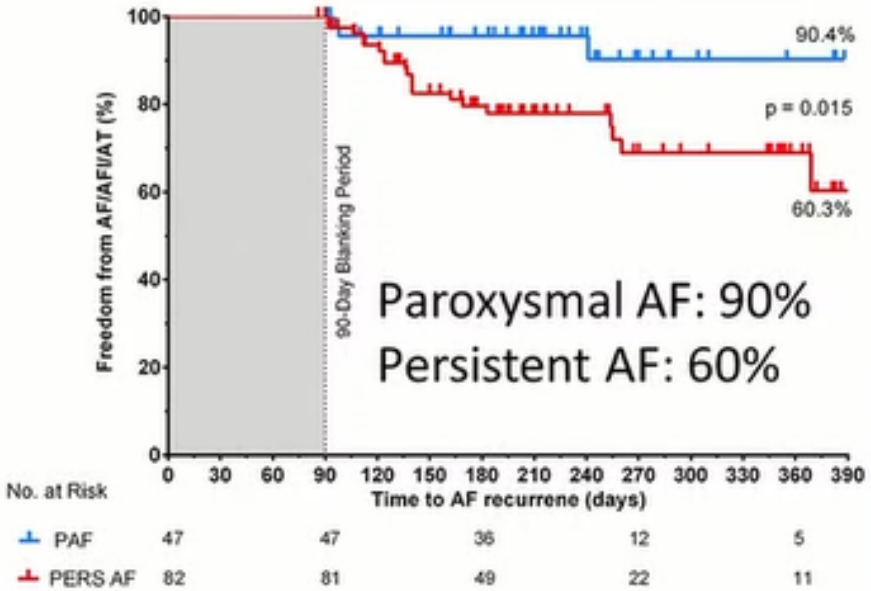


Freedom from AF, AFL or AT: Entire Cohort



Reddy V et al. https://doi.org/10.1016/j.jacep.2021.02.014

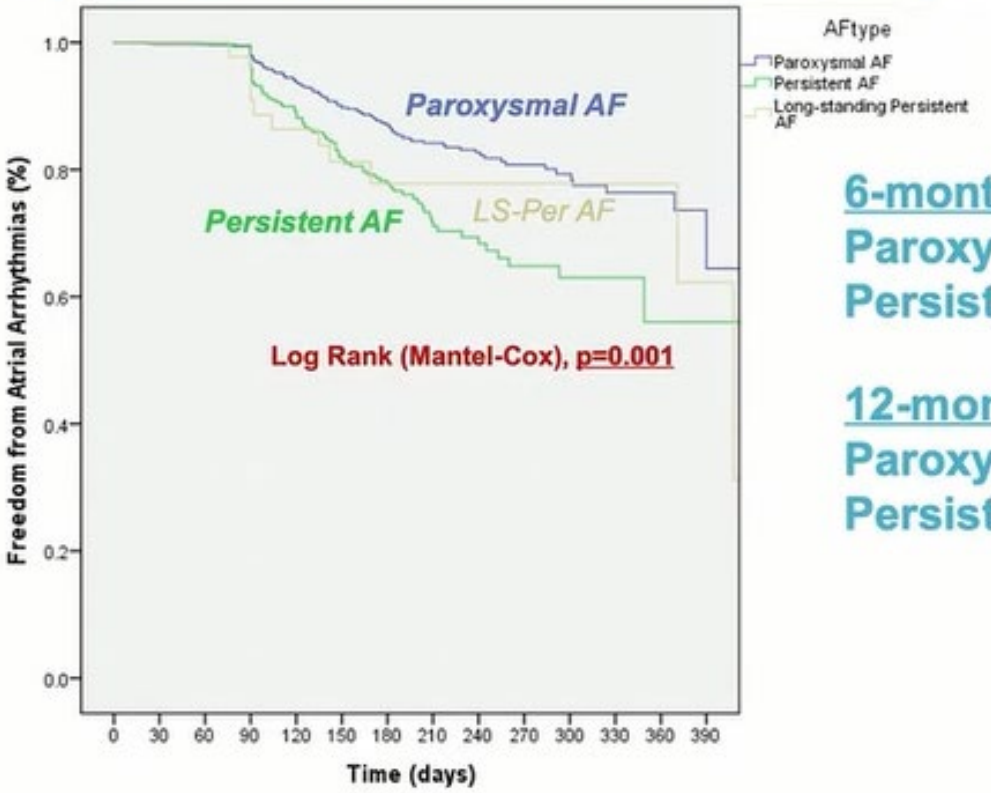
1-year freedom from arrhythmia



Lemoine MD et al. Clinical Research in Cardiology, 22 August 2022

MANIFEST-PF: Efficacy

K-M Analysis of Freedom from AF/AFL: By AF Subtype



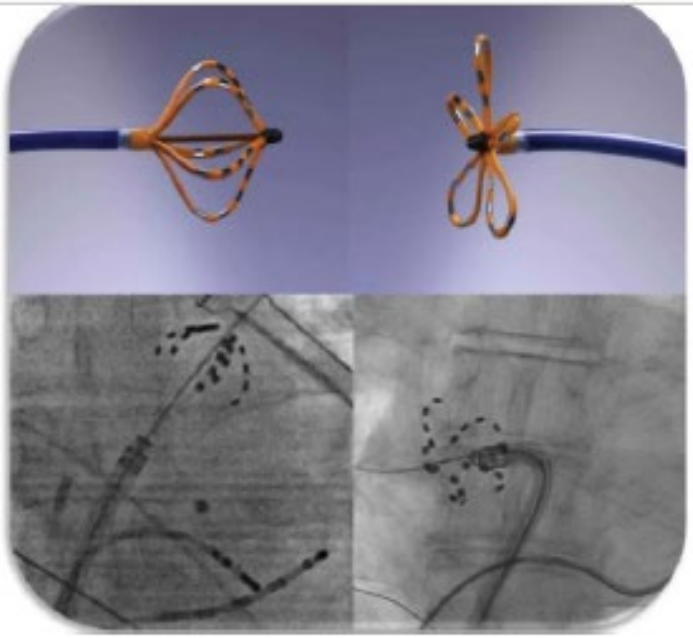
6-month Estimate
Paroxysmal AF: 86.6%
Persistent AF: 79.6%

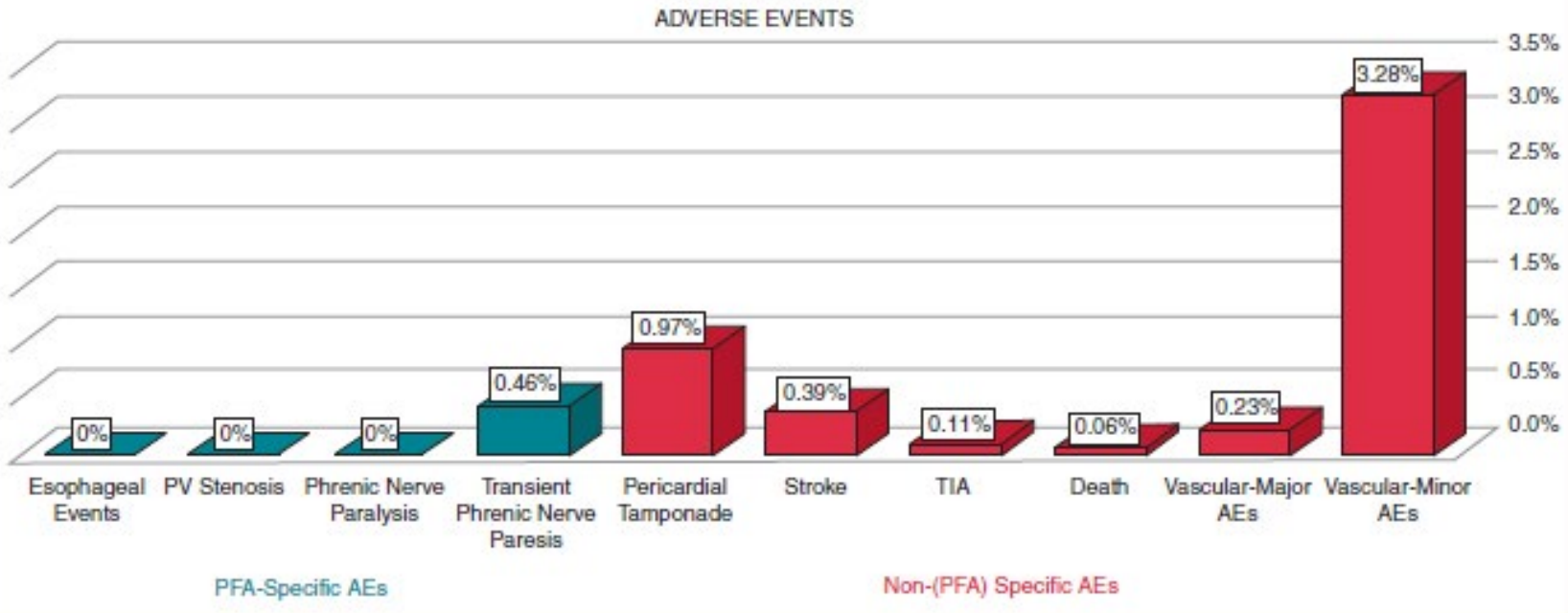
12-month Estimate
Paroxysmal AF: 73.4%
Persistent AF: 58.2%

MANIFEST-PF Survey

Real-World Outcomes of PFA for AF

- 24 centers in Europe
- 90 Operators
- 1,758 Patients
- 99.9% Acute PVI Success Rate





ESC European Society of Cardiology

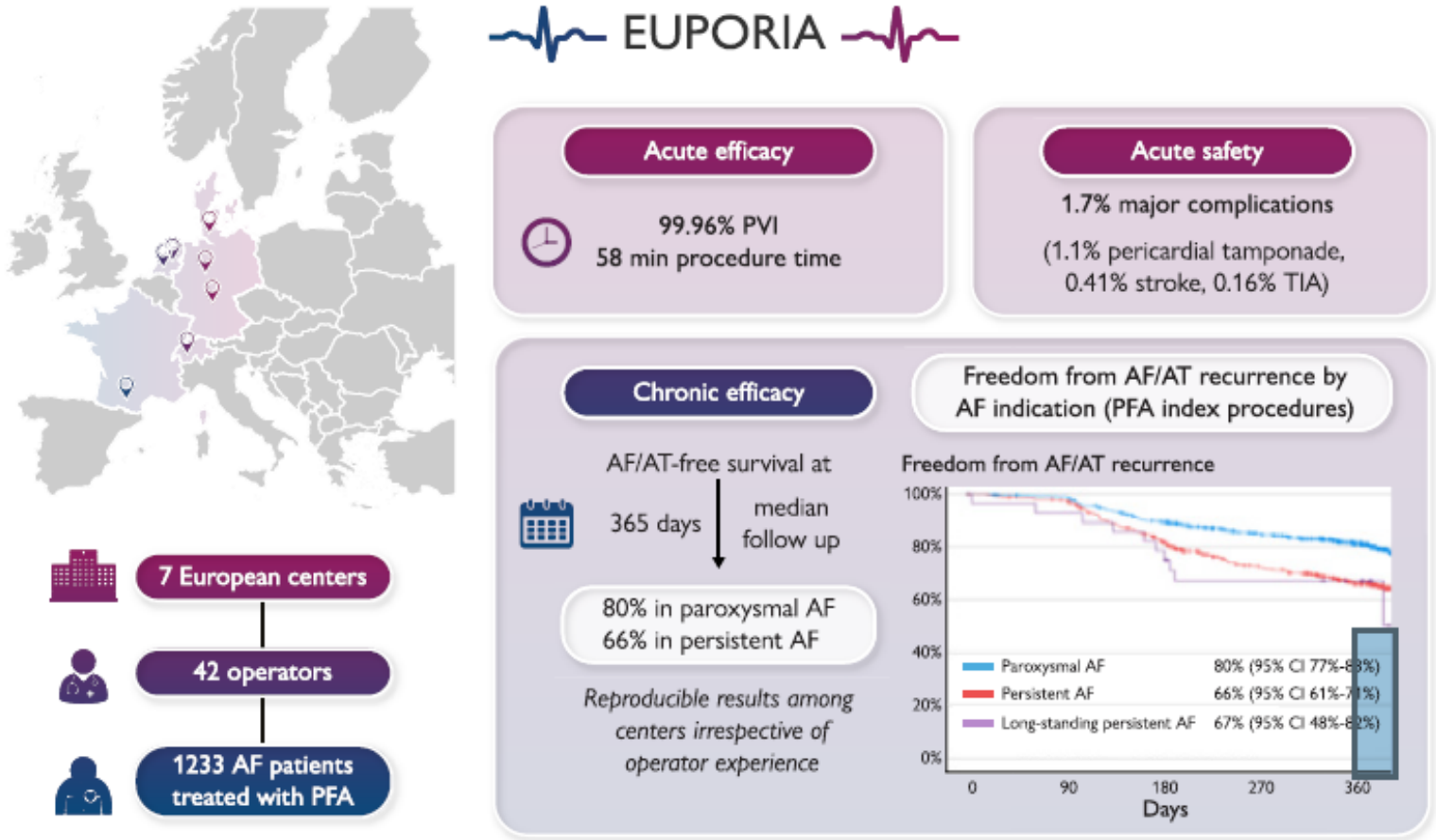
Europace (2023) **25**, 1–11
https://doi.org/10.1093/europace/euad185

CLINICAL RESEARCH

EUropean real-world outcomes with Pulsed field ablatiOn in patients with symptomatic atRIAl fibrillation: lessons from the multi-centre EU-PORIA registry

FARAPULSE system

Graphical Abstract

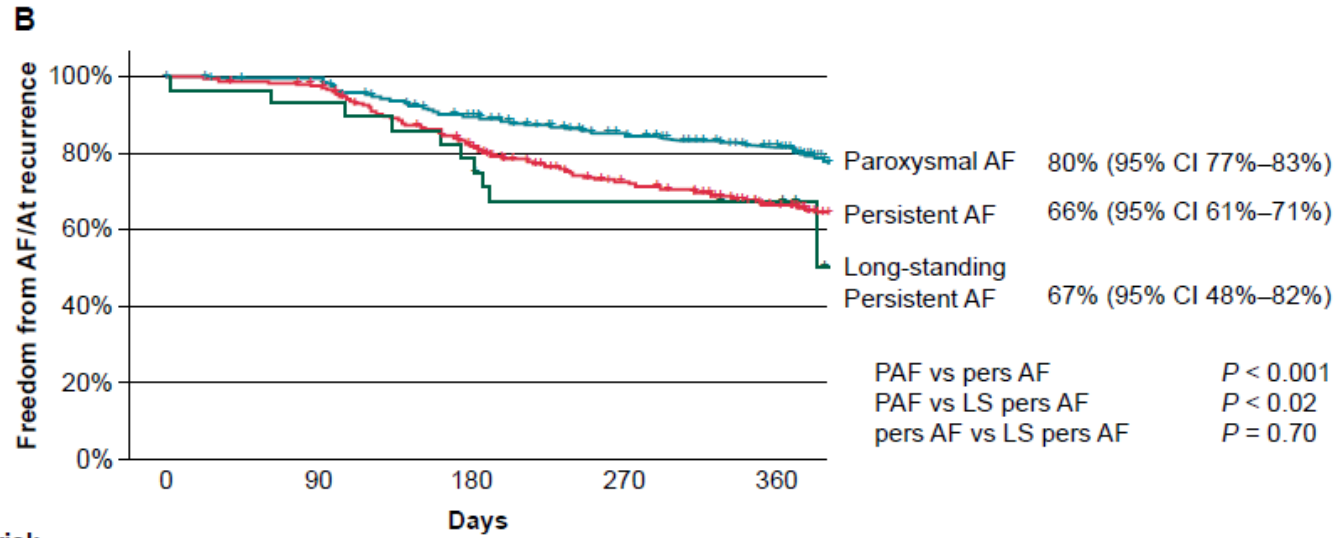


Keywords Ablation • Atrial fibrillation • Pulsed field ablation • Electroporation

Table 3 Procedural complications

Complications	*N* = 1233
Major complications, *n* (%)	**21 (1.7)**
Pericardial tamponade, *n* (%)	14 (1.1)
Stroke, *n* (%)	5 (0.41)[a]
TIA, *n* (%)	2 (0.16)
Minor complications, *n* (%)	**24 (1.9)**
Vascular access site complication	12 (0.97)
Phrenic nerve dysfunction	4 (0.32)[b]
Air embolism	3 (0.24)
Coronary spasm	1 (0.08)
Haemoptysis	1 (0.08)
Pericarditis	2 (0.16)
Pneumonia	1 (0.08)

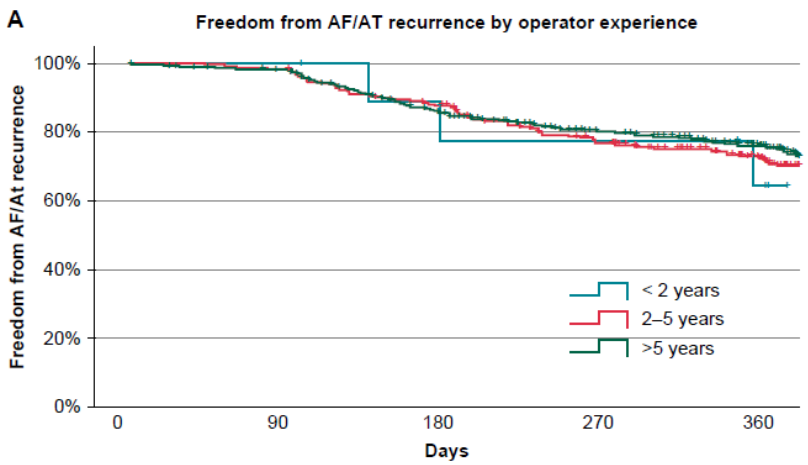
Data are given as absolute number of events and frequency.
TIA, transient ischaemic attack.
[a]Including one fatal stroke.

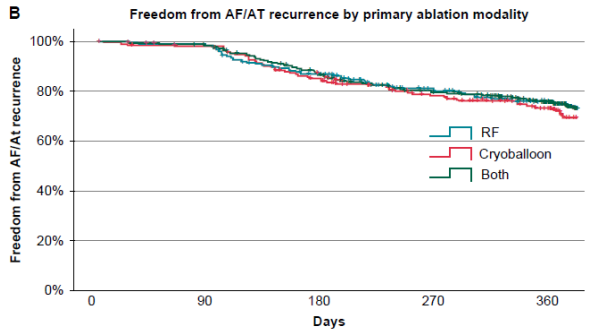


No. at risk

Paroxysmal AF	707	695	615	535	256
Persistent AF	426	410	327	259	134
LS Persistent AF	28	26	20	17	12

Figure 2 Kaplan–Meier curve of atrial fibrillation (AF)/atrial tachycardia (AT)-free survival for (*A*) all patients and (*B*) patients who underwent an pulsed field ablation (PFA) procedure.





No. at risk

RF	322	317	268	211	131
Cryoballoon	190	185	155	129	72
Both	649	631	543	471	342

Figure 3 Kaplan–Meier curves of atrial fibrillation (AF)/atrial tachycardia (AT)-free survival in patients who underwent an index pulsed field ablation (PFA) procedure by (*A*) operator experience and (*B*) operator ablation primary modality.

ORIGINAL RESEARCH

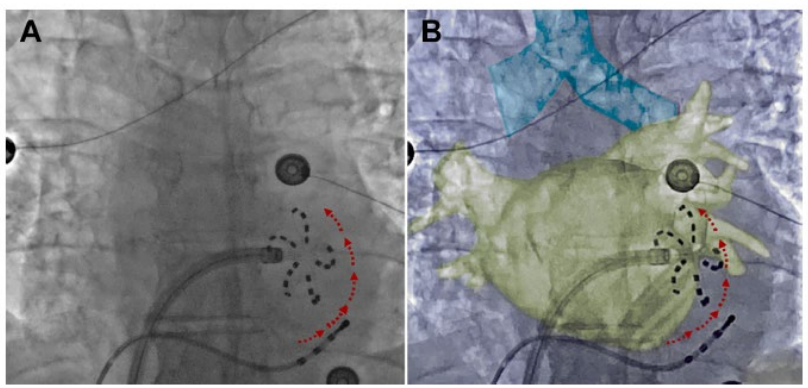
CATHETER ABLATION - ATRIAL FIBRILLATION

Pulsed-Field Ablation on Mitral Isthmus in Persistent Atrial Fibrillation

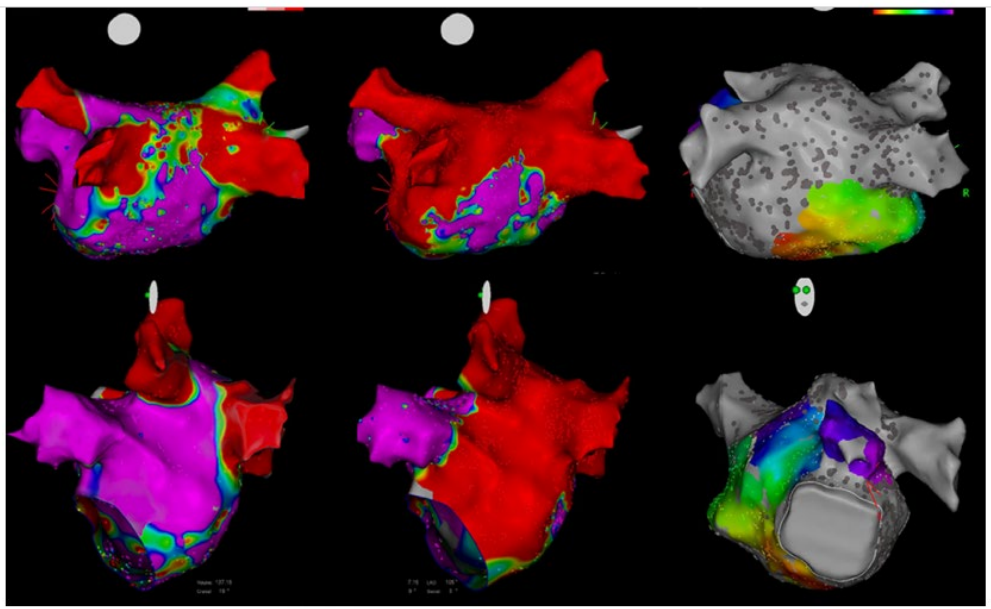
Preliminary Data on Efficacy and Safety

Baptiste Davong, MD,* Raquel Adeliño, MD,* Hubert Delasnerie, MD, Jean-Paul Albenque, MD, Nicolas Combes, MD, Christelle Cardin, MD, Quentin Voglimacci-Stephanopoli, MD, Stéphane Combes, MD,† Serge Boveda, PHD, MD†

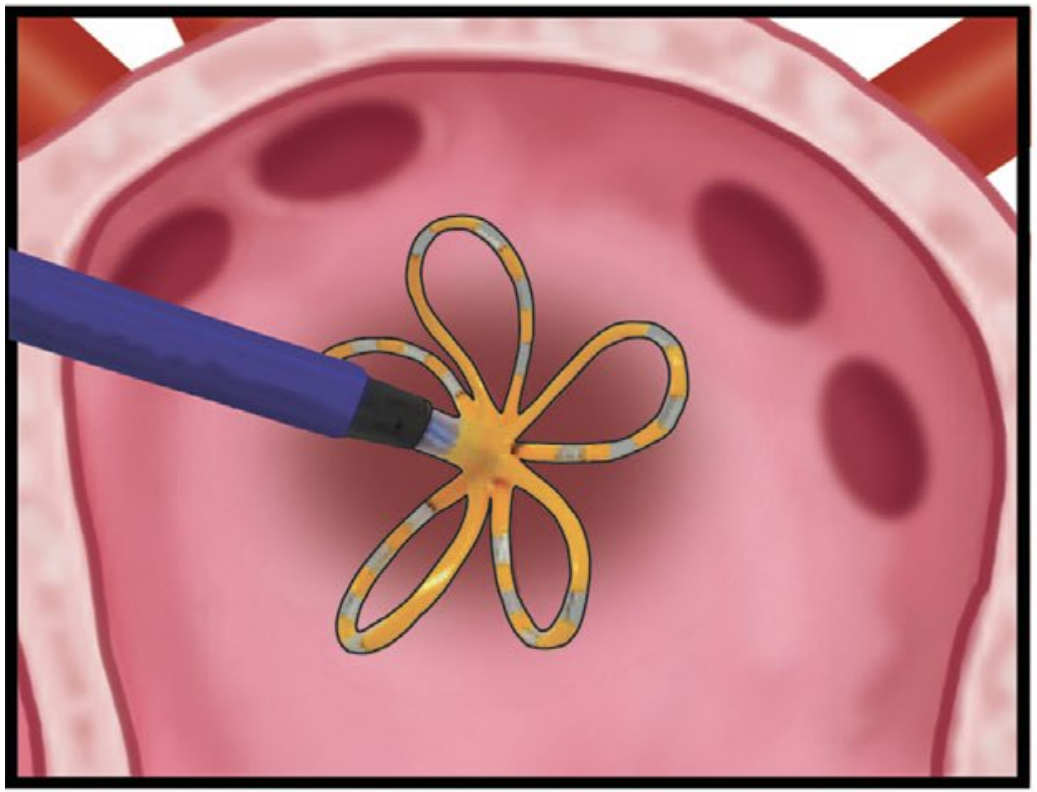
FIGURE 1 Fluoroscopic Example of a Representative Case of Linear Ablation at the Mitral Isthmus



(A) Left anterior oblique 30° view; **(B)** left anterior oblique 30° view with computed tomographic reconstruction. The pentaspline Farawave catheter is positioned at the mitral isthmus in the flower pose. The **red arrows** represent the different positions of the catheter during ablation between the coronary sinus and the left inferior pulmonary vein.



(A) Before and **(B)** immediately after pulsed-field ablation (PFA) in **(top)** posteroanterior and **(bottom)** left lateral views. **(B)** Post-PFA low voltage areas at the targeted substrates (pulmonary veins, posterior wall, and mitral isthmus). **(C)** Post-PFA activation map when pacing from mid-distal coronary sinus: The wavefront blocks at the MI and advances in a clockwise direction from posterior wall to the anterior wall of the left atrium.



Efficacy Outcomes

100% of Acute Success in Achieving

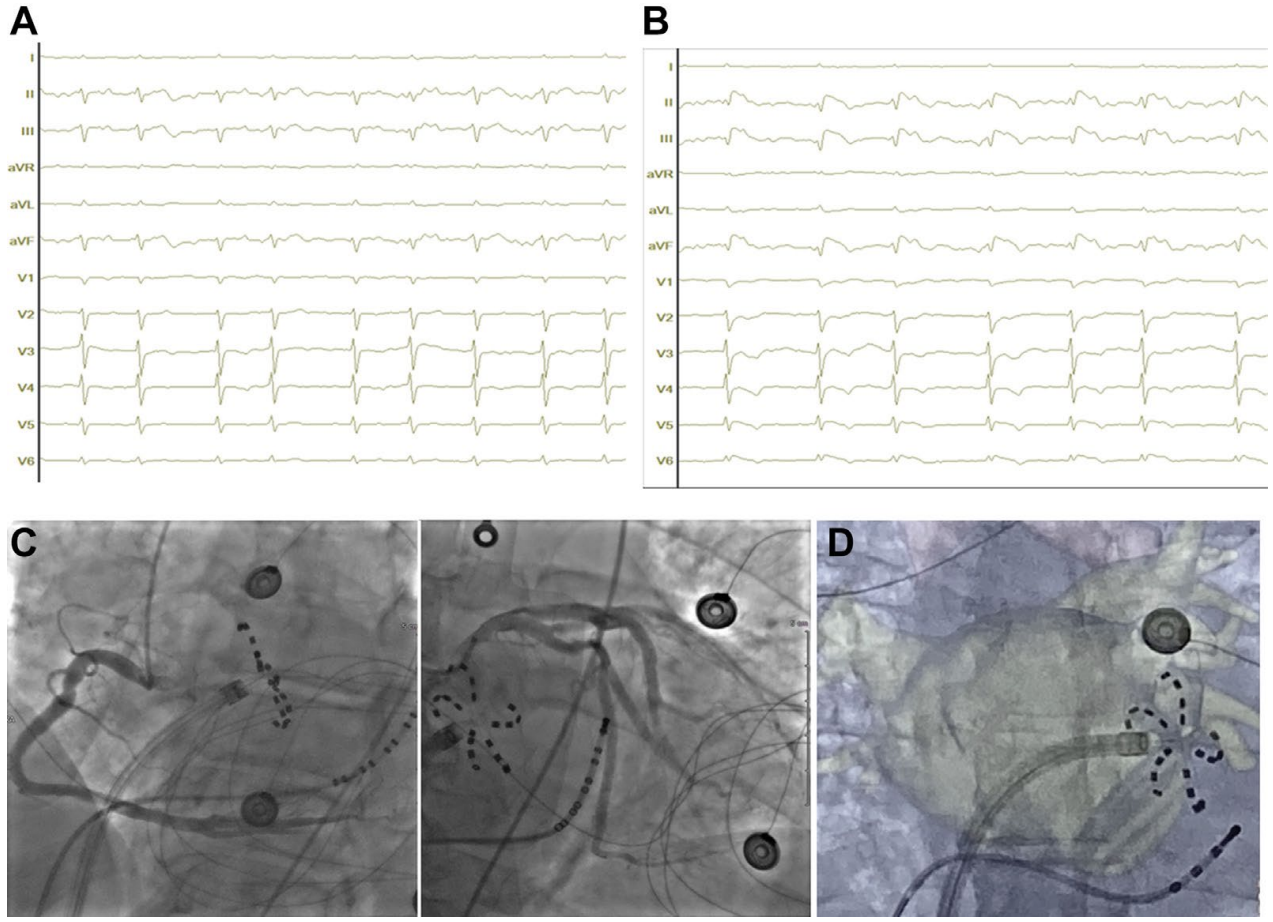
- Pulmonary vein isolation
- Posterior wall isolation
- Mitral isthmus block

Safety Outcomes

Two Cases of Coronary Spasm

(reversible after intravenous nitrates infusion)

Coronary spasm



Received: 20 December 2023 | Revised: 17 February 2024 | Accepted: 28 February 2024

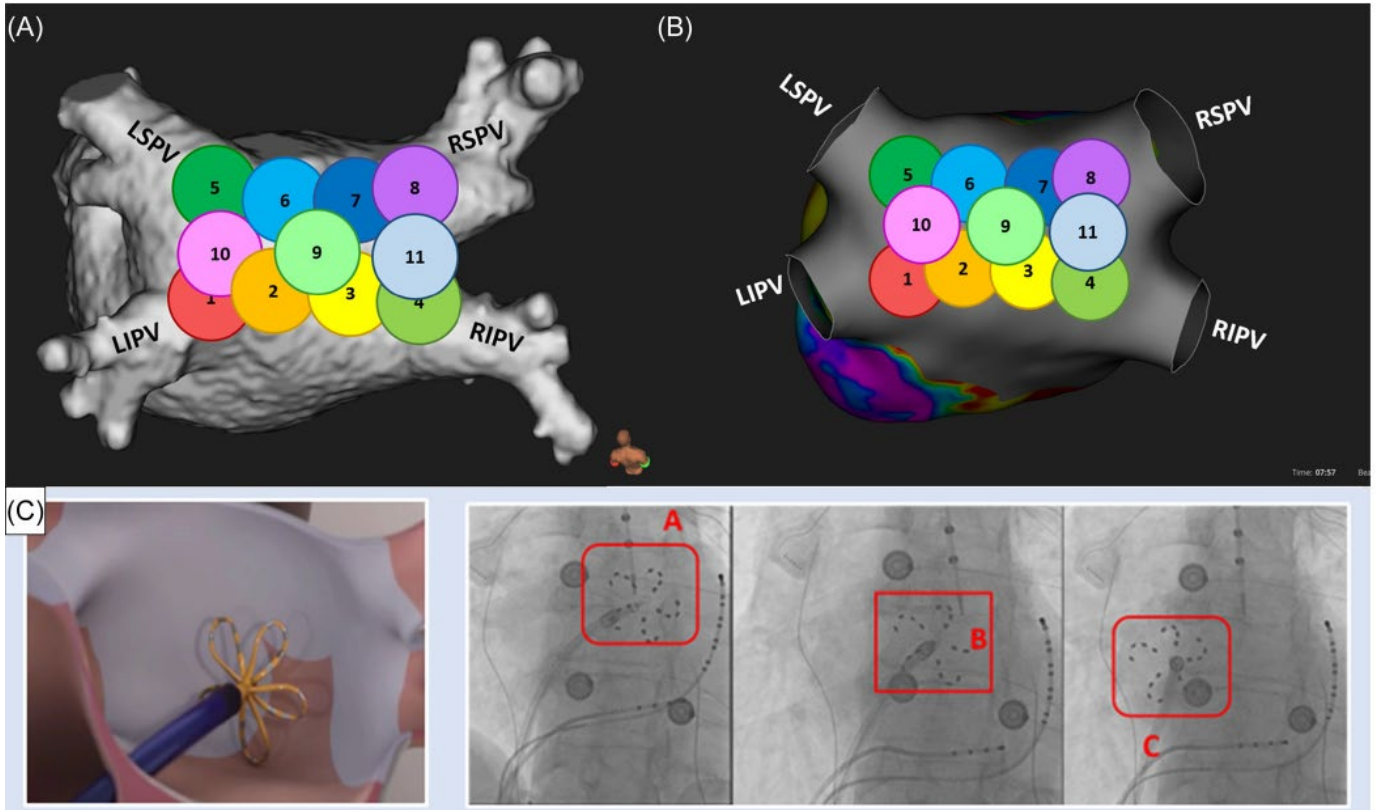
DOI: 10.1111/jce.16246

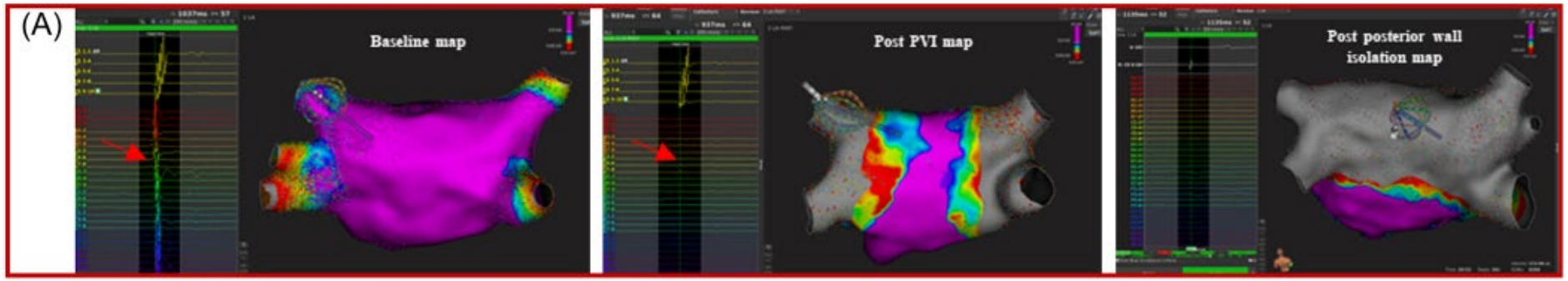
ORIGINAL ARTICLE

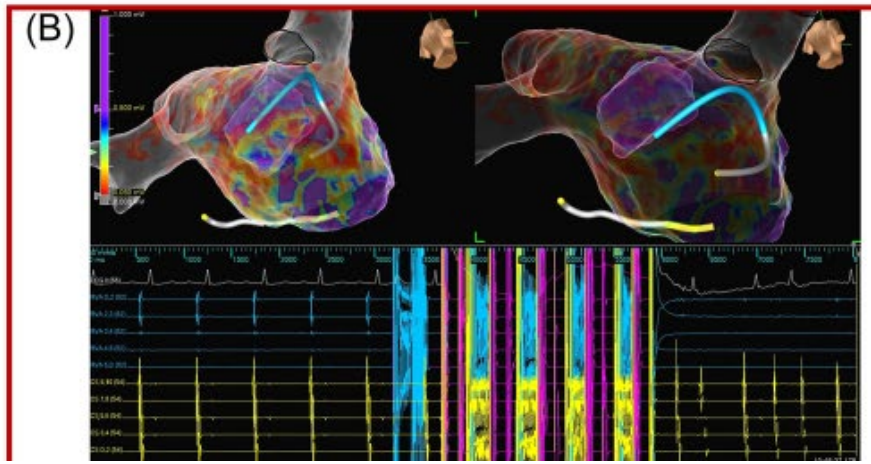
WILEY

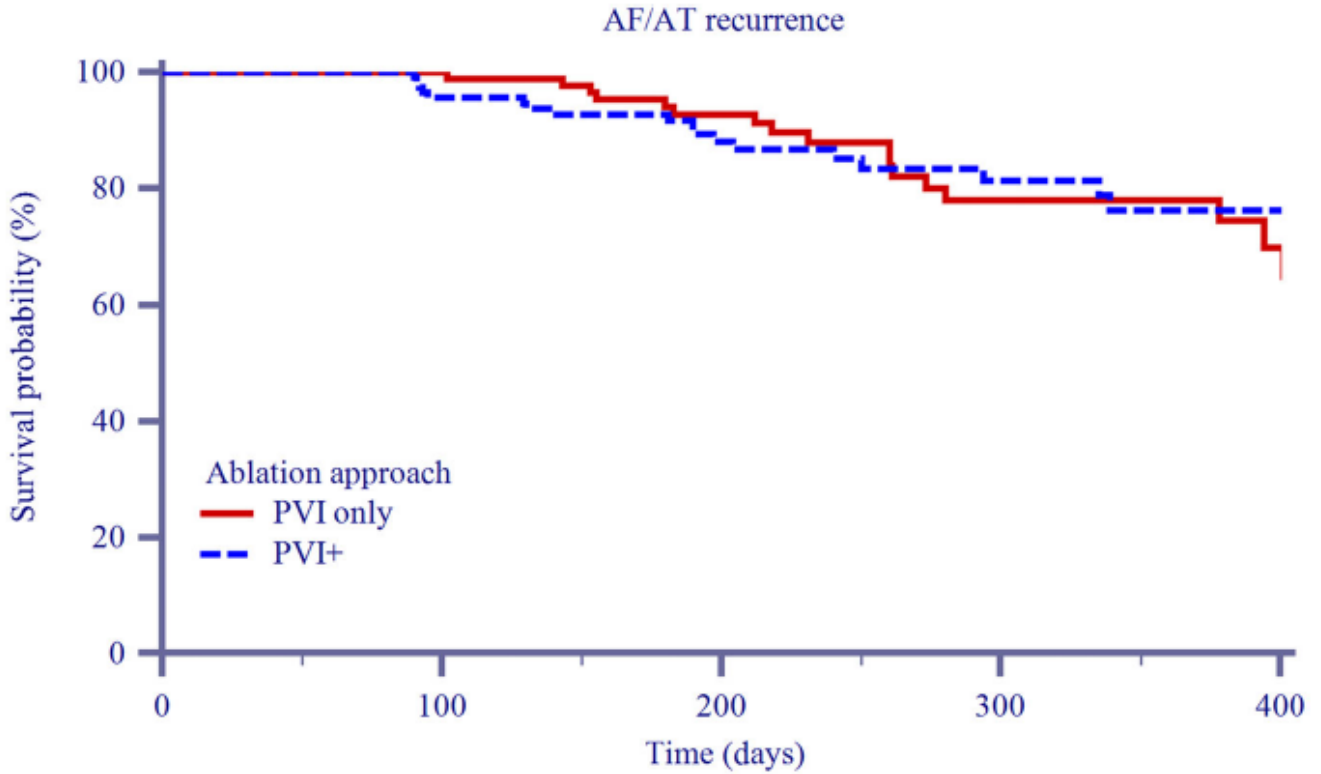
JCE
02.2024

Pulsed field ablation technology for pulmonary vein and left atrial posterior wall isolation in patients with persistent atrial fibrillation




(A)
Baseline map
Post PVI map
Post posterior wall isolation map


(B)


AF/AT recurrence
Survival probability (%)
100
80
60
40
20
0
0
100
200
300
400
Time (days)
Ablation approach
PVI only
PVI+

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VOL. 10, NO. 5, 2024
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ORIGINAL RESEARCH

CATHETER ABLATION - ATRIAL FIBRILLATION

Impact of Left Atrial Posterior Wall Ablation During Pulsed-Field Ablation for Persistent Atrial Fibrillation

Persistent Atrial Fibrillation: A MANIFEST-PF Registry Substudy

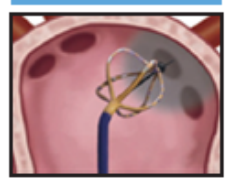
MANIFEST-PF population
N = 1,568

Pers-AF cohort
N = 547

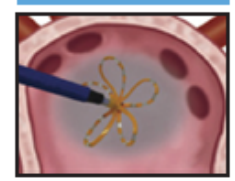
PV isolation

PV isolation + LAPW ablation
N = 131

PV Isolation



LA Posterior Wall Ablation



Population

Adults with PersAF undergoing first-time AF ablation using pulsed-field

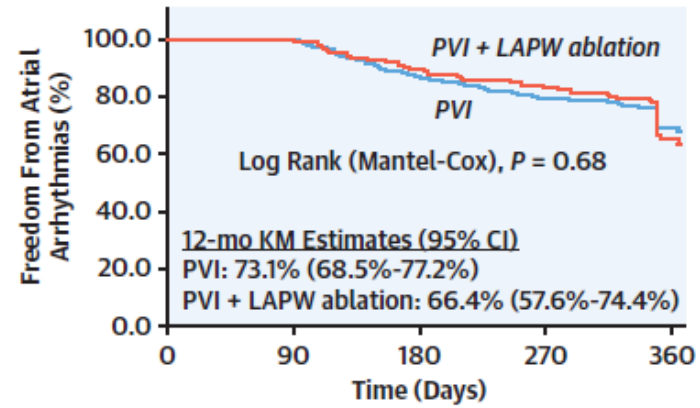
Mean age: 66.3 years

Locations

24 centers from 8 countries

Primary Outcome

Freedom from any atrial arrhythmia of ≥30 seconds with or without antiarrhythmic drugs, after a single ablation procedure



No. of Patients

PVI + LAPW ablation	131	130	112	101	65
PVI	416	413	326	256	167

Conclusion

In this nonrandomized study, addition of LAPW ablation to PVI did not significantly improve freedom from atrial arrhythmia at 1 year compared with PVIalone.

Turagam MK, et al. J Am Coll Cardiol EP. 2024;10(5):900-912.

KM = Kaplan-Meier; LA = left atrial; LAPW = left atrial posterior wall; MANIFEST-PF = Multi-National Survey on the Methods, Efficacy, and Safety on the Post-Approval Clinical Use of Pulsed Field Ablation; PersAF = persistent atrial fibrillation; PVI = pulmonary vein isolation.

HeartRhythm

The Official Journal of the Heart Rhythm Society, The Cardiac Electrophysiology Society, and The Pediatric & Congenital Electrophysiology Society

Heart Rhythm Society SM

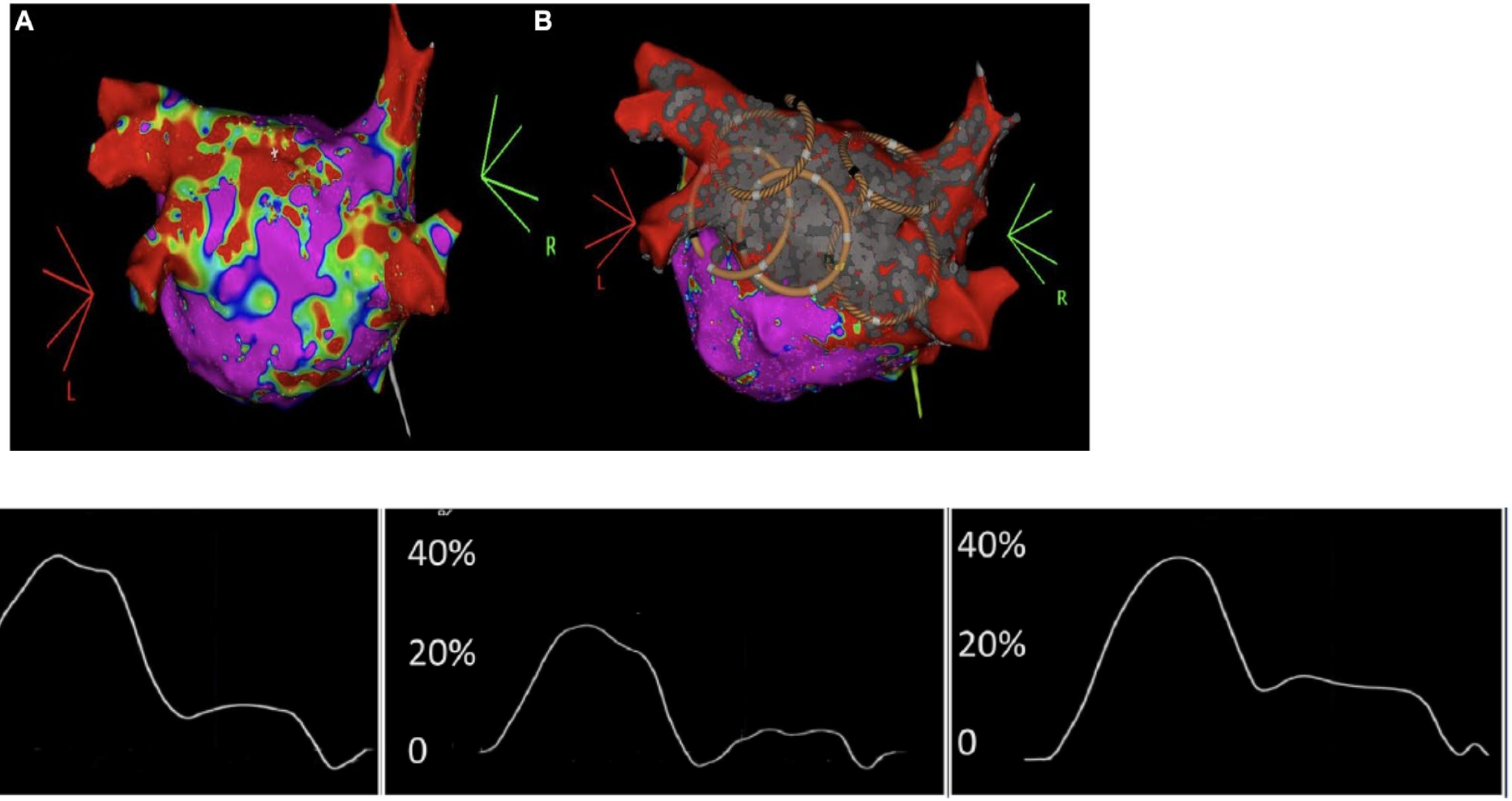
Research Letter

Pulsed field ablation prevents left atrial restrictive physiology after posterior wall isolation in patients with persistent atrial fibrillation

Ariel Banai, MD, Ehud Chorin, MD, Arie Lorin Schwartz, MD, Yuval Levi, MEng, Hend Sliman, MD, Omri Feder, MD, Dana Viskin, MD, Sami Viskin, MD, Shmuel Banai, MD, Raphael Rosso, MD

KEYWORDS Atrial fibrillation; Pulsed field ablation; Ablation; Persistent atrial fibrillation; Echocardiography

(Heart Rhythm 2024;■:1–3) © 2024 Heart Rhythm Society. All rights reserved.



Figure

Bipolar map of the left atrium at baseline (**A**) and after posterior wall isolation (**B**). Box plot show left atrial (LA) strain, active emptying fraction, and expansion index in 15 patients in sinus rhythm before ablation (**C, D, E**) and in the entire cohort (**F, G, H**). Example of left atrial strain before ablation (**I**) and at 24 hours (**J**) and 3 months (**K**) after ablation.

ESC European Society of Cardiology

Europace (2024) **26**, 1–9
https://doi.org/10.1093/europace/euad371

CLINICAL RESEARCH

Severe acute kidney injury related to haemolysis after pulsed field ablation for atrial fibrillation

Sandrine Venier [1]*, Nathan Vaxelaire [1], Peggy Jacon[1], Adrien Carabelli [1], Antoine Desbiolles [1], Frederic Garban [2], and Pascal Defaye [1]

[1]Department of Cardiology, Electrophysiology Unit, University Hospital of Grenoble Alpes France, CS10217, 38043 Grenoble Cedex 9, France; and [2]Department of Hematology, University Hospital of Grenoble Alpes France, CS10217, 38043 Grenoble Cedex 9, France

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Circulation

Circulation. 2023;147:1422–1432.

ORIGINAL RESEARCH ARTICLE

Pulsed Field Ablation for the Treatment of Atrial Fibrillation: PULSED AF Pivotal Trial

Atul Verma, MD; David E. Haines, MD; Lucas V. Boersma, MD; Nitesh Sood, MD; Andrea Natale, MD; Francis E. Marchlinski, MD; Hugh Calkins, MD; Prashanthan Sanders, MBBS; Douglas L. Packer, MD; Karl-Heinz Kuck, MD; Gerhard Hindricks, MD; Birce Onal, PhD; Jeffrey Cerkvenik, MS; Hiroshi Tada, MD; David B. DeLurgio, MD; on behalf of the PULSED AF Investigators

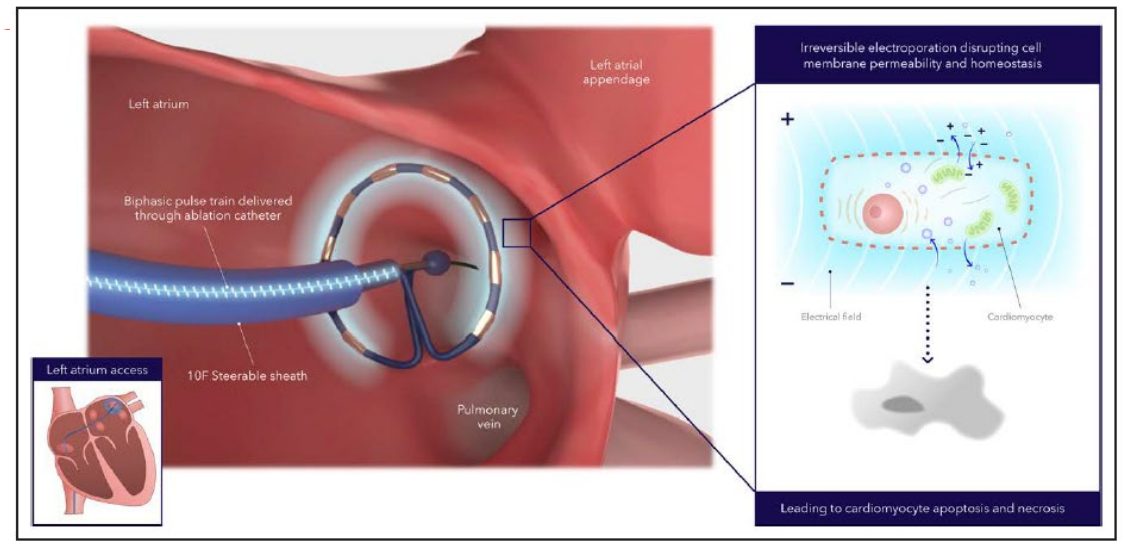
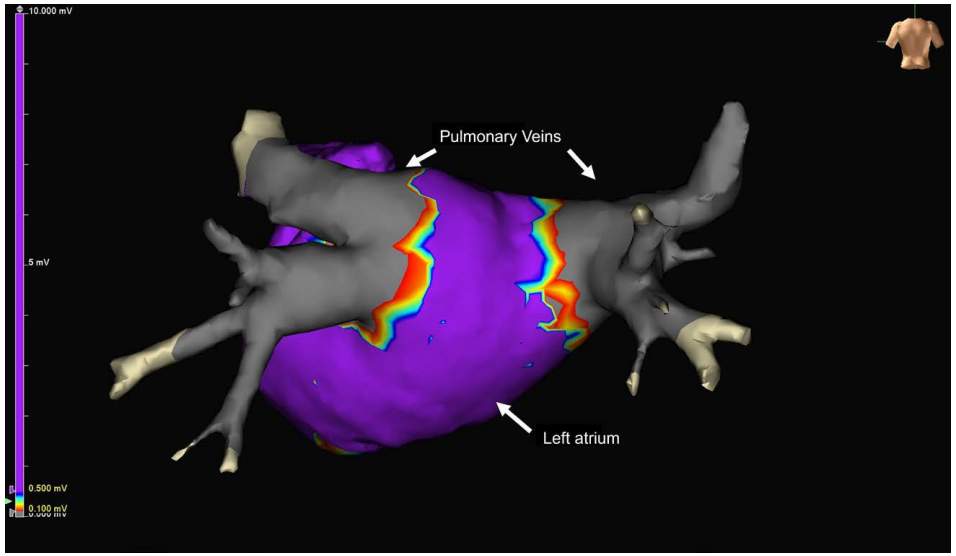


Figure 1. Catheter ablation method with pulsed field ablation system.
Alternating positive and negative electrodes sustains a bipolar electrical field around the catheter that extends into the tissue. The electrical field increases cell membrane permeabilization, which then leads to cell function disruption and eventually to cell death (ie, apoptosis and necrosis).



N=150 (PAF)

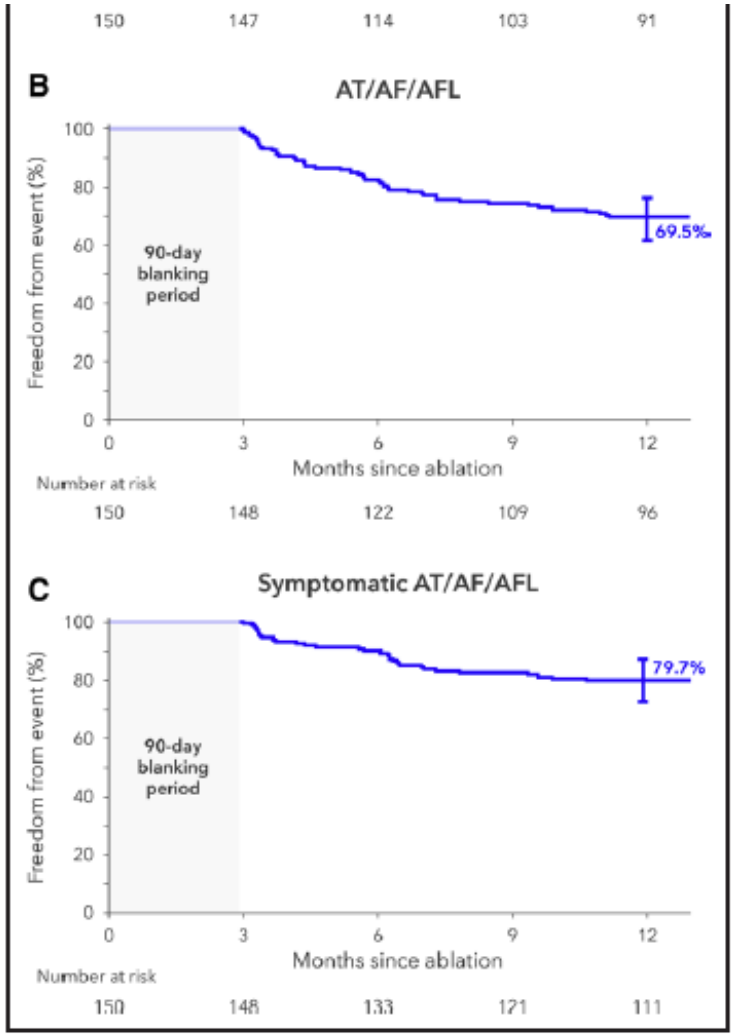


Figure 3. Treatment success at 12 months for paroxysmal atrial fibrillation.

A Primary end point of the study B Any atrial tachyarrhythmia found

N=150 (PersAF)

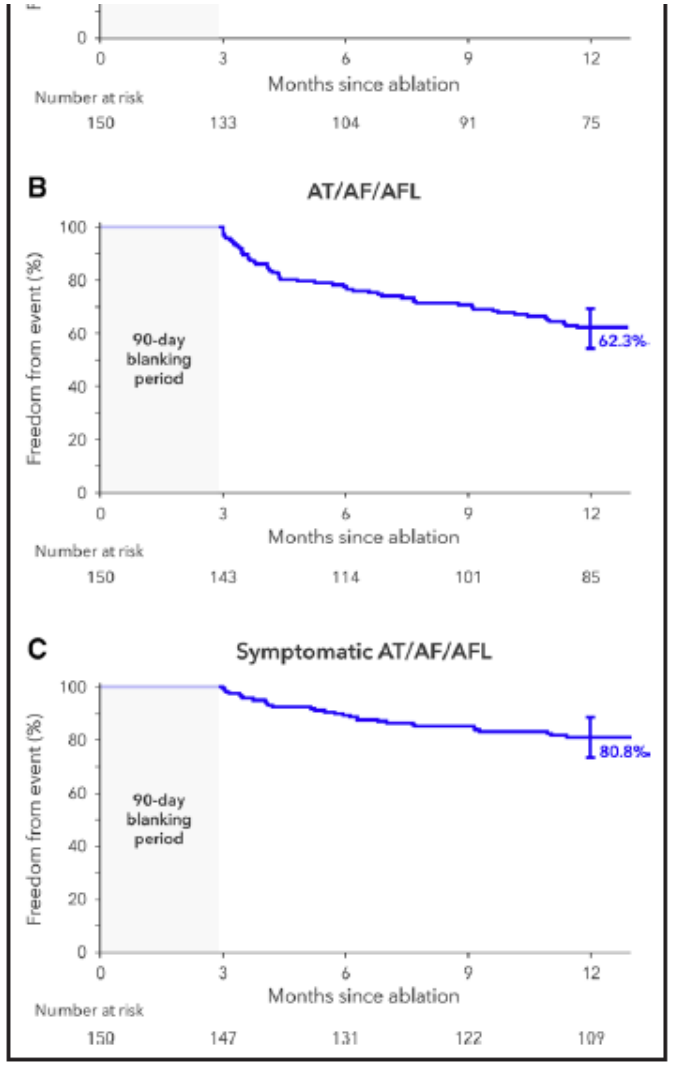


Figure 4. Treatment success at 12 months for persistent atrial fibrillation.

Circulation: Arrhythmia and Electrophysiology

ORIGINAL ARTICLE

Paroxysmal Atrial Fibrillation Ablation Using a Novel Variable-Loop Biphasic Pulsed Field Ablation Catheter Integrated With a 3-Dimensional Mapping System: 1-Year Outcomes of the Multicenter inspIRE Study

Wave I (feasibility phase) in a small cohort of subjects in Europe.

Wave II (pivotal phase): a larger cohort of subjects in Europe and Canada: primary safety and effectiveness end points were evaluated at 12months

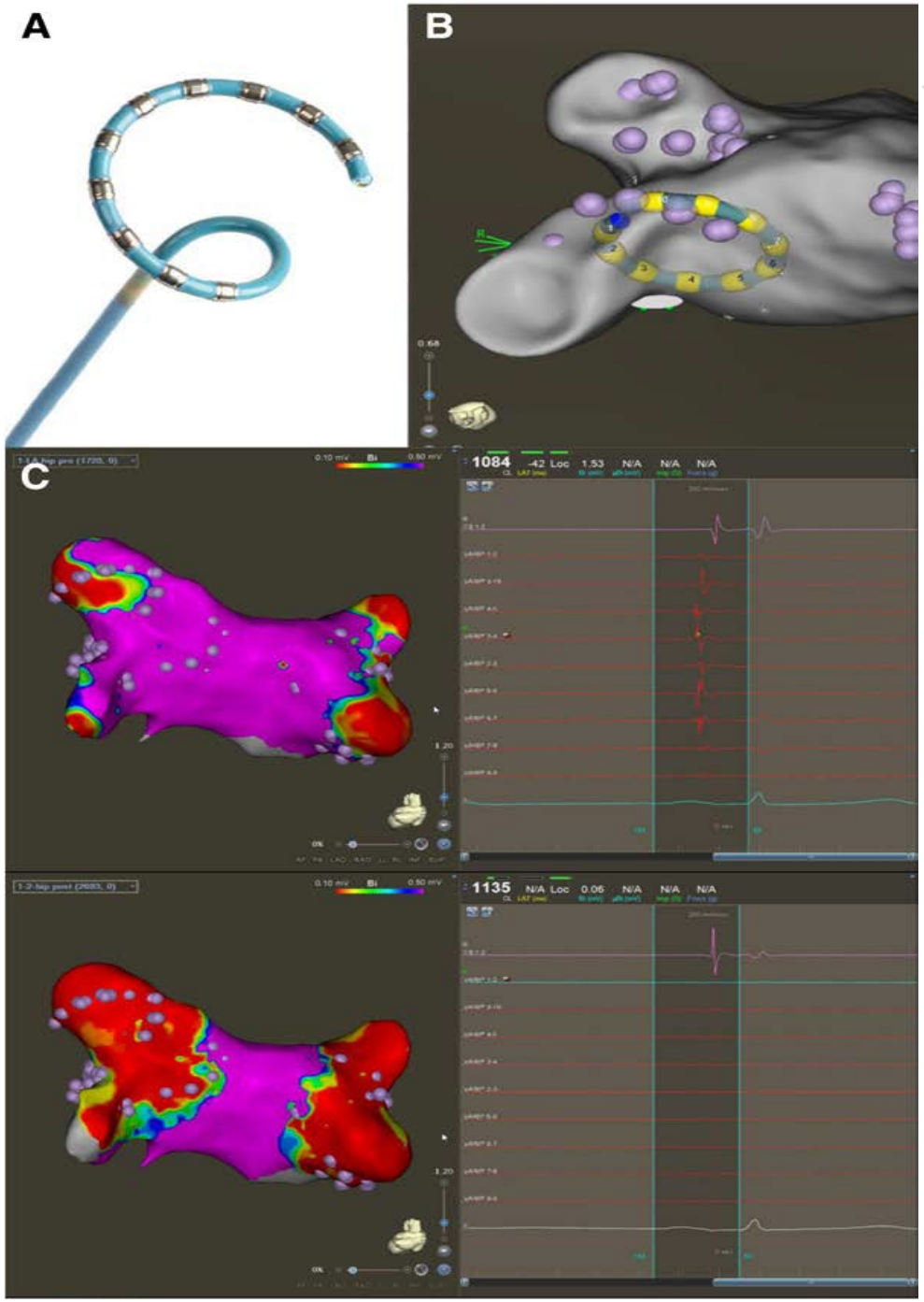
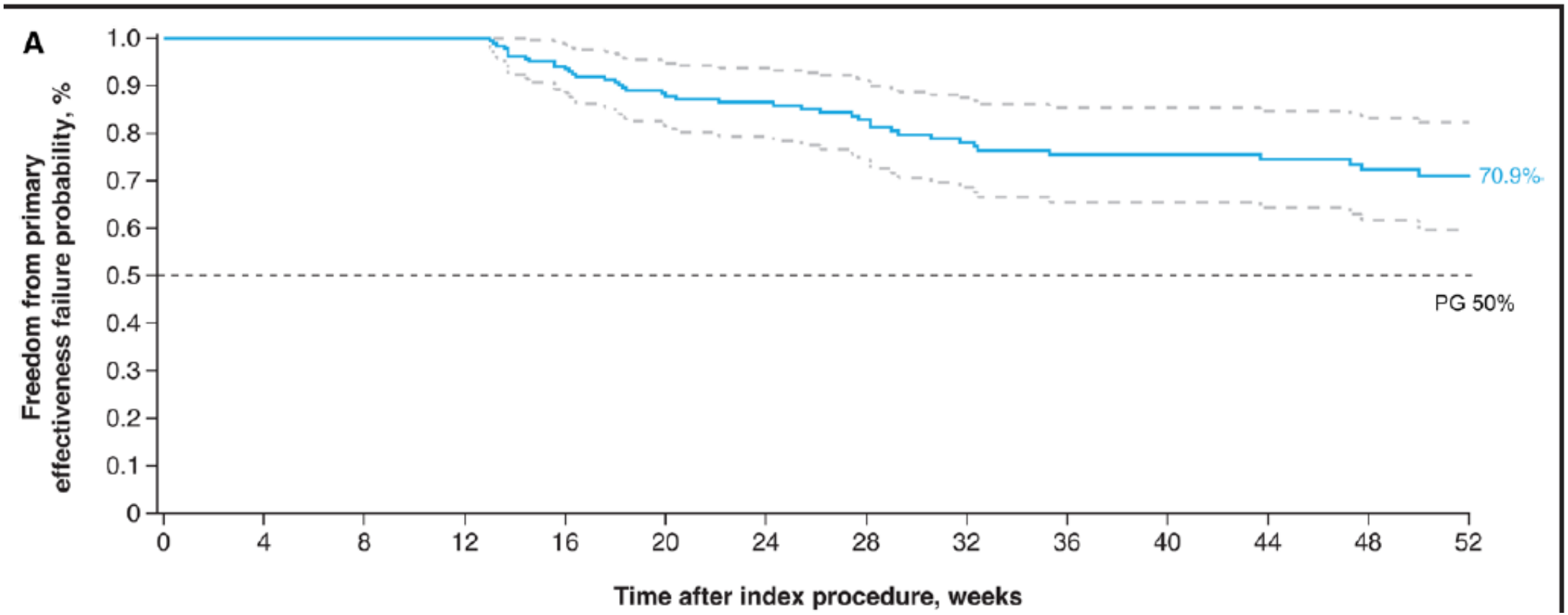


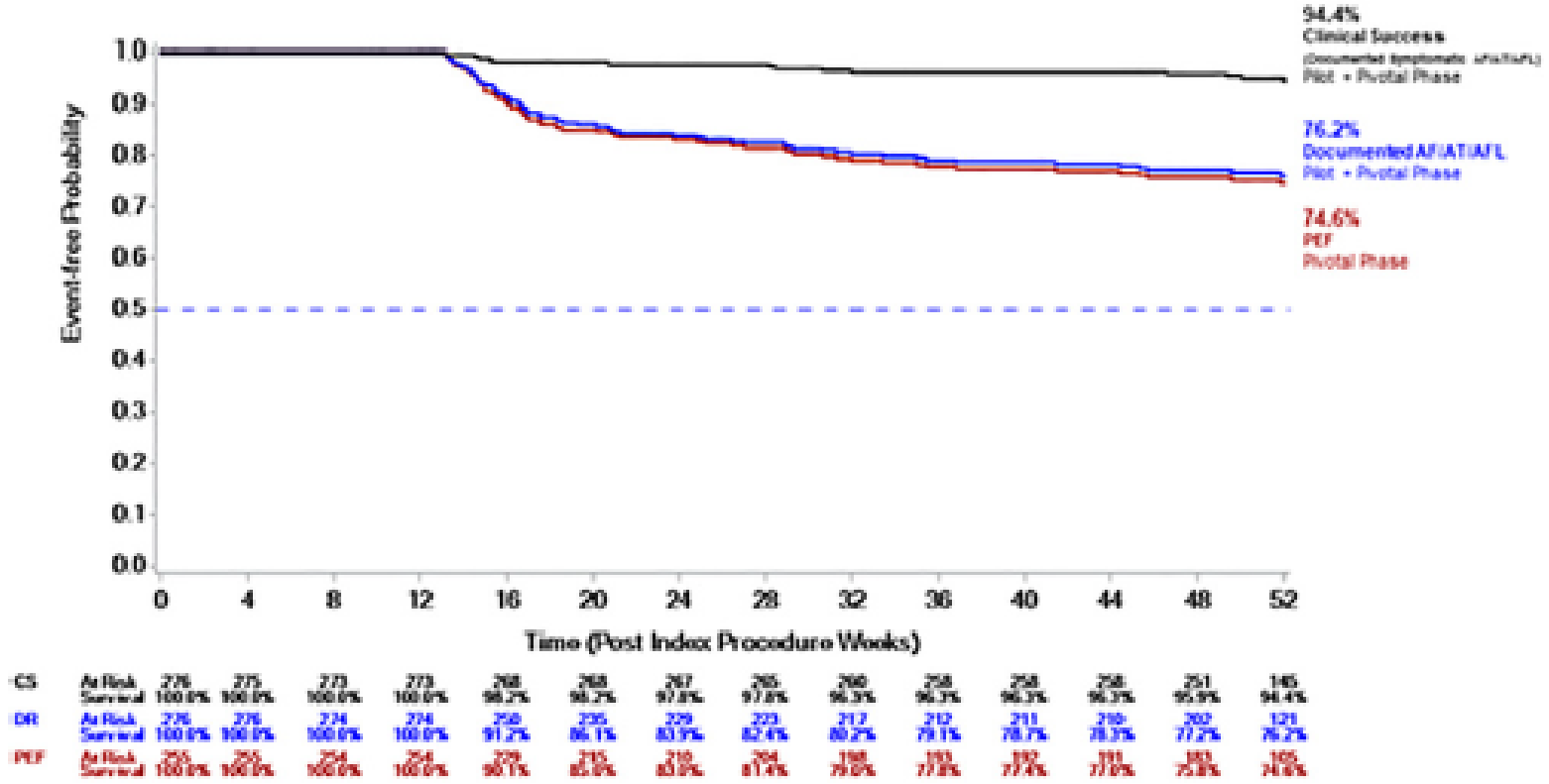
Table 3. Summary of PAEs

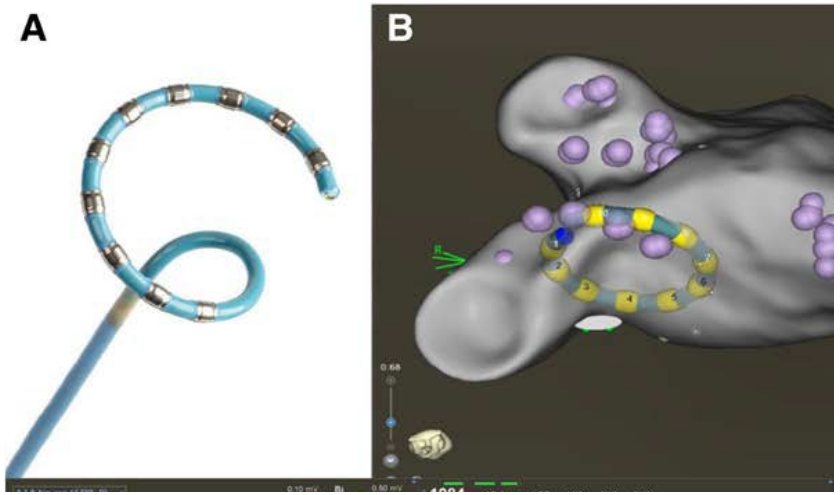
Adverse events*	Wave I (n=40)	Wave II (n=186)
PAEs†	0 (0)	0 (0)
Atrioesophageal fistula	0 (0)	0 (0)
Cardiac tamponade/perforation	0 (0)	0 (0)
Pulmonary vein stenosis	0 (0)	0 (0)
Device- or procedure-related death	0 (0)	0 (0)
Major vascular access complication/bleeding	0 (0)	0 (0)
Myocardial infarction	0 (0)	0 (0)
Pericarditis	0 (0)	0 (0)
Phrenic nerve paralysis (permanent)	0 (0)	0 (0)
Stroke/cerebrovascular accident	0 (0)	0 (0)
Thromboembolism	0 (0)	0 (0)
Transient ischemic attack	0 (0)	0 (0)
Pulmonary vein stenosis subanalysis‡		
Mild	0 (0)	NA
Moderate	0 (0)	NA
Severe	0 (0)	NA


A
Freedom from primary effectiveness failure probability, %
1.0
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0
70.9%
PG 50%
0
4
8
12
16
20
24
28
32
36
40
44
48
52
Time after index procedure, weeks

ADMIRE Study

Figure 1. Kaplan-Meier Curve of 12-Month Freedom from Primary Effectiveness Failure (PEF) – Pivotal (N=255); 12-Month Freedom from Documented AF/AT/AFL Recurrence (DR) – Pilot + Pivotal (N=276); 12-Month Freedom from Documented Symptomatic AF/AT/AFL Recurrence (Clinical Success [CS]) – Pilot + Pivotal (N=276)





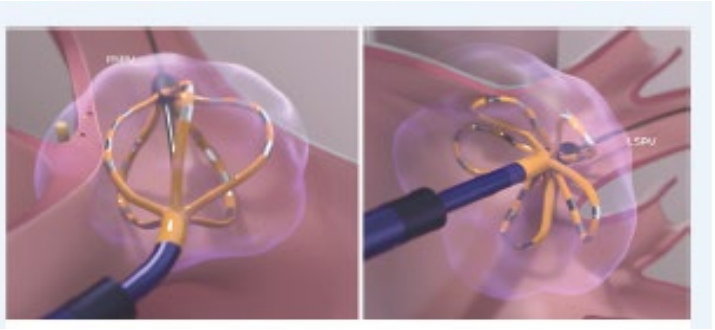
ADVENT , NEJM 08.2023

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Pulsed Field or Conventional Thermal Ablation for Paroxysmal Atrial Fibrillation

The study included refractory PAF pts



607 Were included in the modified intention-to-treat population

305 Underwent pulsed field ablation at index procedure

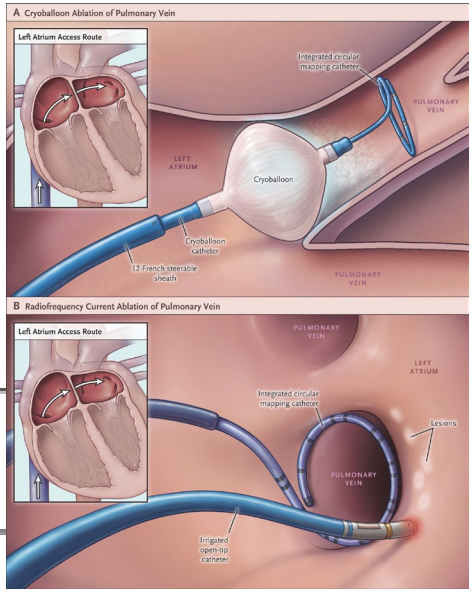
302 Underwent thermal ablation at index procedure

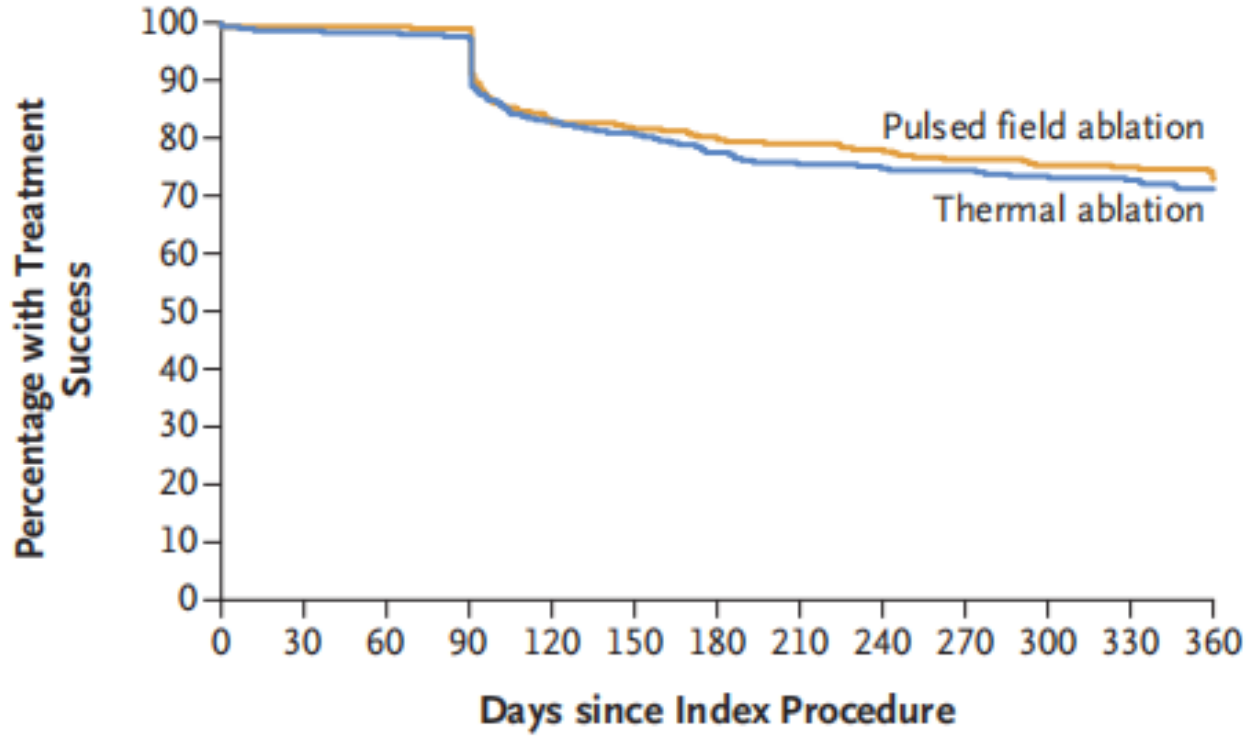
CRYO 135 Pts

RF 167 Pts

304 Were assessed at day 7

302 Were assessed at day 7





No. at Risk					
Pulsed field ablation	301	298	238	228	176
Thermal ablation	296	292	228	219	150

Treatment Success (%)					
Pulsed field ablation	99.3	99.0	79.7	76.4	73.1
Thermal ablation	98.7	97.3	77.5	74.5	71.3

Figure 2. Efficacy Outcomes of Pulsed Field Ablation as Compared with Thermal Ablation.

Table 3. Serious and Nonserious Adverse Events.*

Event	Serious Adverse Events†		Serious or Nonserious Adverse Events‡	
	Pulsed Field Ablation (N=305)	Thermal Ablation (N=302)	Pulsed Field Ablation (N=305)	Thermal Ablation (N=302)
	number of patients (percent)			
Any event	6 (2.0)§	4 (1.3)	7 (2.3)§	6 (2.0)
Death	1 (0.3)	0	1 (0.3)	0
Myocardial infarction	0	0	0	0
Persistent phrenic-nerve palsy	0	0	0	2 (0.7)
Stroke	0	1 (0.3)	0	1 (0.3)
TIA	1 (0.3)	0	1 (0.3)	0
Systemic thromboembolism	0	0	0	0
Cardiac tamponade or perforation	2 (0.7)	0	2 (0.7)	0
Pericarditis	1 (0.3)	0	2 (0.7)	0
Pulmonary edema	1 (0.3)			
Vascular-access complication	1 (0.3)			
Heart block	0			
Gastric motility or pyloric spasm	0			
Pulmonary vein stenosis	0			
Atrioesophageal fistula	0			

CONCLUSIONS

Among patients with paroxysmal atrial fibrillation receiving a catheter-based therapy, pulsed field ablation was noninferior to conventional thermal ablation with respect to freedom from a composite of initial procedural failure, documented atrial tachyarrhythmia after a 3-month blanking period, antiarrhythmic drug use, cardioversion, or repeat ablation and with respect to device- and procedure-related serious adverse events at 1 year. (Funded by Farapulse–Boston Scientific; ADVENT ClinicalTrials.gov number, NCT04612244.)

ESC European Society of Cardiology
Europace (2023) **25**, 1–8
https://doi.org/10.1093/europace/euad329

CLINICAL RESEARCH

Efficacy and safety of pulmonary vein isolation with pulsed field ablation vs. novel cryoballoon ablation system for atrial fibrillation

Patrick Badertscher [1,2]*†, Simon Weidlich [1,2]†, Sven Knecht [1,2], Niklas Stauffer [1,2], Philipp Krisai [1,2], Gian Voellmin [1,2], Stefan Osswald [1,2], Christian Sticherling [1,2]‡, and Michael Kühne [1,2]‡

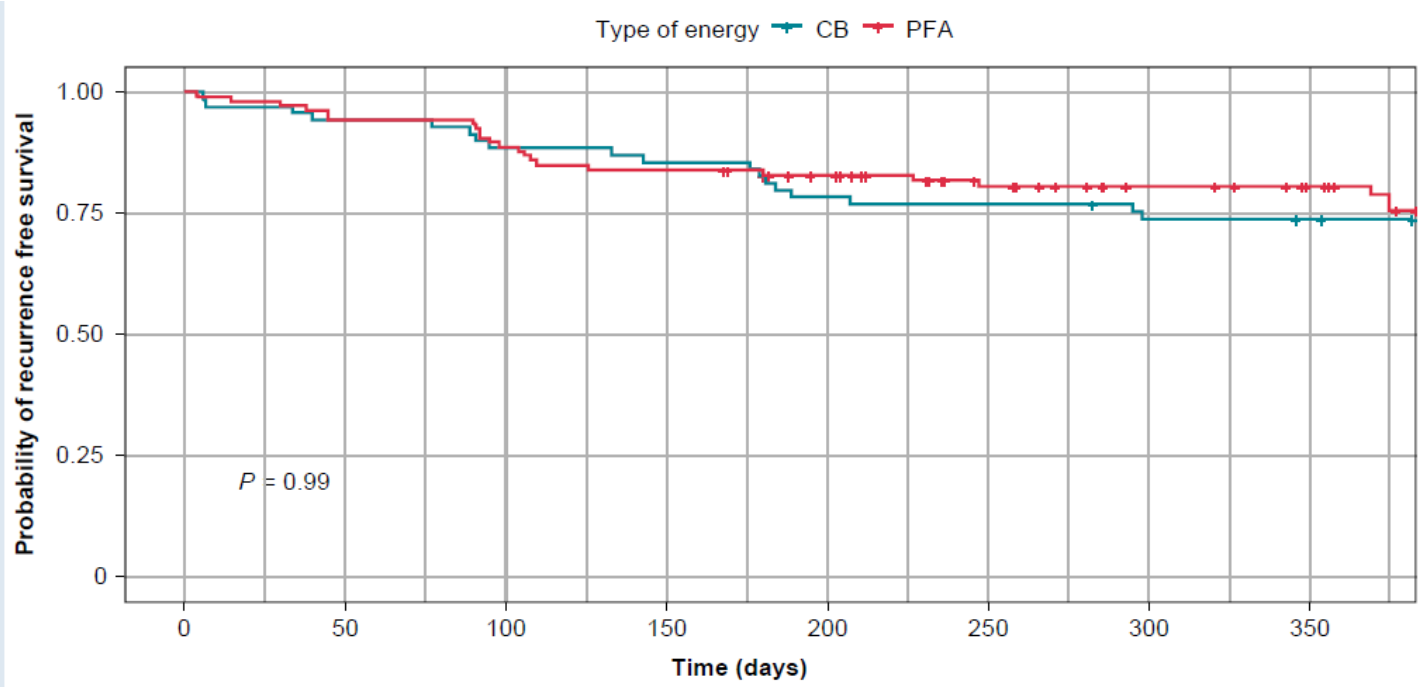


Table 2 Comparison between the procedural characteristics

	CB, *N* = 75	PFA, *N* = 106	Overall, *N* = 181	*P*-value
Total procedure duration	58 (48–69)	55 (43–64)	56 (45–66)	0.087
LA dwell time, min	37 (31–48)	38 (30–49)	37 (30–48)	0.871
Fluoroscopy time, min	11 (8.7–16)	11 (9.3–14)	11 (9.2–14.1)	0.814
Hs-cTnT 1 day after PVI	989 (745–1380)	1520 (996–1940)	1160 (856–1730)	**<0.001**
Number of applications	5 (4–7)	32 (32–34)		
First pass isolation	42 (56%)	88 (83%)	130 (72%)	**<0.001**

CB, cryoballoon; Hs-cTnT, high-sensitivity cardiac troponin T; LA, left atrium; PFA, pulsed field ablation. **Bold**, statistical significance.

Table 3 Comparison between the complications

	CB, *N* = 75	PFA, *N* = 106	Overall, *N* = 181	*P*-value
Overall	3	3	6	0.69
PN palsy	3	0	3	0.069
Stroke	0	0	0	
Tamponade	0	2	2	0.512
Vascular access complications	0	0	0	
Other[a]	0	1	1	1

ESC European Society of Cardiology

Europace (2024) **26**, 1–10
https://doi.org/10.1093/europace/euae016

CLINICAL RESEARCH

Pulsed electric field, cryoballoon, and radiofrequency for paroxysmal atrial fibrillation ablation: a propensity score-matched comparison

Methods and results

Propensity score matching was adopted to compare PVI-only ablation outcomes via the Farawave™ system (Group PFA), cryoballoon (Group CRYO), or focal radiofrequency (Group RF) (PFA:CRYO:RF ratio = 1:2:2). Among 1572 (mean age: 62.4 ± 11.3 years; 42.5% females) PAF patients undergoing first time PVI with either PFA ($n = 174$), CRYO ($n = 655$), or RF ($n = 743$), propensity score matching yielded 174 PFA, 348 CRYO, and 348 RF patients. First-pass isolation was achieved

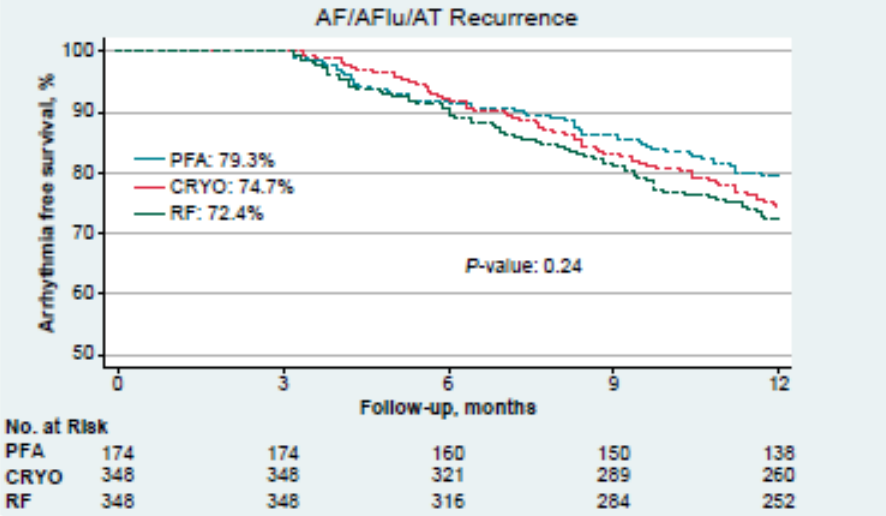
1572 Paroxysmal AF patients undergoing pulmonary vein isolation (4 institutions)

1:2:2 Propensity score-matching comparison

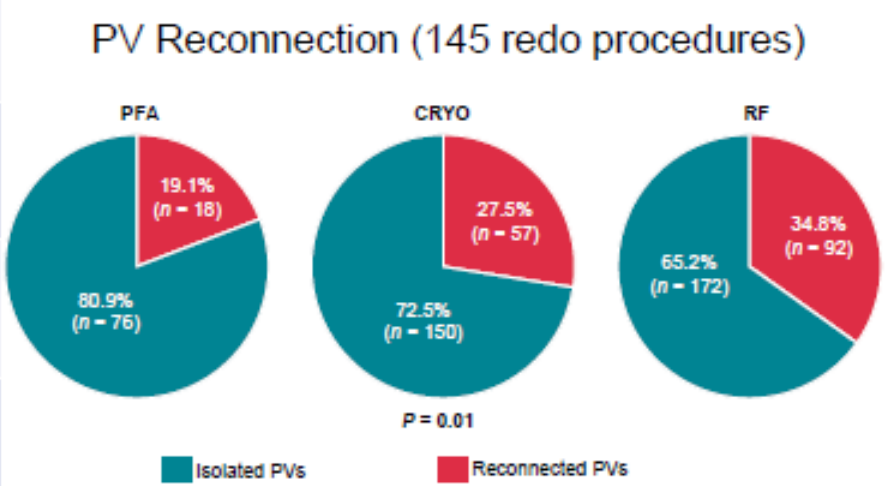
174 Patients

348 Patients

348 Patients



Procedural Time, min	52 ± 15	65 ± 22	85 ± 25	<0.001
Fluoroscopy Time, min	15 ± 3	18 ± 8	13 ± 7	<0.001
Major Complications	1.1% (*n* = 2)	1.1% (*n* = 4)	0.9% (*n* = 3)	0.92
Minor Complications	2.3% (*n* = 4)	7.5% (*n* = 26)	4.6% (*n* = 16)	0.034



ARTICLE IN PRESS

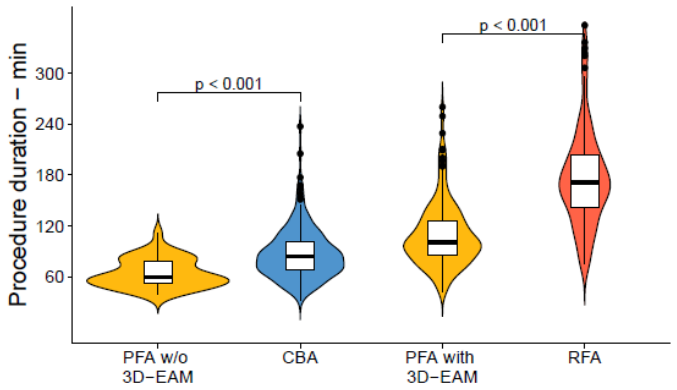
HeartRhythm

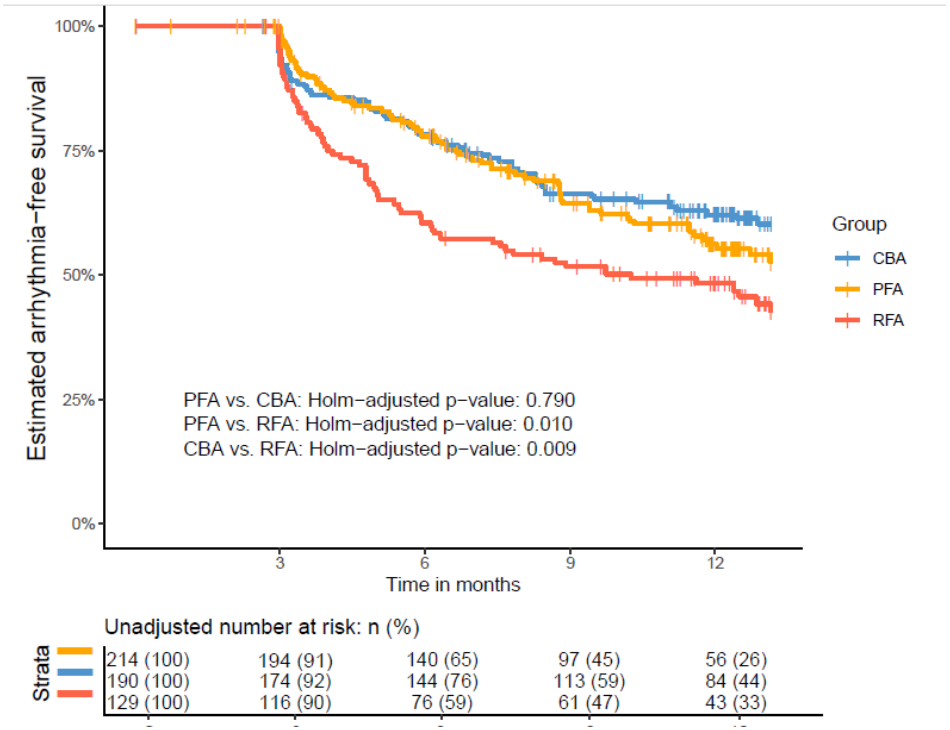
The Official Journal of the Heart Rhythm Society, The Cardiac Electrophysiology Society, and The Pediatric & Congenital Electrophysiology Society

Heart Rhythm Society SM

Pulsed-field vs cryoballoon vs radiofrequency ablation: Outcomes after pulmonary vein isolation in patients with persistent atrial fibrillation

($P < .001$).





PFA group

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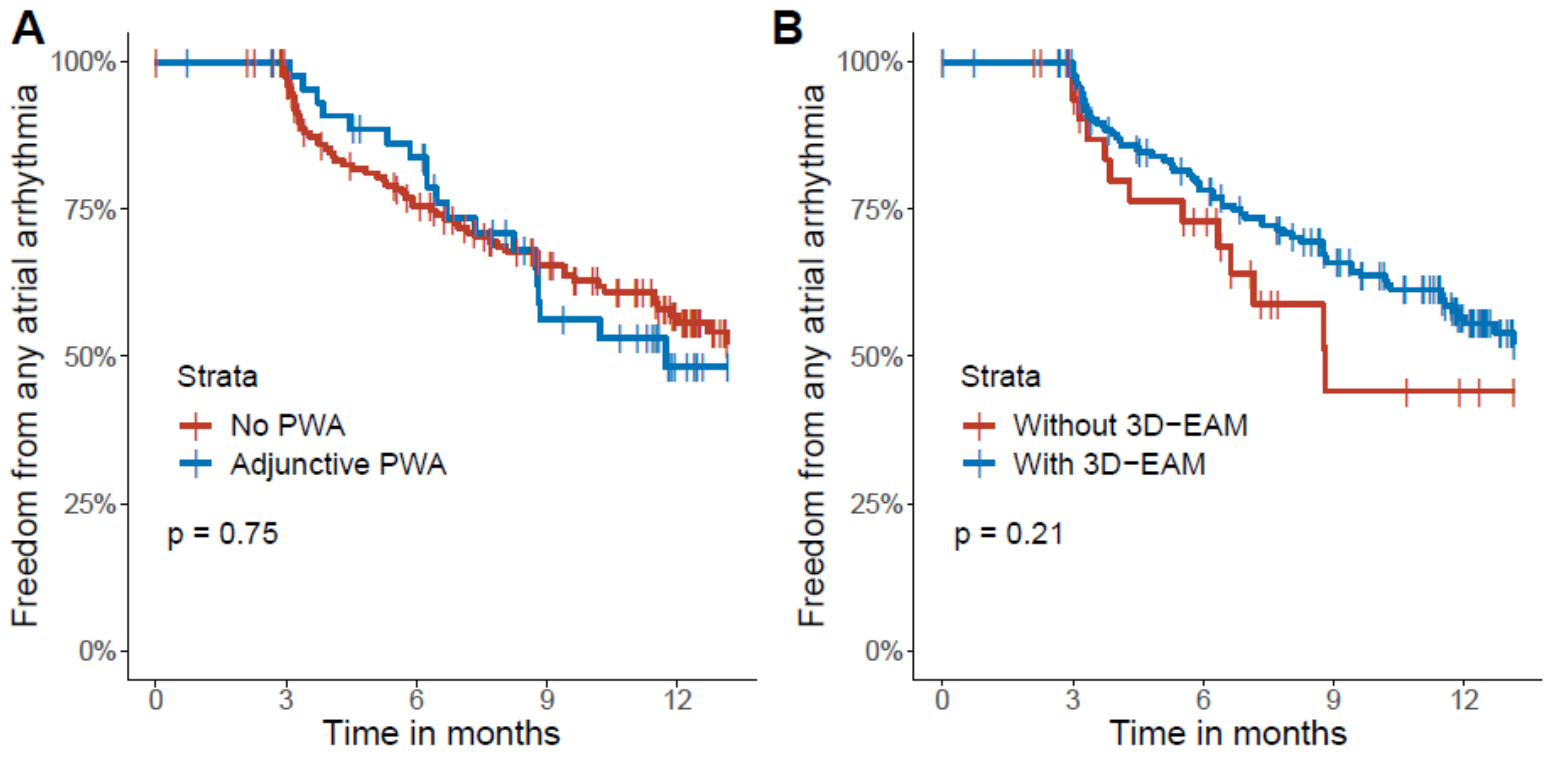
Heart Rhythm, Vol ■, No ■, ■ 2024



Pulsed-field ablation versus thermal ablation for atrial fibrillation: A meta-analysis

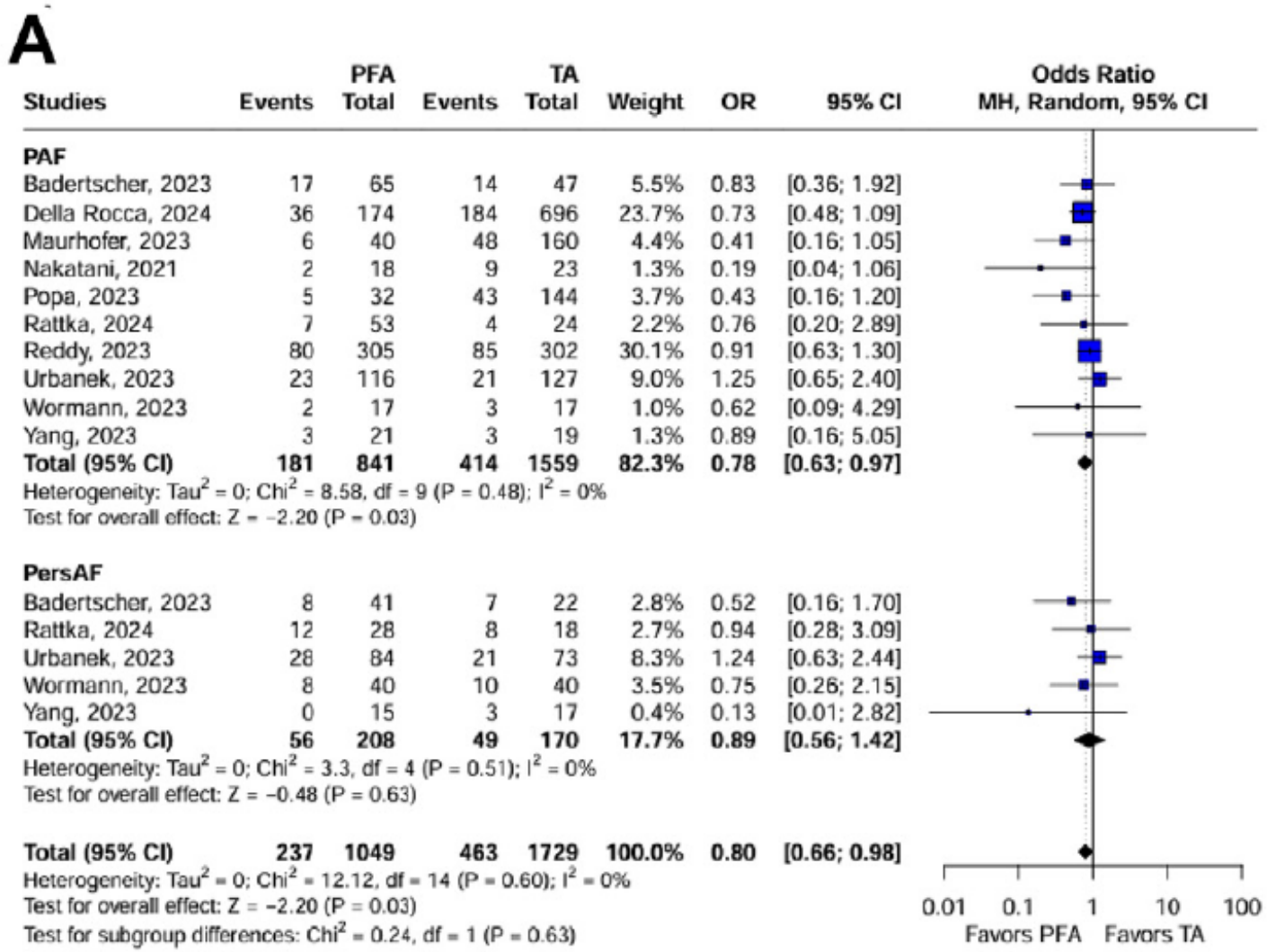
Maria Clara Azzi Vaz de Campos, MS,* Vitor Ryuiti Yamamoto Moraes, MS,†
Rafael Ferreira Daher, MS,* José Pedro Cassemiro Micheleto, MS,‡
Luiza Azzi Vaz de Campos, MS,* Guilherme Fleury Alves Barros, MS,§
Heitor Martins de Oliveira, MS,* Lorrany Pereira Barros, MS,*
Antonio da Silva Menezes Jr., MD, PhD*§

(Heart Rhythm O2 2024;-:1–11)

CONCLUSION :Compared to thermal ablation, PFA showed better results with regard to acute and long-term efficacy but significant differences in safety, with lower (peri)esophageal injury rates but higher tamponade rates in procedural data.

(peri-)esophageal injuries,including temporary or permanent phrenic nerve palsy,phrenic nerve injury, esophageal injury, and atrioesophageal fistula

Long-term procedure efficacy



ESC European Society of Cardiology
Europace (2023) **25**, 1–11
https://doi.org/10.1093/europace/euad147

Pulsed field ablation using focal contact force-sensing catheters for treatment of atrial fibrillation: acute and 90-day invasive remapping results

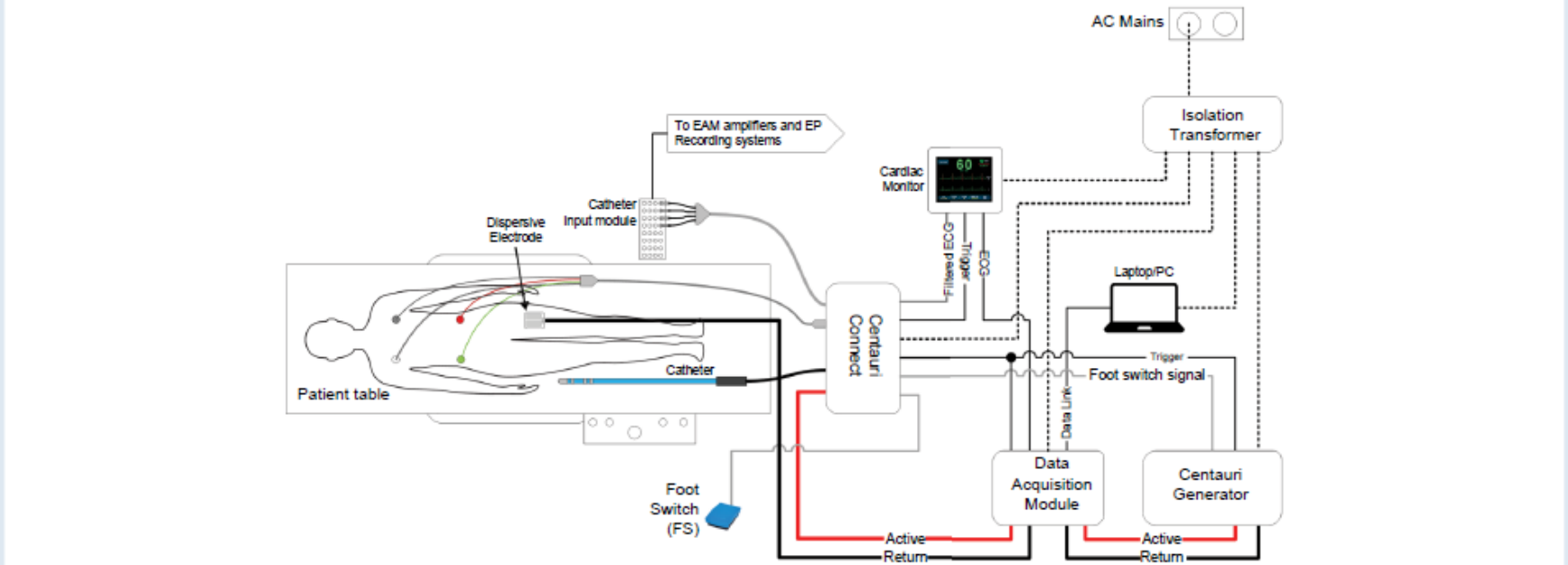


Figure 1 Configuration of the CENTAURI System in a standard EP laboratory. ECG, electrocardiogram; EP, electrophysiology.

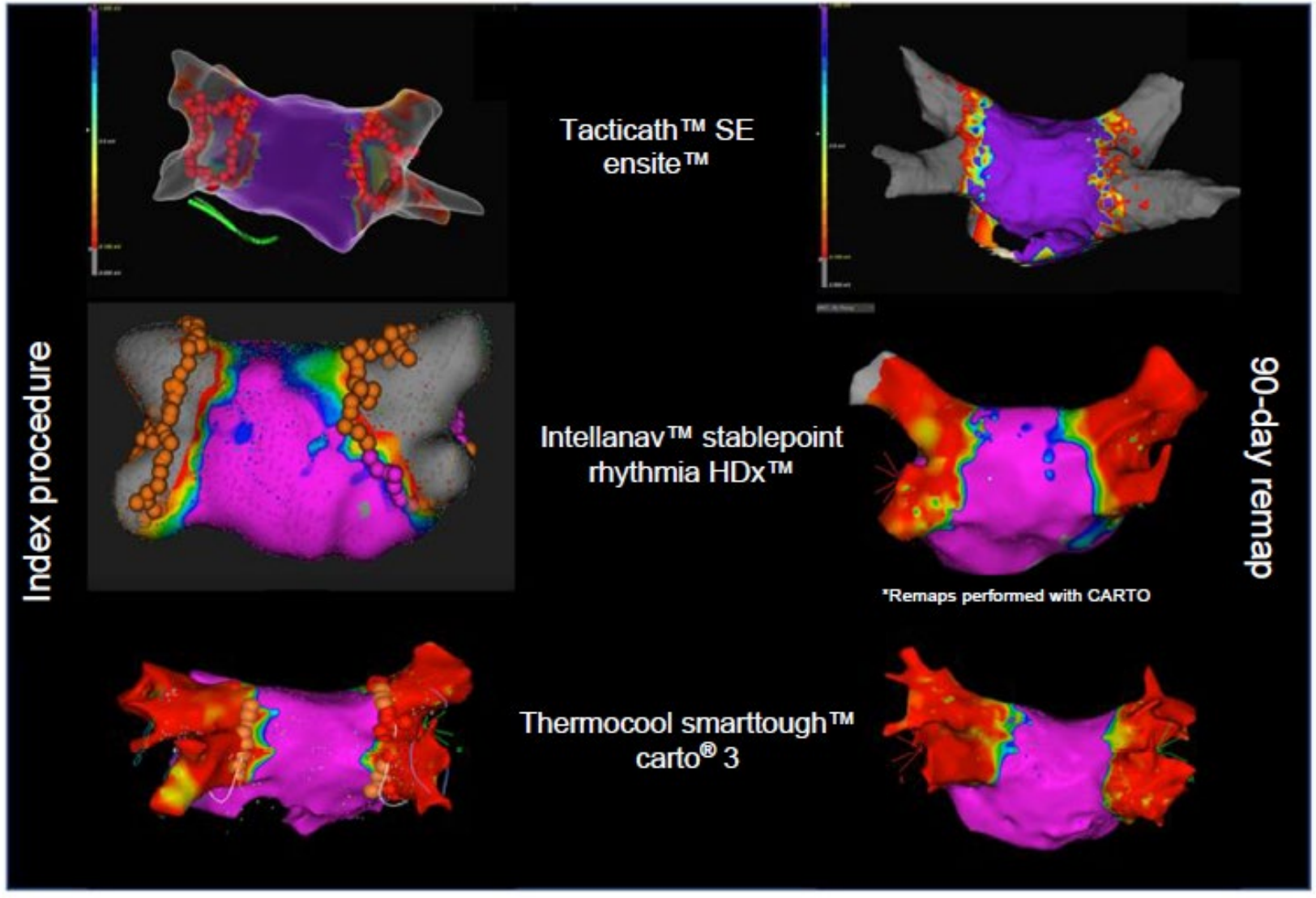


Figure 3 Acute PVI and 90-day chronic PVI durability were assessed using high-density remapping to verify entrance and/or exit bloc
correlated with placement of PEF applications, and 90-day remaps confirmed no degradation of the line of block created at the index

Journal of Interventional Cardiac Electrophysiology (2024) 67:99–109
https://doi.org/10.1007/s10840-023-01570-4

Focal pulsed field ablation and ultrahigh-density mapping — versatile tools for all atrial arrhythmias? Initial procedural experiences

Martin H. Ruwald[1] · Arne Johannessen[1] · Morten Lock Hansen[1] · Martin Haugdal[1] · Rene Worck[1] · Jim Hansen[1]

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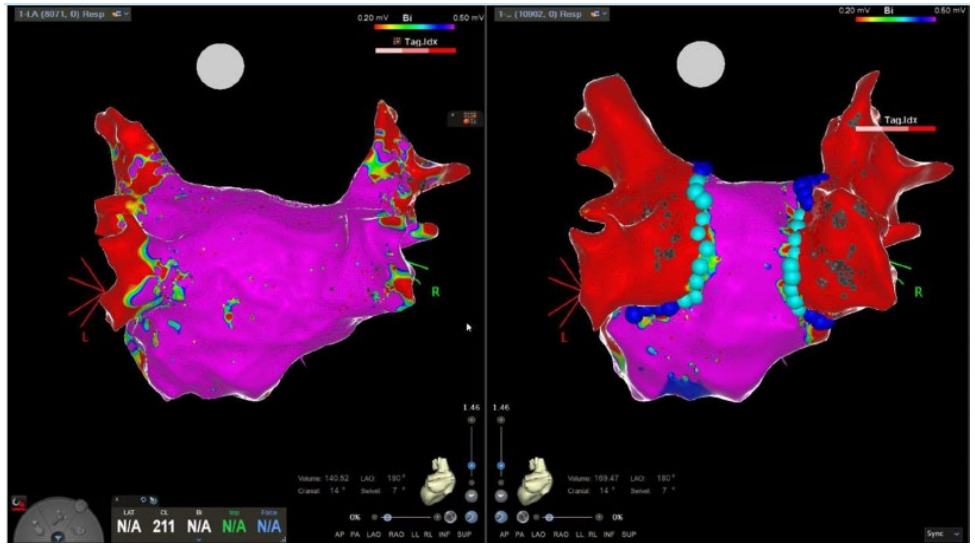
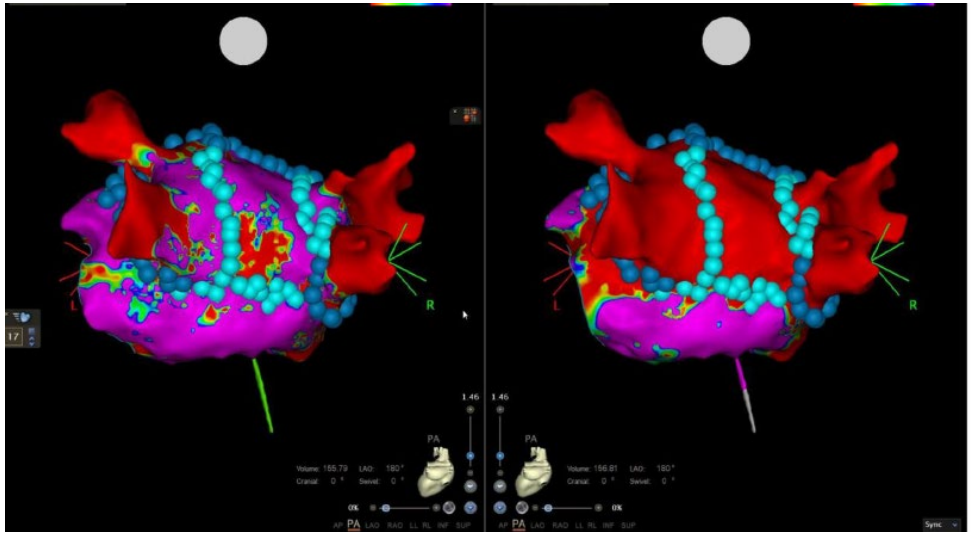
Abstract

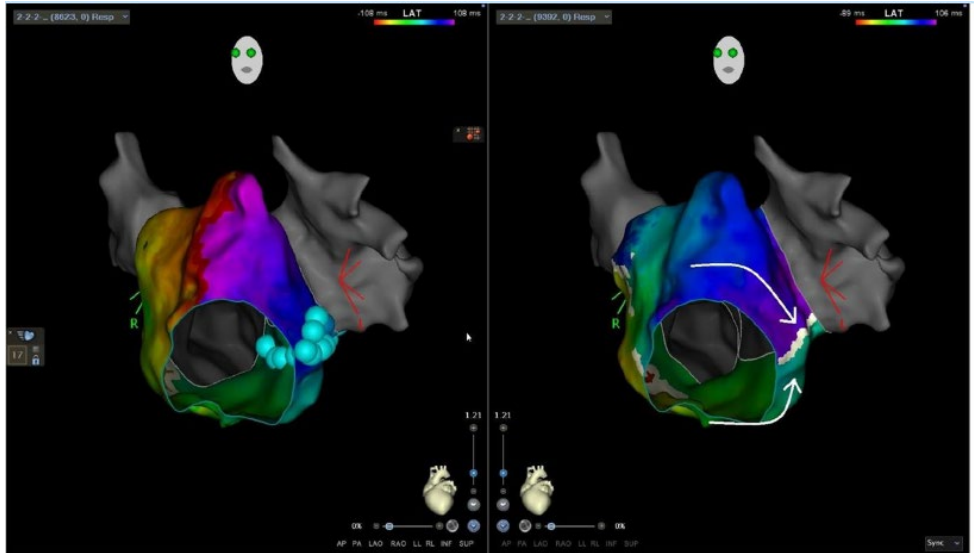
Background Focal pulsed field ablation (FPFA) is a novel and promising method of cardiac ablation. The aim of this study was to report the feasibility, short-term safety, and procedural findings for a broad spectrum of ablated atrial arrhythmias.

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.

Focal PFA







JACC: CLINICAL ELECTROPHYSIOLOGY VOL. 9, NO. 8, 2023
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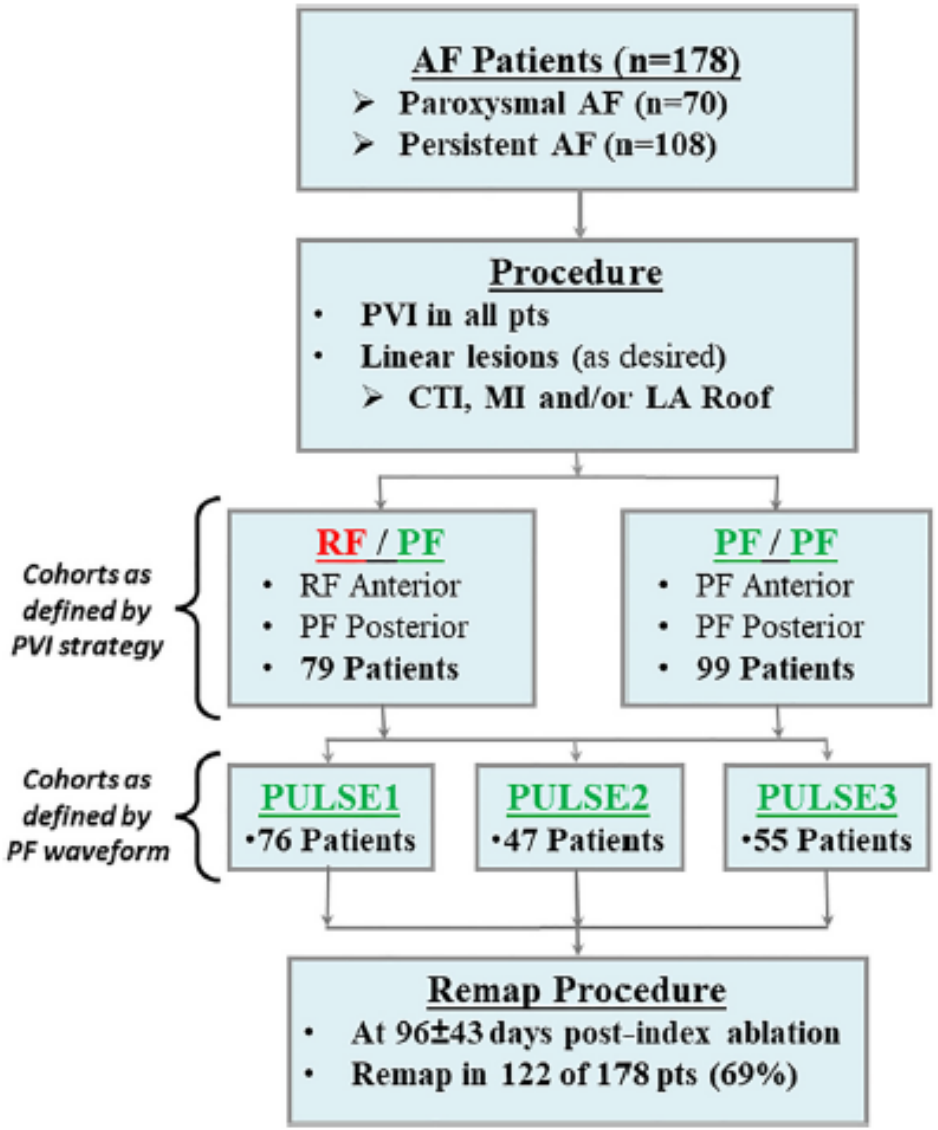
ORIGINAL RESEARCH

CATHETER ABLATION OF ATRIAL FIBRILLATION

A Focal Ablation Catheter Toggling Between Radiofrequency and Pulsed Field Energy to Treat Atrial Fibrillation

Vivek Y. Reddy, MD,[a,b] Petr Peichl, MD, PhD,[c] Elad Anter, MD,[d] Gediminas Rackauskas, MD, PhD,[e] Jan Petru, MD,[a] Moritoshi Funasako, MD,[a] Kentaro Minami, MD,[a] Jacob S. Koruth, MD,[b] Andrea Natale, MD,[f] Pierre Jais, MD,[g] Germanas Marinskis, MD, PhD,[e] Audrius Aidietis, MD, PhD,[e] Josef Kautzner, MD, PhD,[c] Petr Neuzil, MD, PhD[a]

FIGURE 1 The CONSORT Diagram



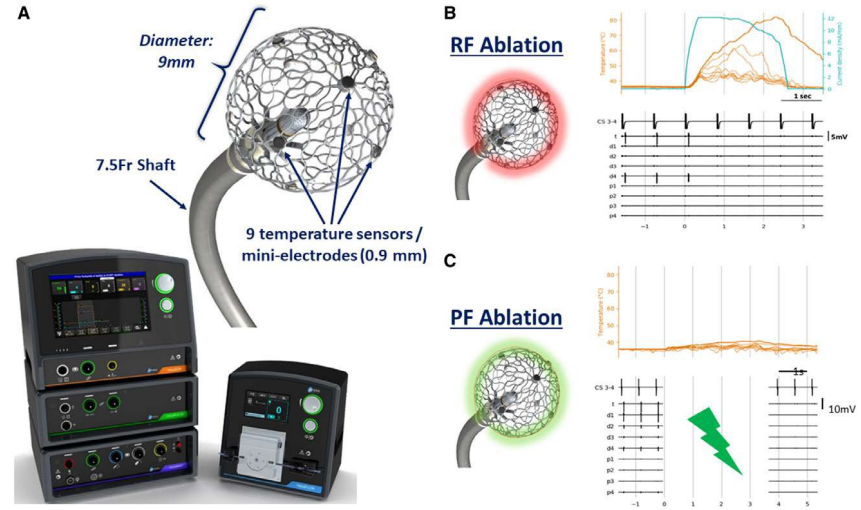
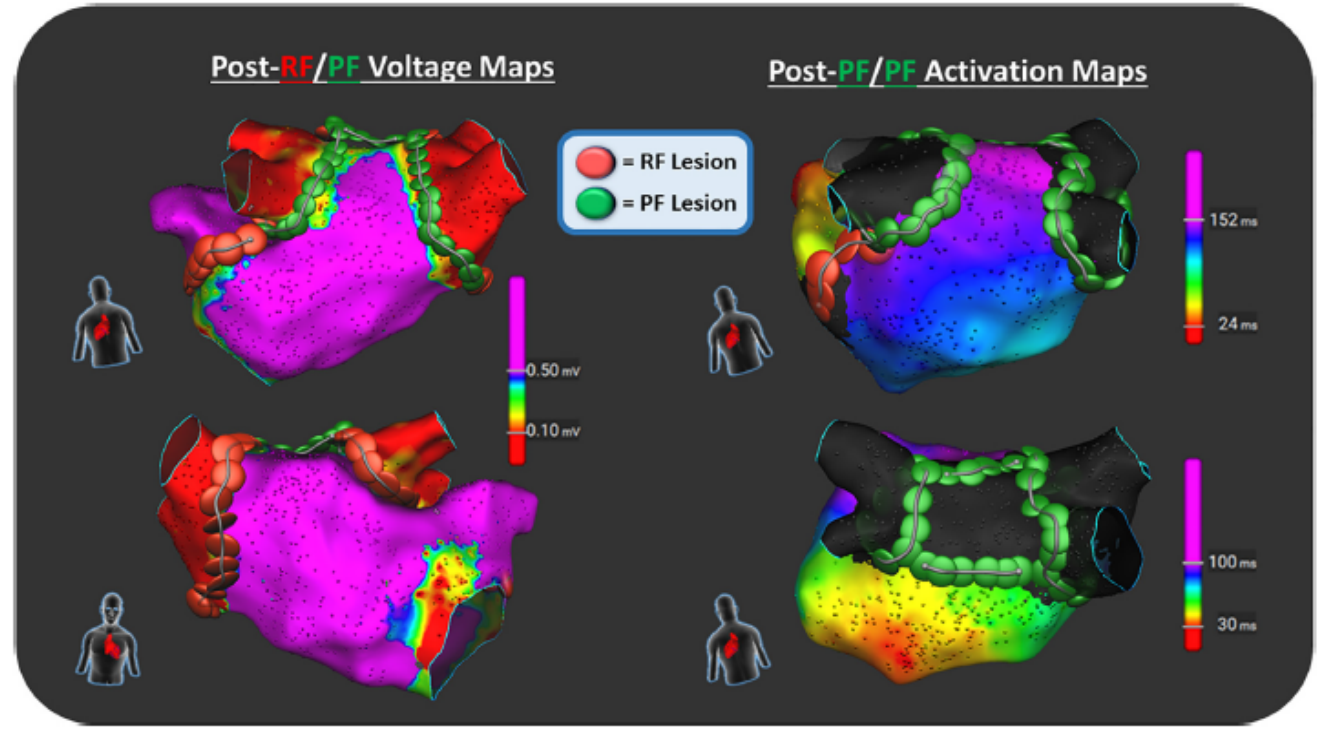
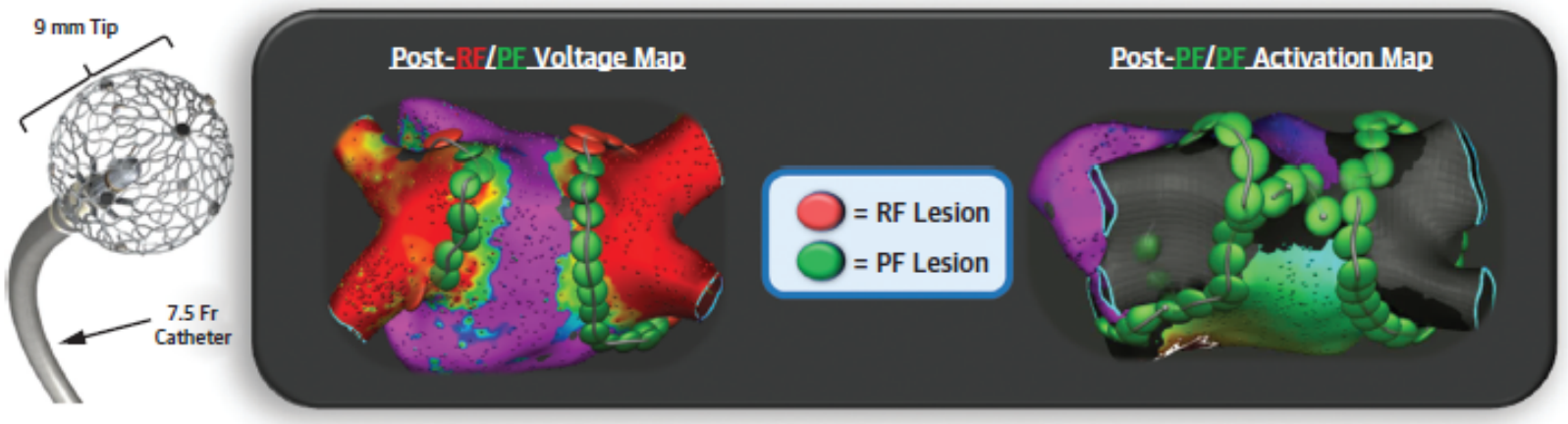


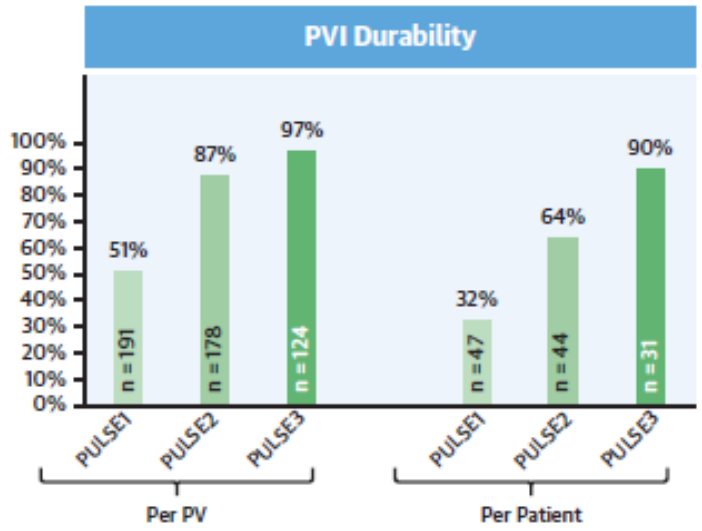
FIGURE 2 Ablation Strategies Based on PVI: RF/PF vs PF/PF

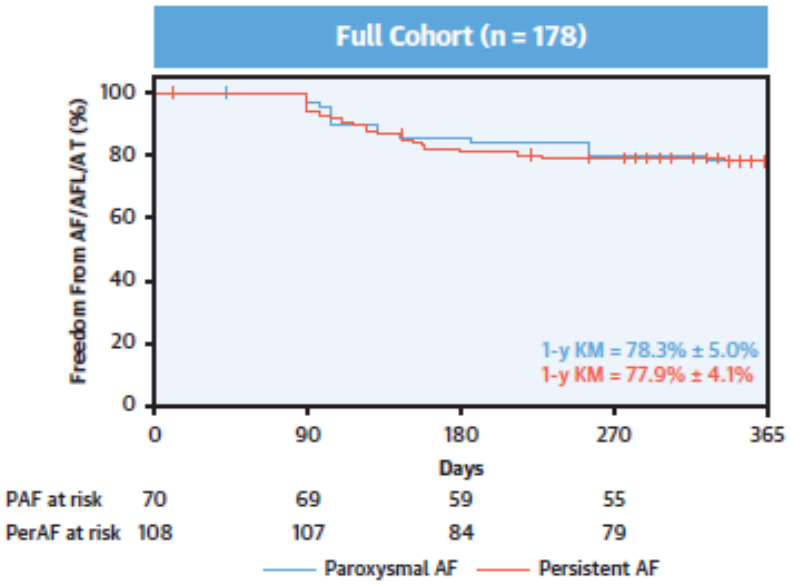


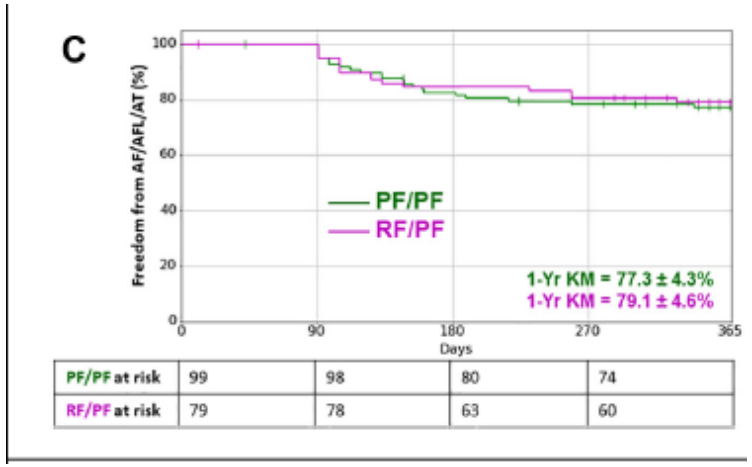
The 2 types of PVI strategies are shown. Note that in both, PF energy is used for ablation along the posterior LA, but anterior ablation varies between the 2 strategies.

CENTRAL ILLUSTRATION Atrial Fibrillation Ablation With a Combination RF/PF Focal Ablation Catheter









Reddy VY, et al. J Am Coll Cardiol EP. 2023;9(8):1786-1801.

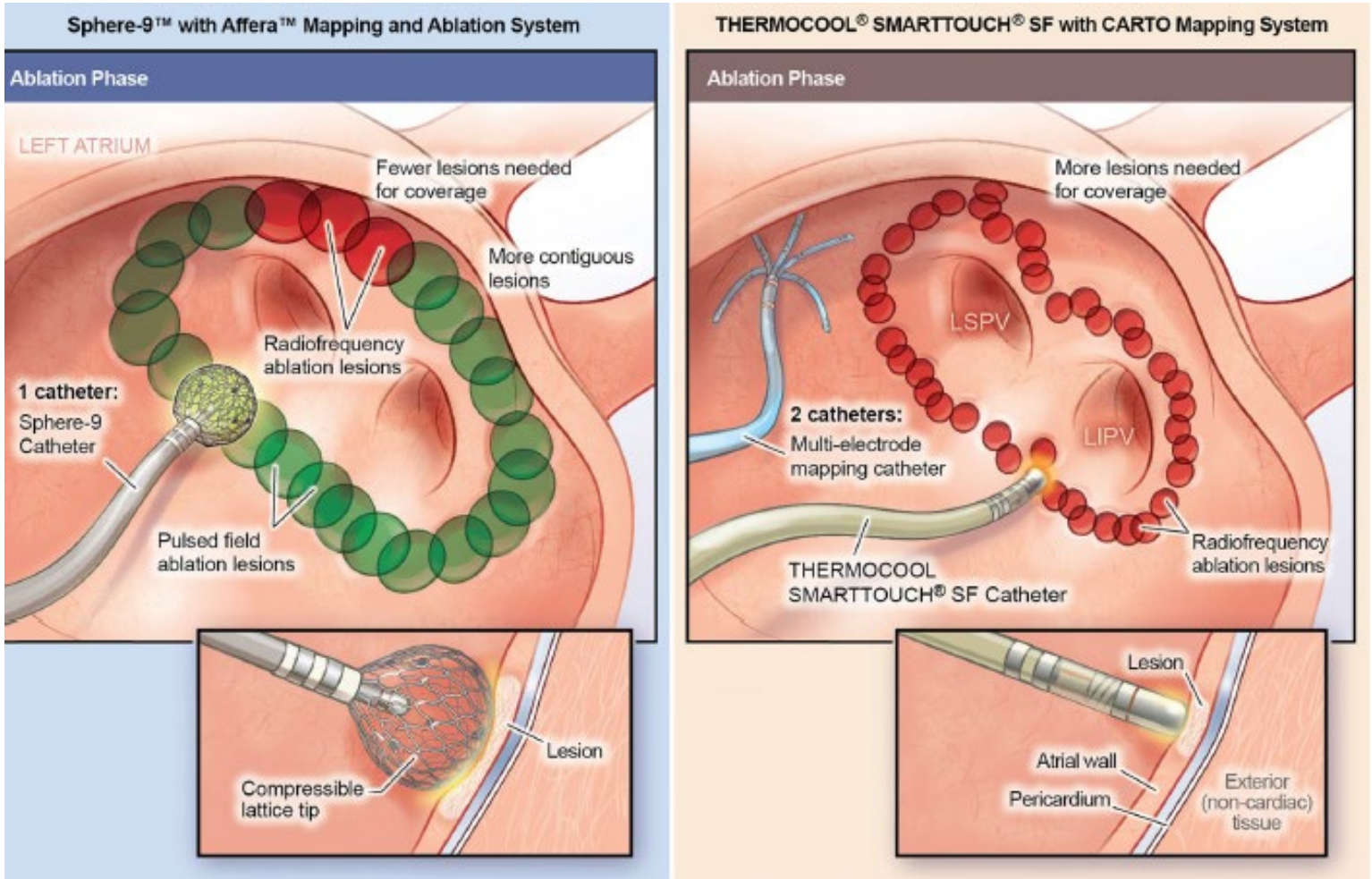
AFL = atrial flutter; Pf = pulsed field; PV = pulmonary vein; PVI = pulmonary vein isolation; REF = radiofrequency.

nature medicine

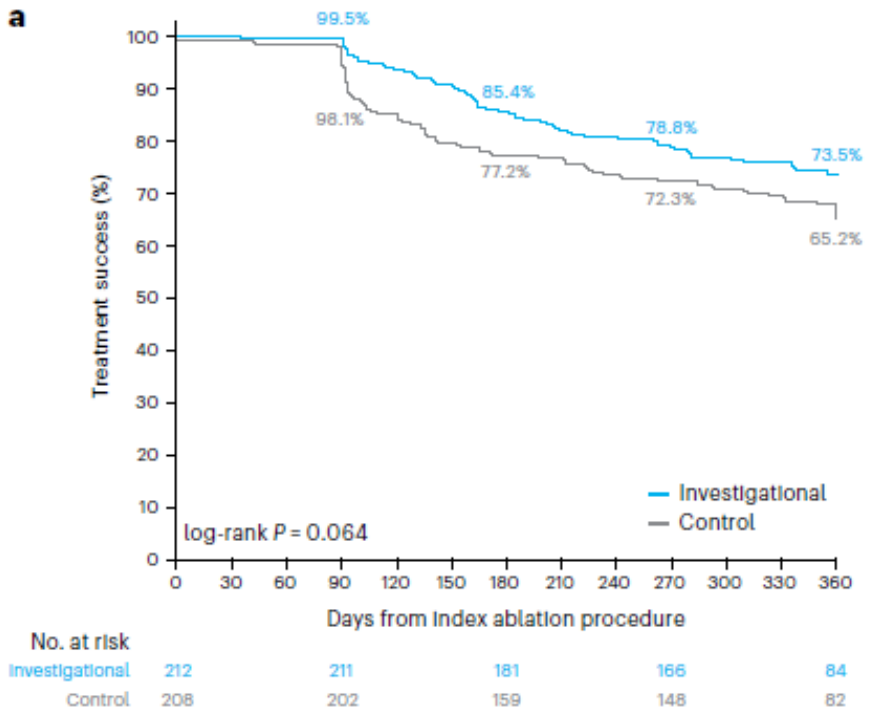
Article

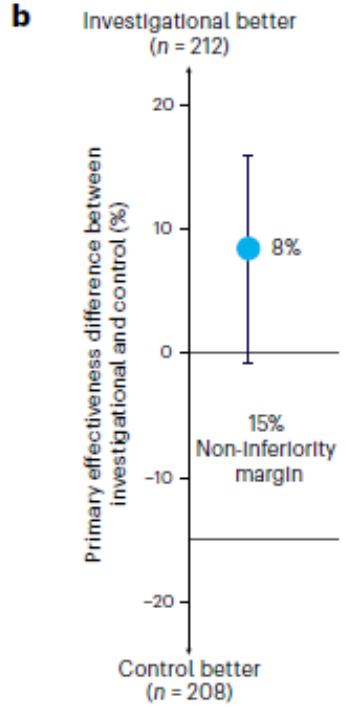
https://doi.org/10.1038/s41591-024-03022-6

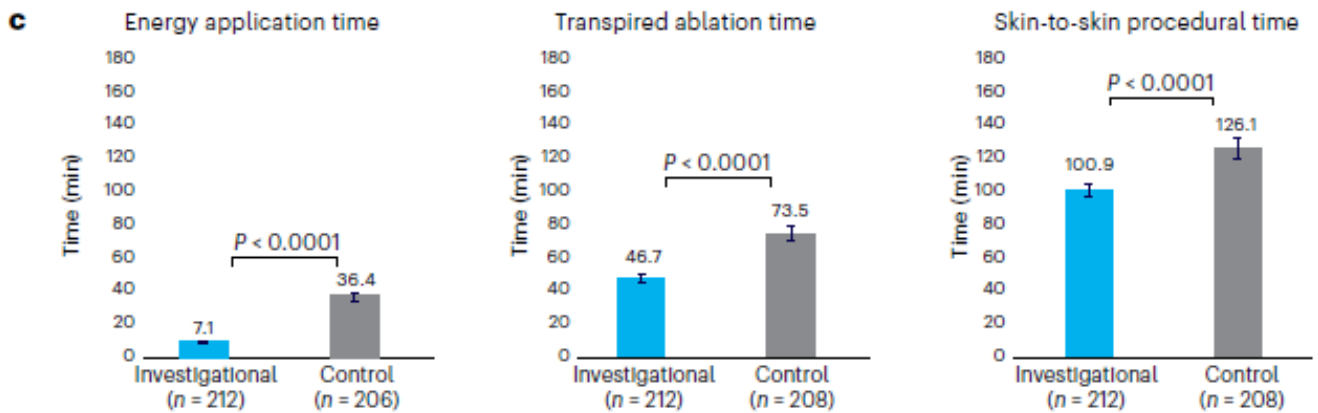
Dual-energy lattice-tip ablation system for persistent atrial fibrillation: a randomized trial



https://doi.org/10.1038/s41591-024-03022-6

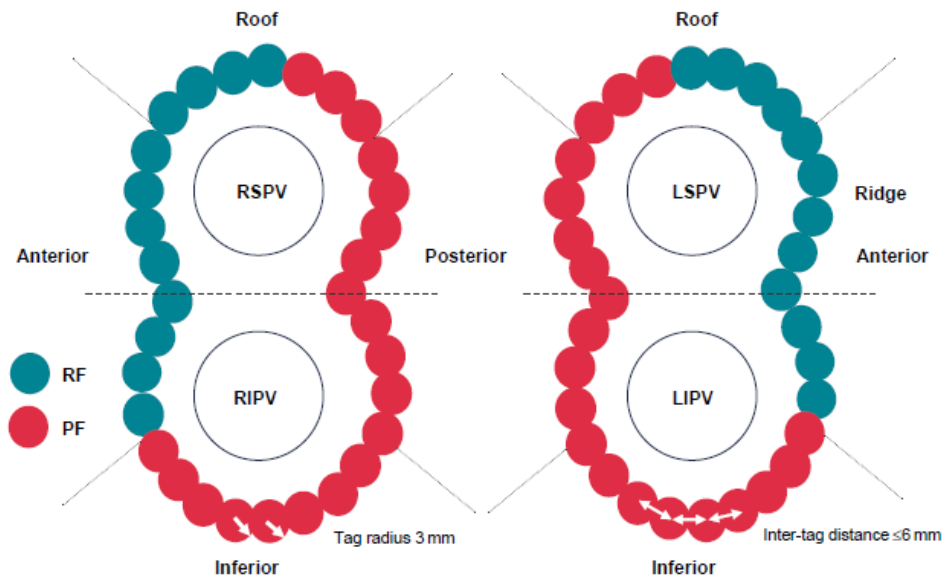




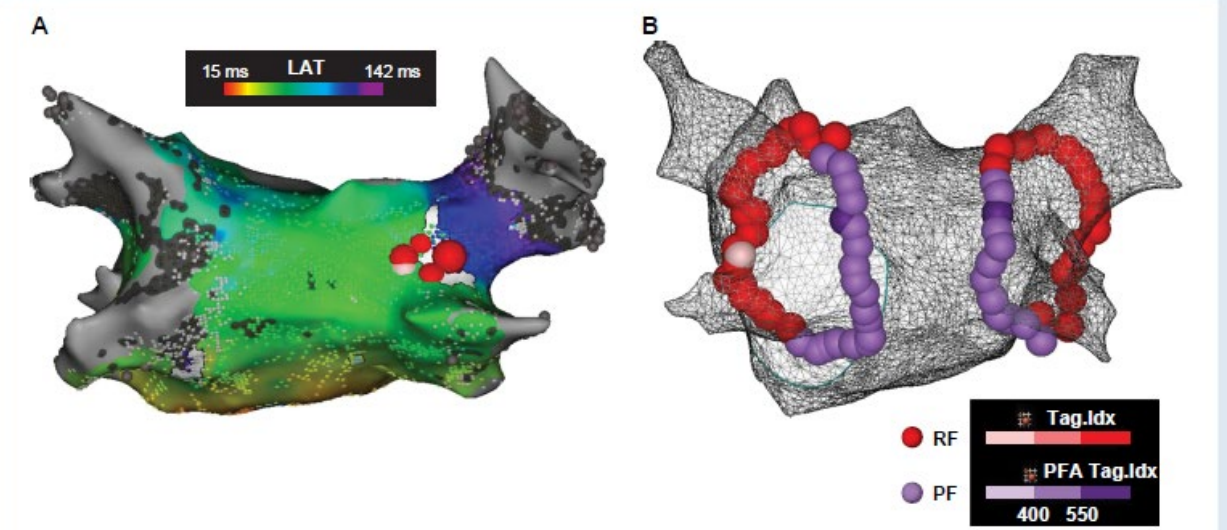


ESC European Society of Cardiology
Europace (2024) **26**, euae088
https://doi.org/10.1093/europace/euae088

Dual energy for pulmonary vein isolation using dual-energy focal ablation technology integrated with a three-dimensional mapping system: SmartfIRE 3-month results



	Anterior	Roof	Ridge	Carina	Posterior	Inferior
Target RF/PF index	550	550	550	550	400	400



SmartfIRE 3-month results: PVI with dual-energy focal ablation catheter integrated with 3D mapping system showed high acute effectiveness and PV durability with low fluoroscopy exposure

Study design

- Age 18–75 years
- Drug-refractory symptomatic PAF

9 European centres

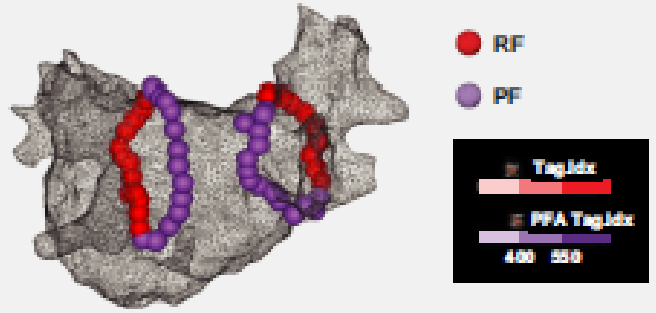
21 Operators

149 Patients

Primary endpoints:

- Safety: PAEs
- Effectiveness: acute PVI

Ablation procedure



Target index anterior, 550; posterior, 400; inter-tag distance, ≤6 mm; tag size, 3 mm.

Additional safety assessments (up to 3 months):

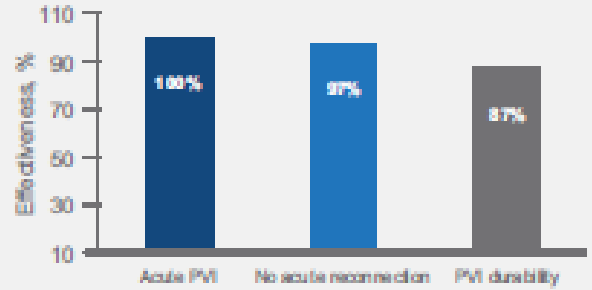
- Oesophageal endoscopy
- Neurological assessment
- Cardiac CT/MRA

PVI durability assessment (75 days):

- Remapping procedure

Results

97% No acute reconnection per vein



Safety

4.4% PAE

- 2 PV stenosis
- 2 cardiac tamponade
- 1 stroke
- 1 pericarditis

- 0 coronary spasm
- 0 phrenic injury
- 0 oesophageal thermal injury
- 3.3% SCL

4.2 min Median fluoroscopy time

3D, three-dimensional; CT, computed tomography; MRA, magnetic resonance angiogram; PAE, primary adverse event; PAF,paroxysmal atrial fibrillation; PF, pulsed field; PV, pulmonary vein; PVI, pulmonary vein isolation; RF, radiofrequency; SCL, silent cerebral lesion.

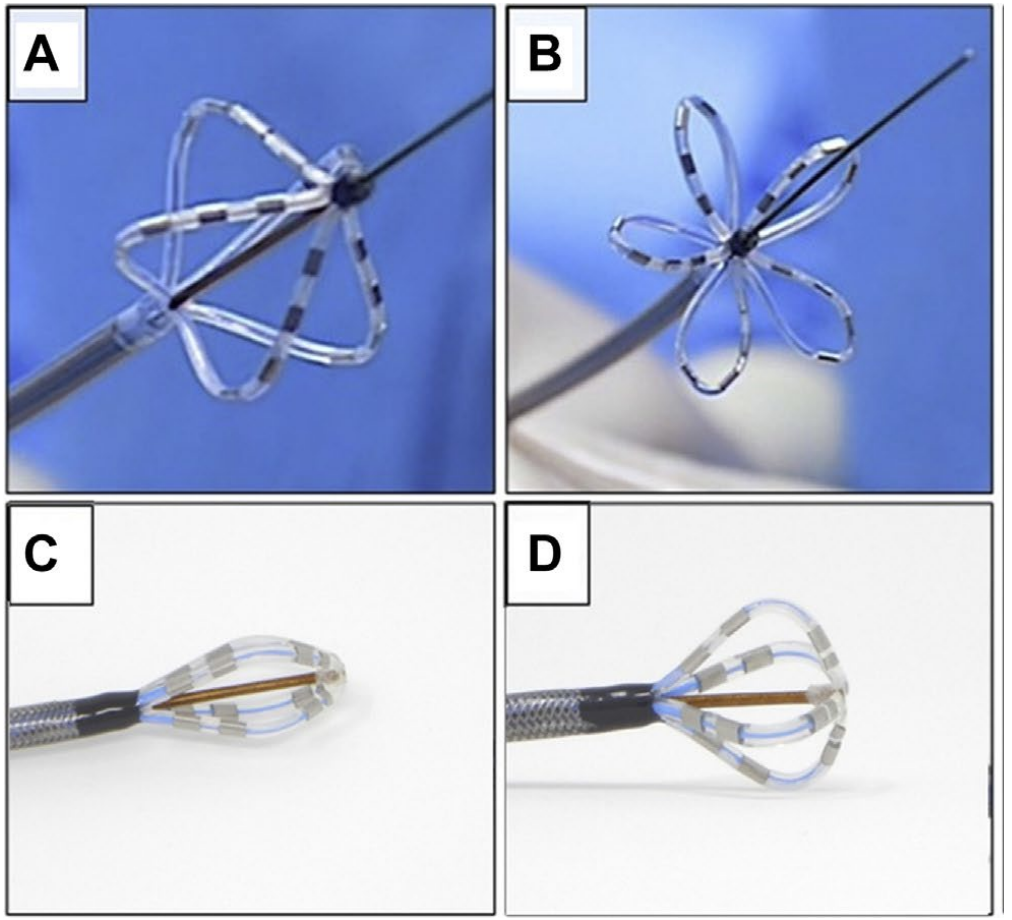
Images are courtesy of © Biosense Webster, Inc. All rights reserved.

Future developments: focal PFA, AI based models integrated in 3D system, PF mapping

Biosense Webster funding new PFA research

Michael Walter | February 08, 2024 | Cardiovascular Business | Electrophysiology

Varipulse images courtesy of Biosense Webster.



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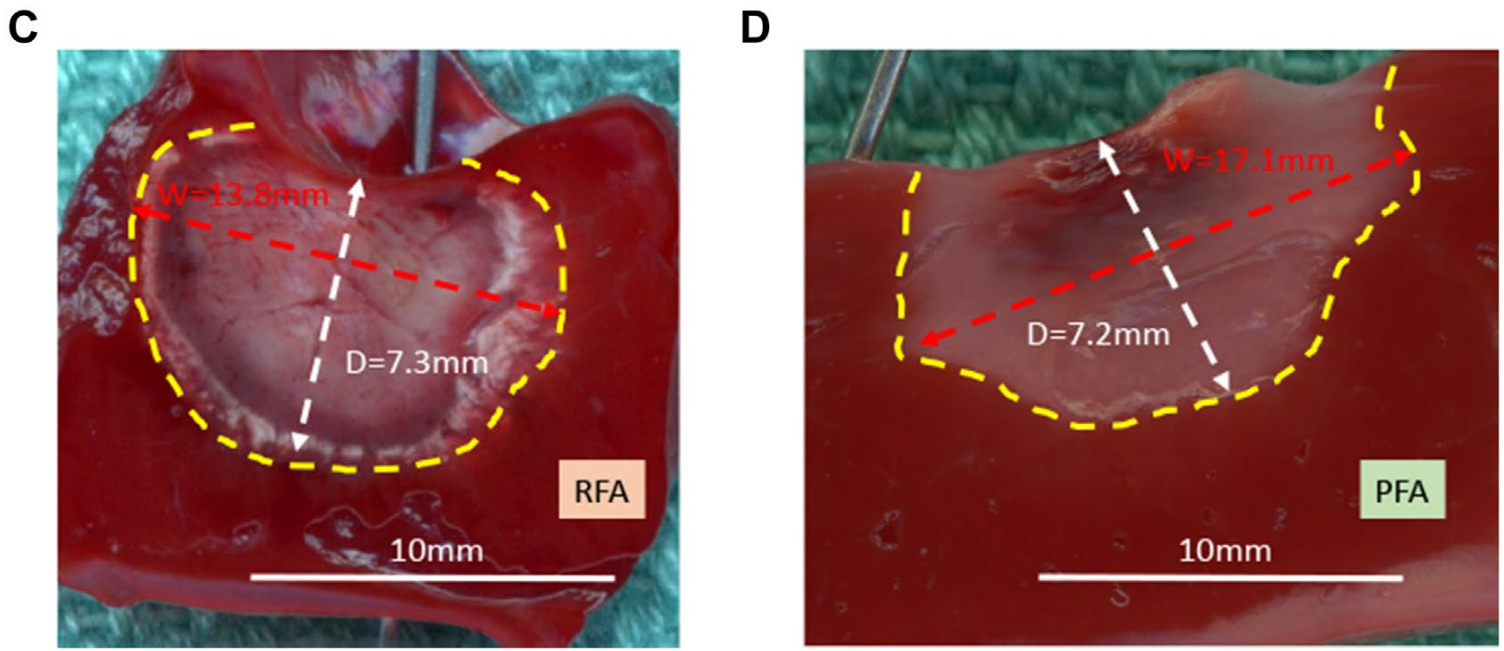
ORIGINAL RESEARCH

Comparative Efficacy and Safety of Pulsed Field Ablation Versus Radiofrequency Ablation of Idiopathic LV Arrhythmias

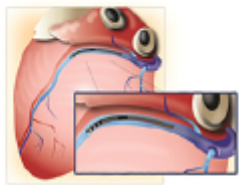
Arwa Younis, MD,[a] Chadi Tabaja, MD,[a] Ryan Kleve, MS, MBA,[b] Kara Garrott, PhD,[b] Lauren Lehn, BS,[b] Eric Buck, MS,[b] Ayman A. Hussein, MD,[a] Shady Nakhla, MD,[a] Hiroshi Nakagawa, MD, PhD,[a] Alison Krywanczyk, MD,[c] Tyler Taigen, MD,[a] Mohamed Kanj, MD,[a] Jakub Sroubek, MD, PhD,[a] Walid I. Saliba, MD,[a] Oussama M. Wazni, MD, MBA,[a] Pasquale Santangeli, MD, PhD[a]

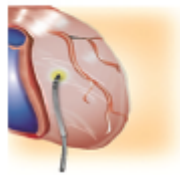


CENTRAL ILLUSTRATION Comparative Efficacy and Safety of PFA vs RFA in Common Idiopathic LV-VAs Locations

10 Pigs were randomized to RFA vs. PFA using an investigational RFA/PFA CF/LI measuring focal ablation catheter

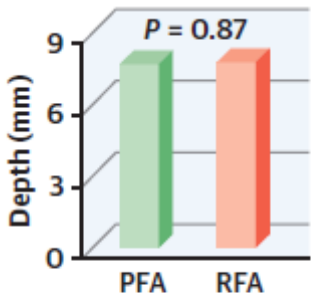
LV Septum (LV-IVS)	Papillary Muscle (PAP)	LV Summit (LVS)	Epicardium (EPI)

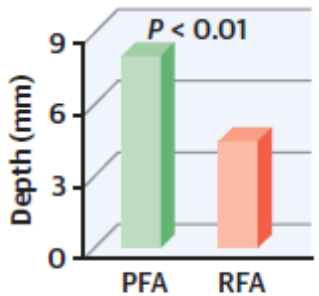


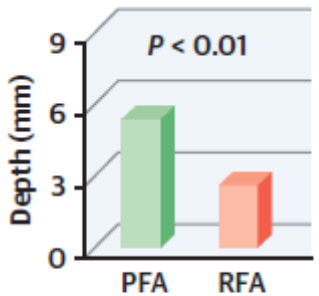


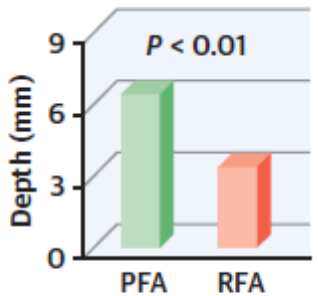
7 Days Survival–Angiography, Echo and Euthanasia

Efficacy Results









Safety Results

No safety events were reported for both modalities

	PFA	RFA
VF	0%	50%

	PFA	RFA
VF	0%	30%
Pop	0%	16%

	PFA	RFA
ST Elevation/ Depression	80%	0%

Younis A, et al. J Am Coll Cardiol EP. 2024;■(■):■-■.

Conclusions

- PFA is effective modality in paroxysmal and persistent AFIB: comparable with thermal energy
- Can be used as single shot (+/- EAM) or point by point ablation (+EAM)
- Extra PV linear lesion can be performed using single shot PFA devices. However, the clinical significance is questionable in persistent AFIB.
- Focal dual energy (PFA/RF) integrated in 3D system is promising and may has better clinical outcome in persistent AFIB

medicina

MDPI

Review

Recurrences after Pulsed Field Ablation of Atrial Fibrillation: Incidence, Mechanisms, Predictors, and Comparison with Thermal Energy

Riccardo Vio [1,*], Enrico Forlin [1,2] and Paolo China [1]

Refinement of the procedural workflow and its impact in the success of the ablation remain to be investigated.

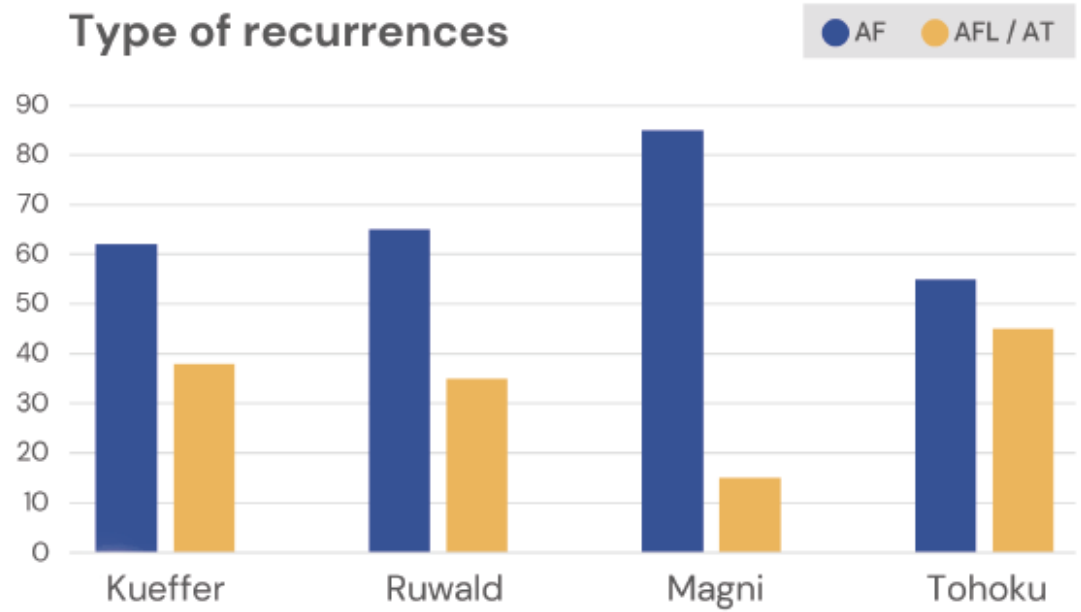


Figure 1. Arrhythmias responsible for recurrences after PFA ablation. AF = atrial fibrillation; AFL = atrial flutter; and AT = atrial tachycardia. Kueffer [31]; Ruwald [18]; Magni [16]; Tohoku [17].