New Frontiers in Ablative Therapy: Pulse Field Ablation

Troy Hounshell, DO

Disclosures

- Consult Fees and Honoraria
  - Boston Scientific
  - Medtronic

Objectives

- Define reversible vs irreversible electroporation
- Discuss the advantages of Pulse Field ablation (PFA)
  - Esophagus
  - Phrenic
  - Pulmonary vein stenosis
  - Speed
  - Durable Isolation
- Discuss supportive literature in cardiac ablation using PFA

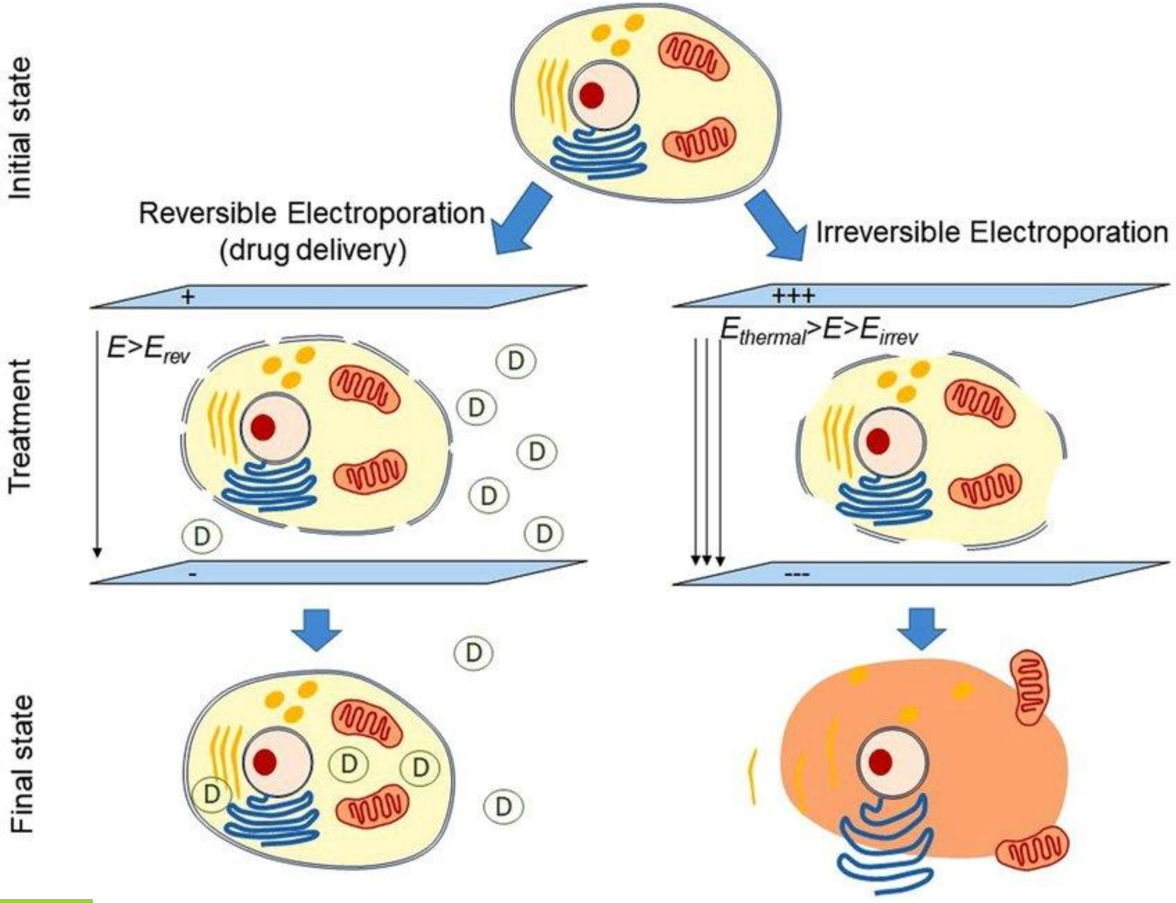
What is electroporation

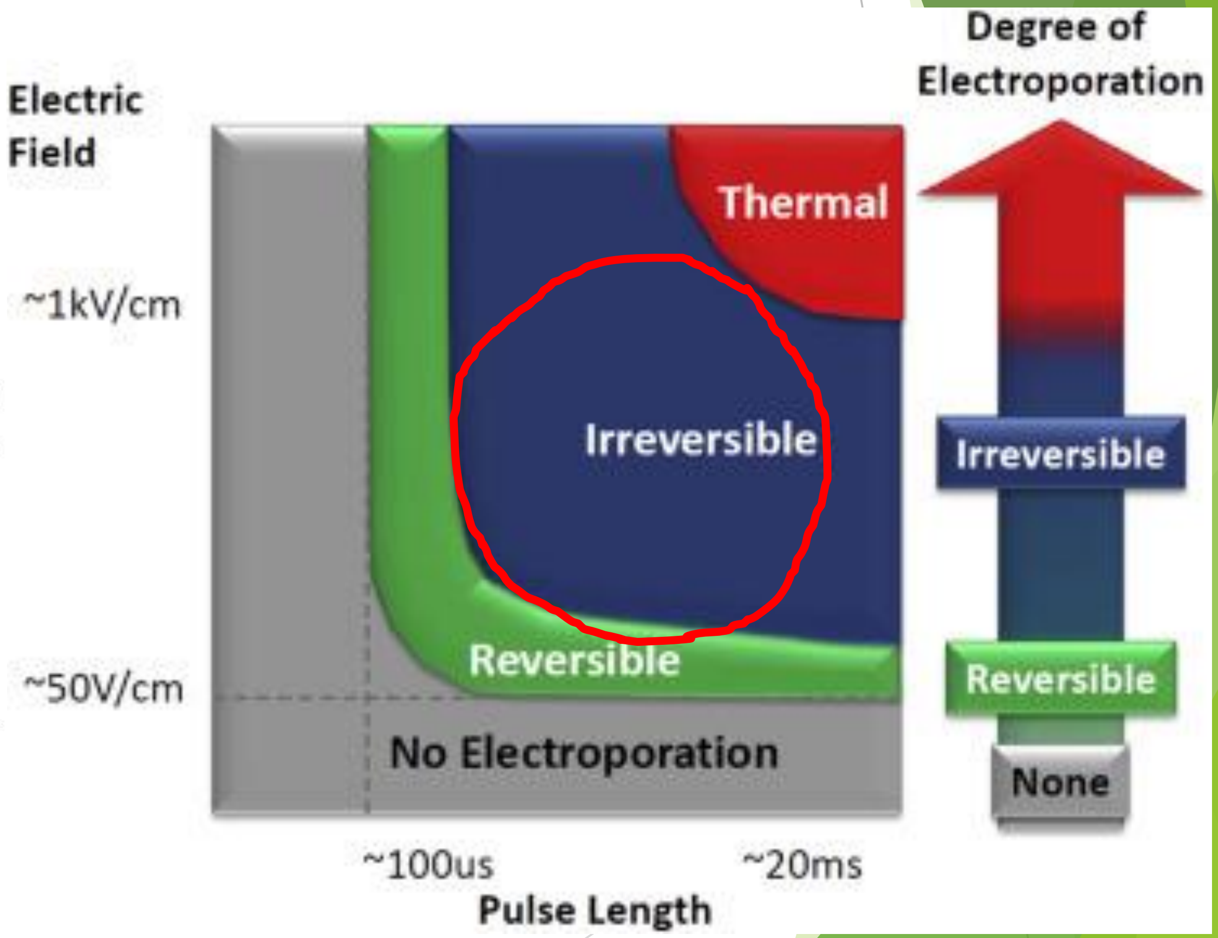
- Brief electrical pulses that create transient or permanent pores in the plasma membrane.
- Dates back to as early as 1970’s
- Normal transmembrane voltage 0.5-1.0V
- The transmembrane voltage, $\Delta U(t)$, induced by electric fields varies in direct proportion to the diameter of the cell that is the target
- Electroporation of mammalian cells, for example, requires smaller electric fields (<10 kV/cm) than does electroporation of yeasts or bacteria (12.5–16.5 kV/cm)

Cold Spring Harb Protoc; doi:10.1101/pdb.top096271

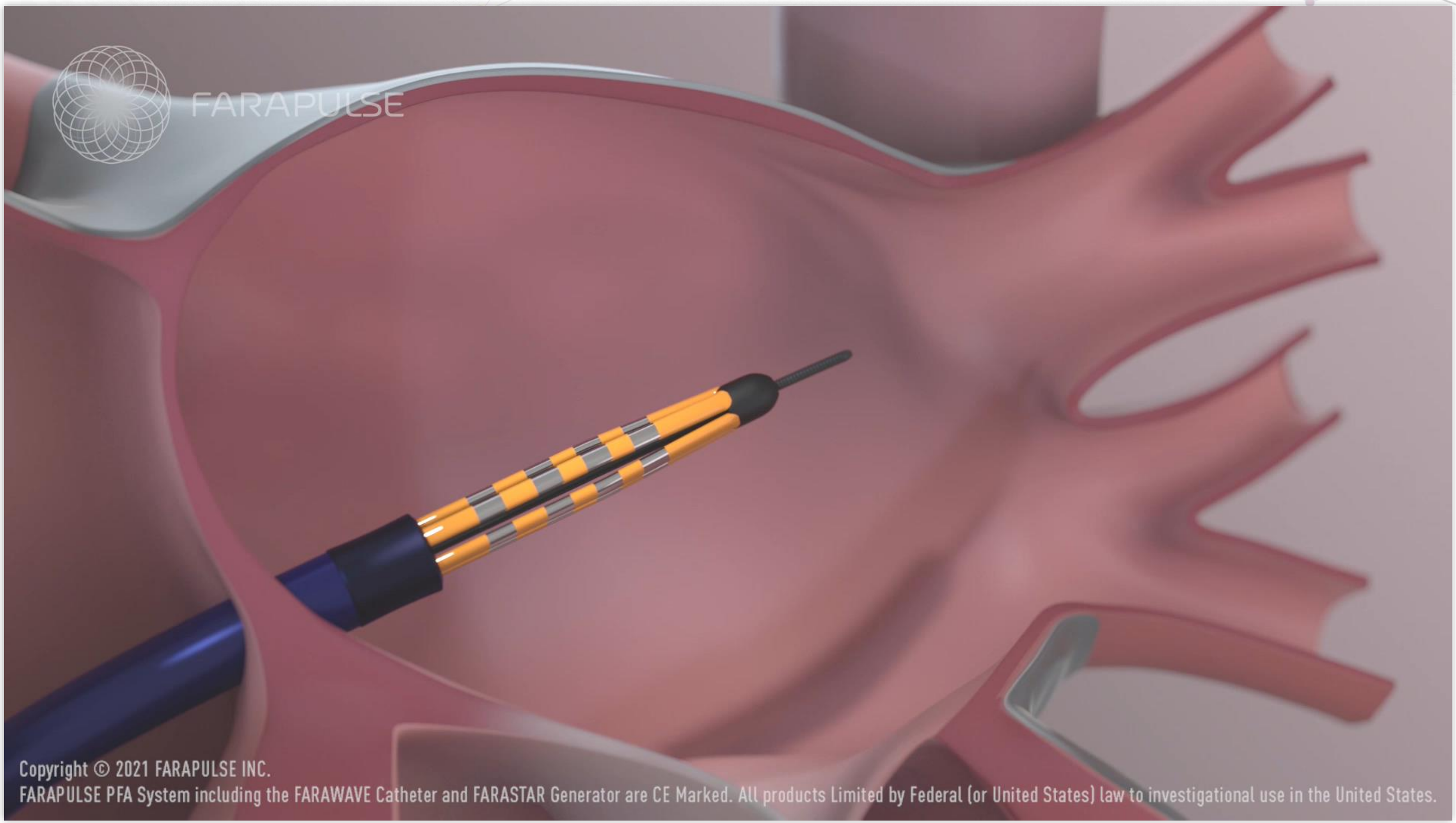
Reversible vs Irreversible Electroporation

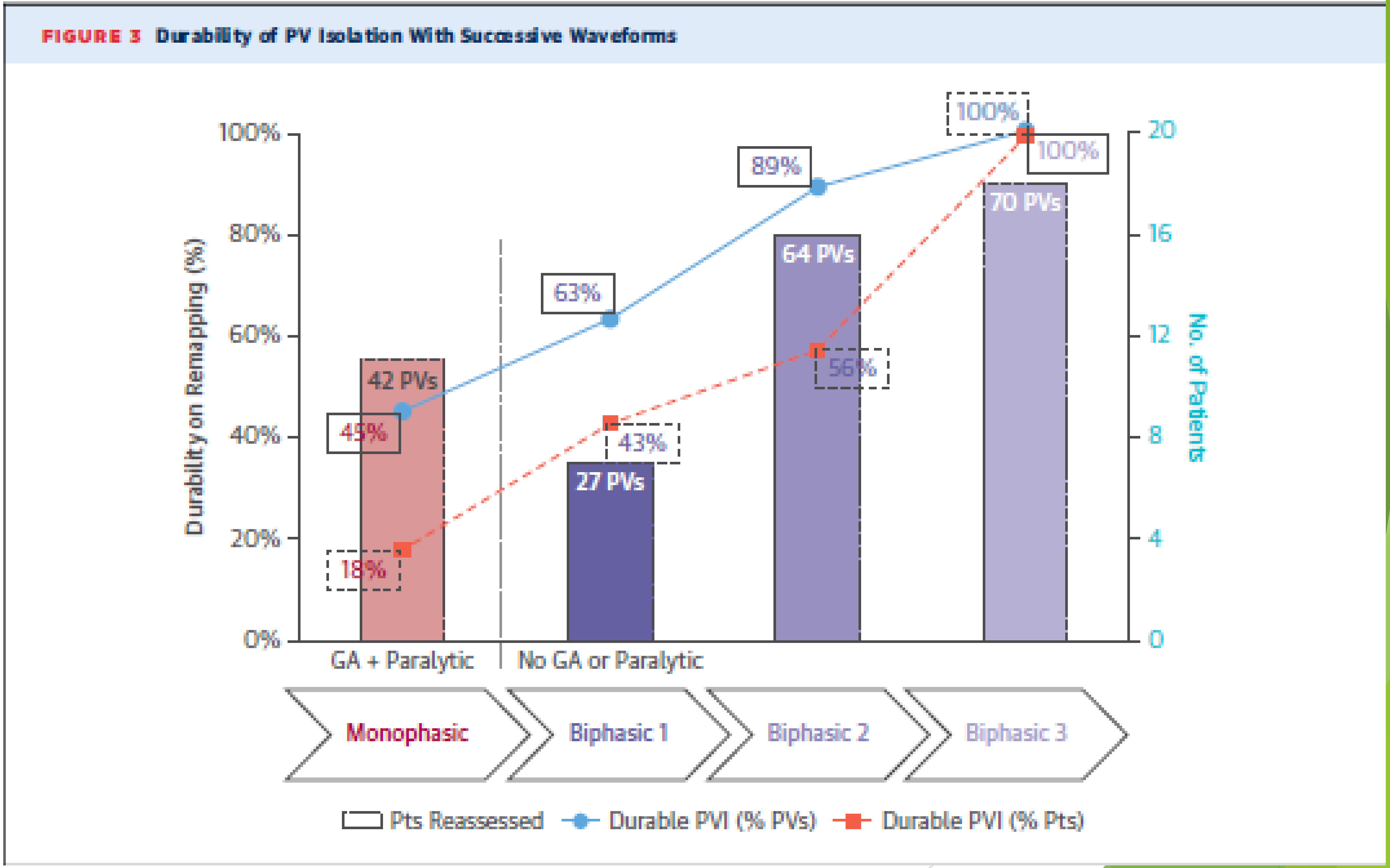
- Cell killing is dependent on field strength and the total time of treatment (Sale and Hamilton 1967). The most likely cause of cell killing is the inability to restore membrane structure and barrier function, leading to rupture of cell membranes, a rapid loss of ionic balance, and massive efflux of cellular components.





FARAPULSE PFA System





Reddy. J Am Coll Cardiol 2019;74:315-26

Advantages

PFA Group (IMPULSE/PEFCAT)

RFA Group (TOCCASTAR)

80 Patients-> 299 PVs

PV narrowing/stenosis was observed in 0% (0 of 133) and 12.0% (20 of 166) of PVs in the PFA and RFA cohort, respectively

Ostial dimensional changes after pulmonary vein isolation: Pulsed field ablation vs radiofrequency ablation

Check for updates

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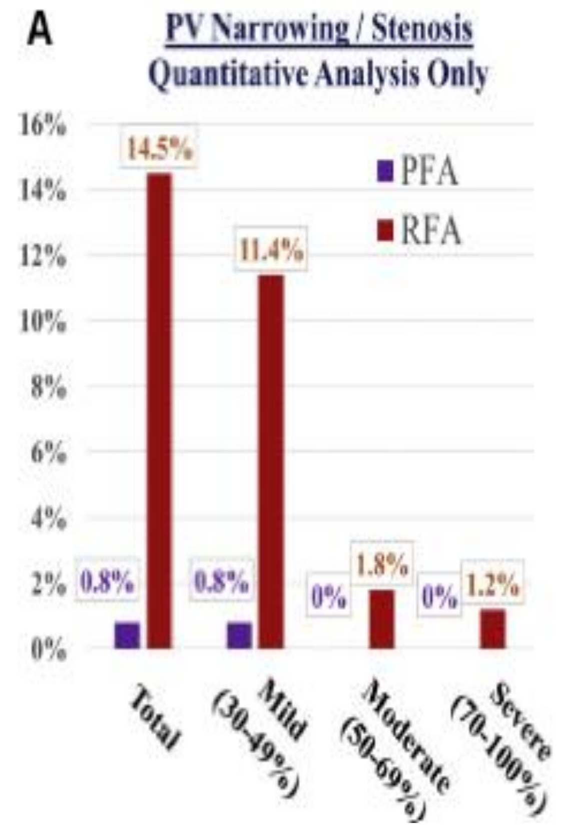
Heart Rhythm 2020;17:1528–1535



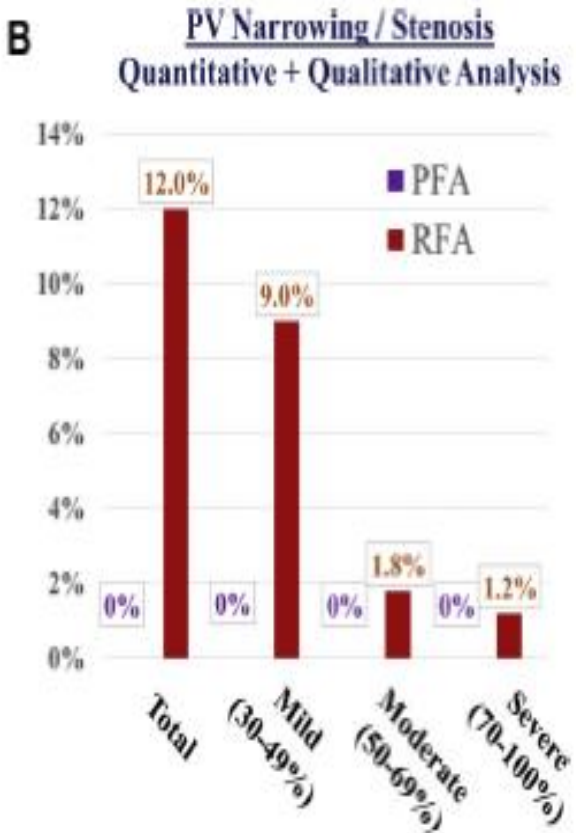
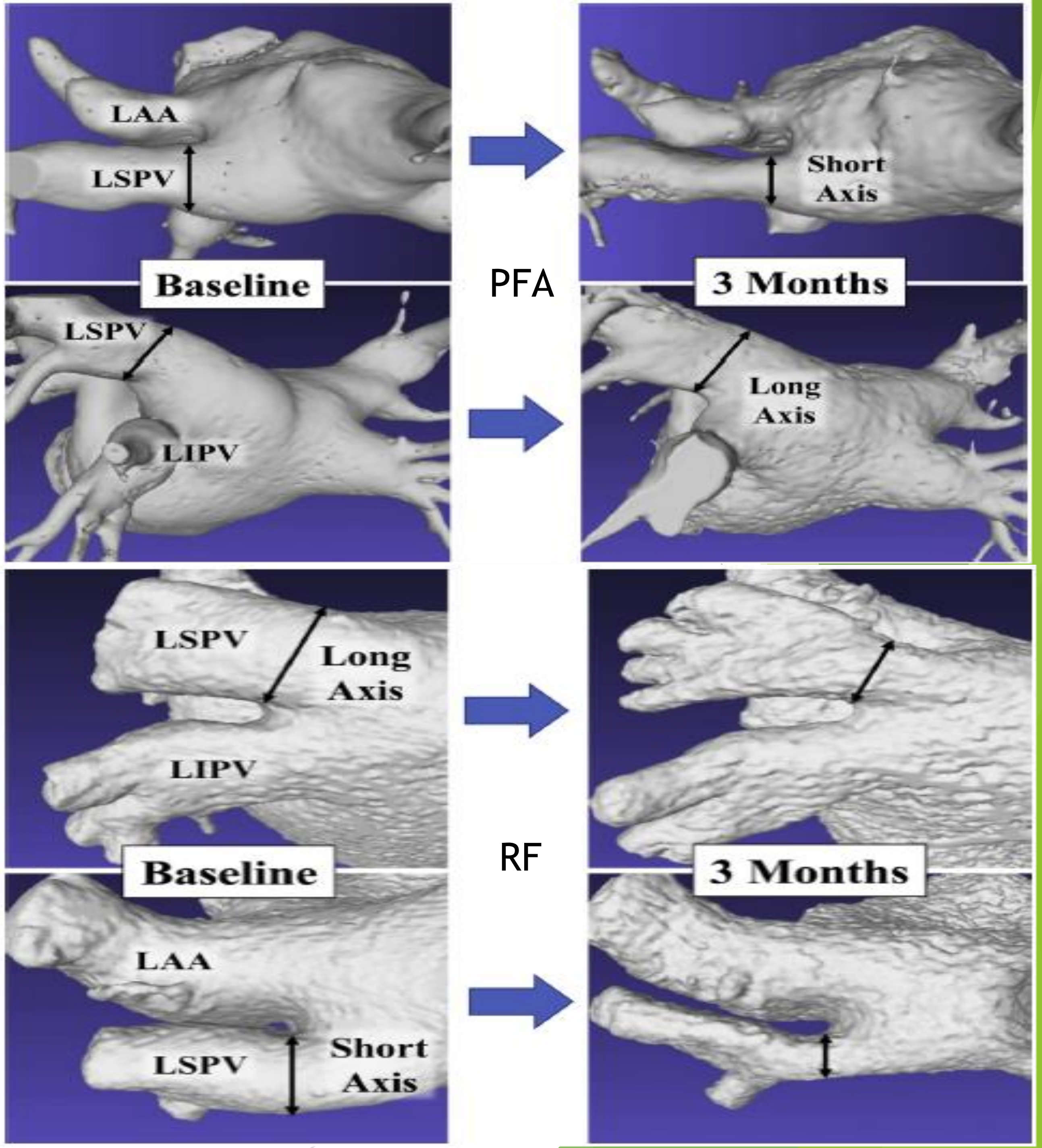


Table 2 Pulmonary vein ostial diameters (mm) before and after ablation

Variable	Axis	PFA N	PFA Pre	PFA Post	PFA *P*	RFA n	RFA Pre	RFA Post	RFA *P*
RSPV	Long	32	21.0 ± 3.6	21.0 ± 3.7	.844	43	20.0 ± 2.8	18.8 ± 3.2	.001
	Short		19.2 ± 3.9	19.6 ± 4.0	.216		18.4 ± 3.6	16.3 ± 3.6	<.001
RIPV	Long	36	19.9 ± 2.7	19.7 ± 2.9	.645	43	18.6 ± 3.7	17.6 ± 4.1	.005
	Short		17.6 ± 3.4	18.3 ± 3.3	.046		16.7 ± 3.4	15.3 ± 3.4	<.001
LSPV	Long	28	22.1 ± 2.7	22.4 ± 2.8	.317	37	20.4 ± 3.2	16.8 ± 4.5	<.001
	Short		15.9 ± 2.5	16.1 ± 3.1	.532		13.9 ± 3.2	11.4 ± 3.7	<.001
LIPV	Long	31	17.6 ± 2.8	17.9 ± 2.7	.245	37	17.0 ± 3.1	13.9 ± 4.4	<.001
	Short		14.1 ± 2.9	14.2 ± 3.1	.679		11.6 ± 2.6	9.8 ± 3.4	<.001
LCV	Long	6	30.2 ± 4.0	30.7 ± 4.1	.620	6	32.6 ± 2.7	26.8 ± 3.9	.003
	Short		19.0 ± 3.4	20.6 ± 3.5	.110		15.9 ± 0.9	13.4 ± 2.3	.084
Total	Long	133	20.5 ± 4.0	20.7 ± 4.1	.408	166	19.5 ± 4.3	17.2 ± 4.7	<.001
	Short		16.9 ± 3.7	17.3 ± 4.0	.009		15.3 ± 4.1	13.4 ± 4.4	<.001



Advantages

Compared the effects of newer biphasic PFA with RFA in a in vivo porcine model

10 animals, under general anesthesia, the lower esophagus was deflected toward the inferior vena cava using an esophageal deviation balloon, and ablation was performed from within the inferior vena cava at areas of esophageal contact.

ORIGINAL ARTICLE

Pulsed Field Ablation Versus Radiofrequency Ablation

Esophageal Injury in a Novel Porcine Model

Jacob S. Koruth, MD; Kenji Kuroki, MD; Iwanari Kawamura, MD; Richard Brose, MS; Raju Viswanathan, PhD; Eric D. Buck, MS; Elina Donskoy, MD, PhD; Petr Neuzil, MD, PhD; Srinivas R. Dukkipati, MD; Vivek Y. Reddy, MD

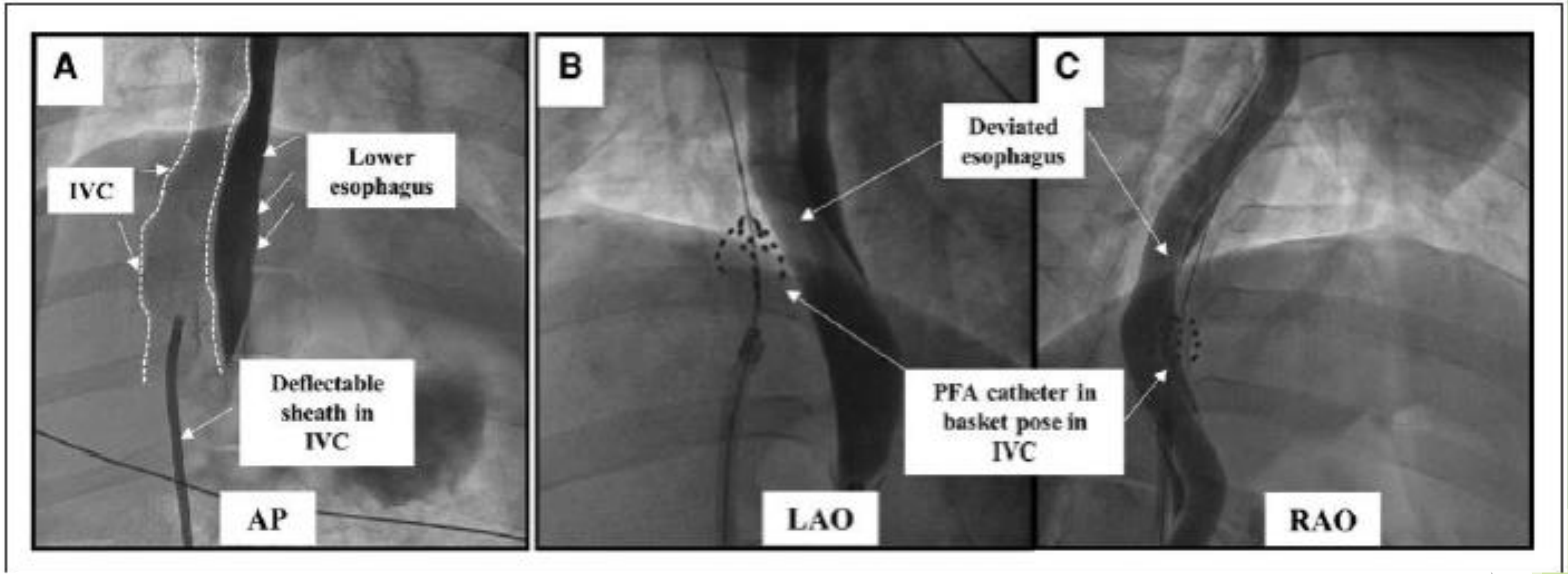
BACKGROUND: Pulsed field ablation (PFA) can be myocardium selective, potentially sparing the esophagus during left atrial ablation. In an in vivo porcine esophageal injury model, we compared the effects of newer biphasic PFA with radiofrequency ablation (RFA).

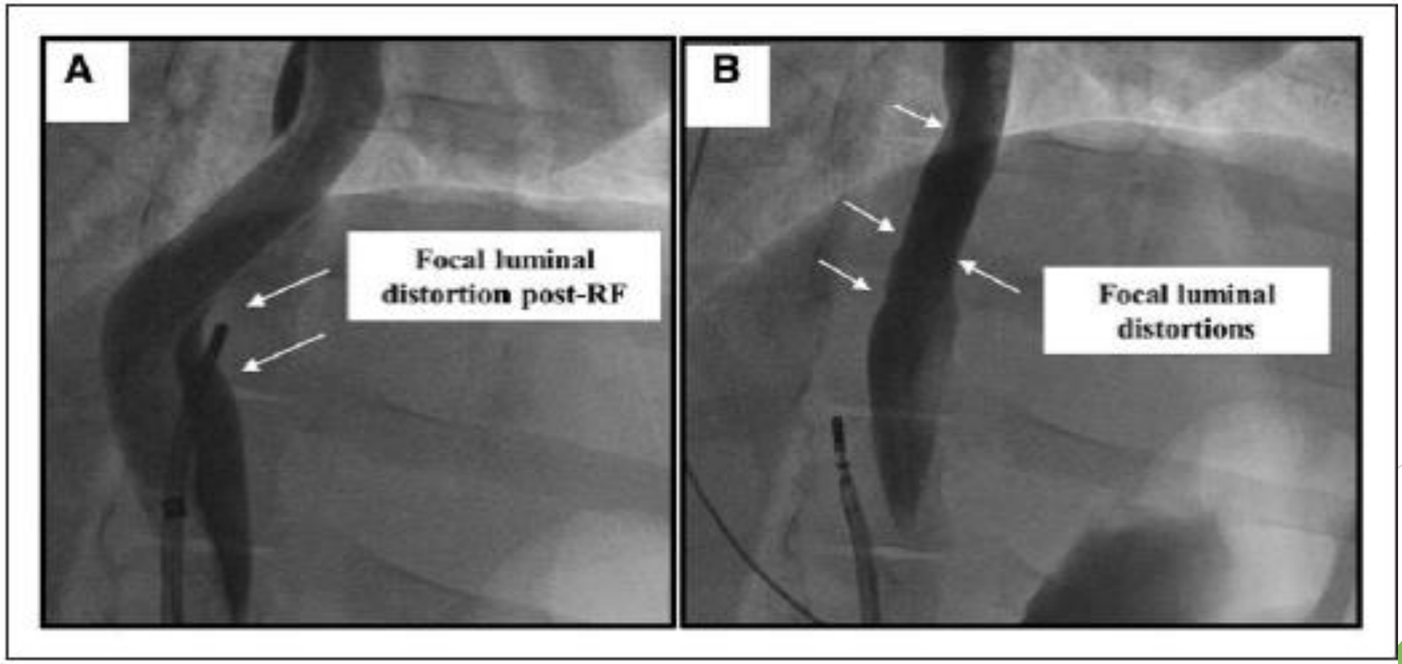
METHODS: In 10 animals, under general anesthesia, the lower esophagus was deflected toward the inferior vena cava using an esophageal deviation balloon, and ablation was performed from within the inferior vena cava at areas of esophageal contact. Four discrete esophageal sites were targeted in each animal: 6 animals received 8 PFA applications/site (2 kV, multispline catheter), and 4 animals received 6 clusters of irrigated RFA applications (30 W×30 seconds, 3.5 mm catheter). All animals were survived to 25 days, sacrificed, and the esophagus submitted for pathological examination, including 10 discrete histological sections/esophagus.

RESULTS: The animals weight increased by 13.7±6.2% and 6.8±6.3% (P=0.343) in the PFA and RFA cohorts, respectively. No PFA animals (0 of 6, 0%) developed abnormal in-life observations, but 1 of 4 RFA animals (25%) developed fever and dyspnea. On necropsy, no PFA animals (0 of 6, 0%) demonstrated esophageal lesions. In contrast, esophageal injury occurred in all RFA animals (4 of 4, 100%; P=0.005): a mean of 1.5 mucosal lesions/animal (length, −21.8±8.9 mm; width, −4.9±1.4 mm) were observed, including one esophago-pulmonary fistula and deep esophageal ulcers in the other animals. Histological examination demonstrated tissue necrosis surrounded by acute and chronic inflammation and fibrosis. The necrotic RFA lesions involved multiple esophageal tissue layers with evidence of arteriolar medial thickening and fibrosis of periesophageal nerves. Abscess formation and full-thickness esophageal wall disruptions were seen in areas of perforation/fistula.

CONCLUSIONS: In this novel porcine model of esophageal injury, biphasic PFA induced no chronic histopathologic esophageal changes, while RFA demonstrated a spectrum of esophageal lesions including fistula and deep esophageal ulcers and abscesses.

Circ Arrhythm Electrophysiol. 2020;13:e008303. DOI: 10.1161/CIRCEP.119.008303





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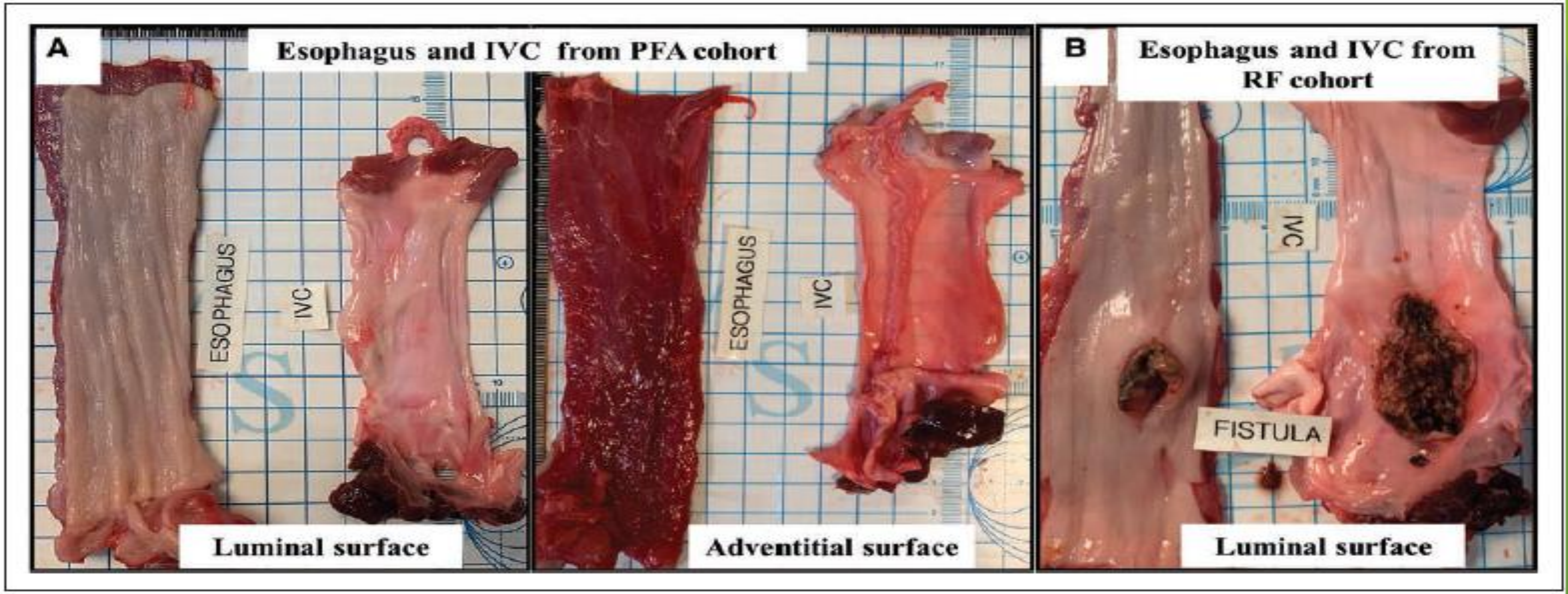

	No. of Applications	Dose	Pathology
PFA animals 1–6	32 applications/swine	2000 V/application	No abnormalities detected; no evidence of ablation
RF animal 1	25 applications	30 W/30 s application	Fistulous connection between IVC and the esophagus with involvement of the lung
RF animal 2	24 applications	30 W/30 s application	Two discrete esophageal ulcerations: lung abscess in area of adherence
RF animal 3	25 applications	30 W/30 s application	Partially healed esophageal lesions; abscess within lung in area of adherence
RF animal 4	24 applications	30 W/30 s application	Partially healed esophageal lesions adherent to the lung

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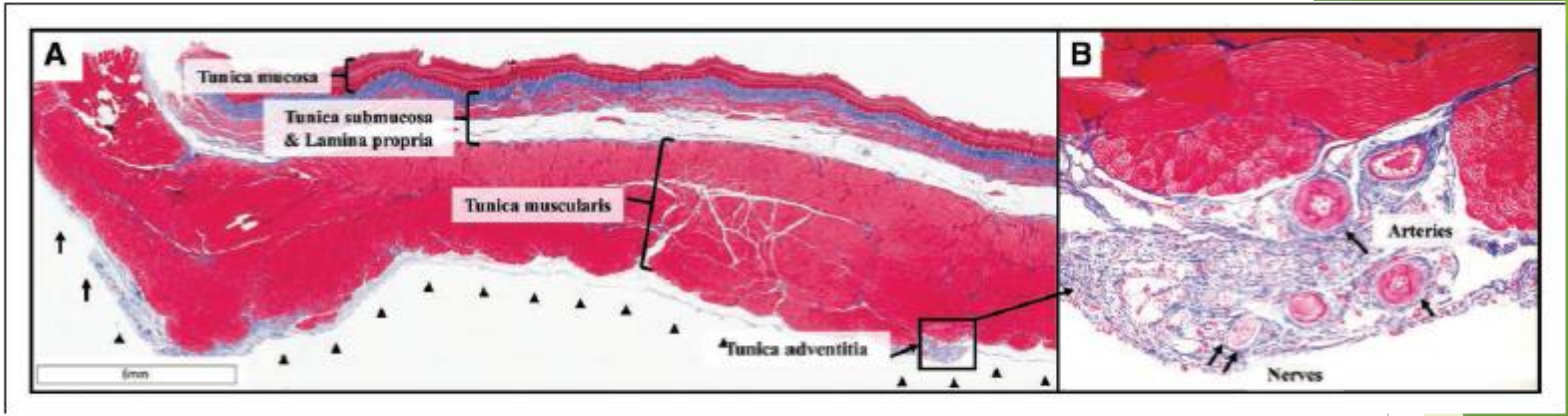
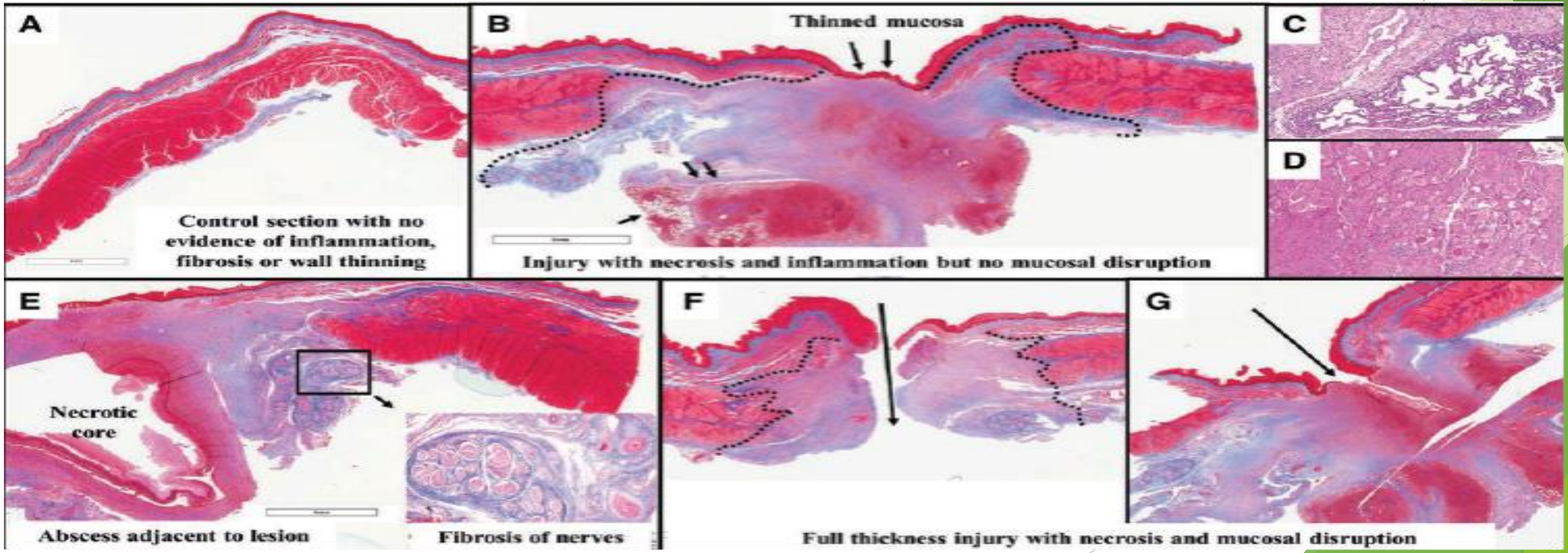
PFA



RF



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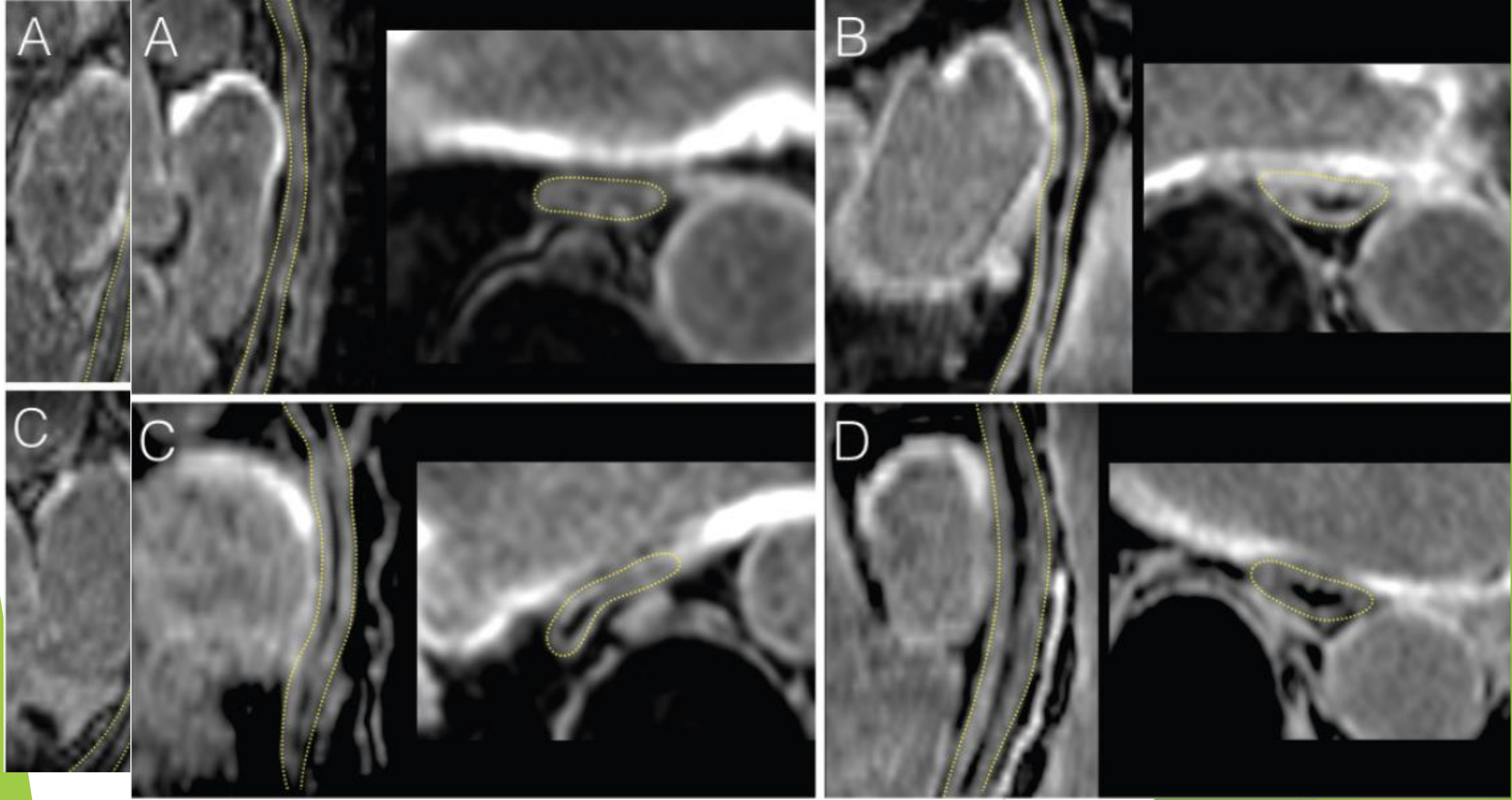

Cochet. Et al, Europace (2021) 23, 1391–1399

Advantages

Structural and mechanical differences between myocardial tissue ablated with PFA and thermal ablation

CMR Pre, <3H, and 3 months post ablation

18 PFA patients

23 Thermal (16RF and 7Cryo)

ESC European Society of Cardiology
Europace (2021) 00, 1–10
doi:10.1093/europace/euab155

CLINICAL RESEARCH

Pulsed field ablation prevents chronic atrial fibrotic changes and restrictive mechanics after catheter ablation for atrial fibrillation

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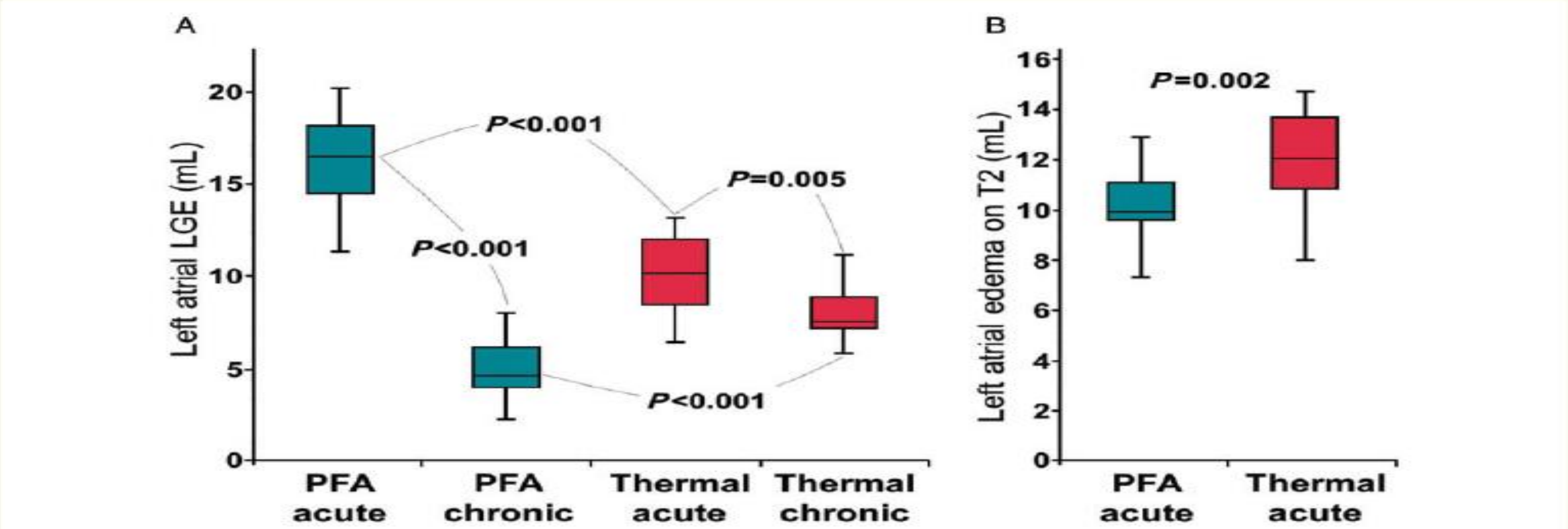
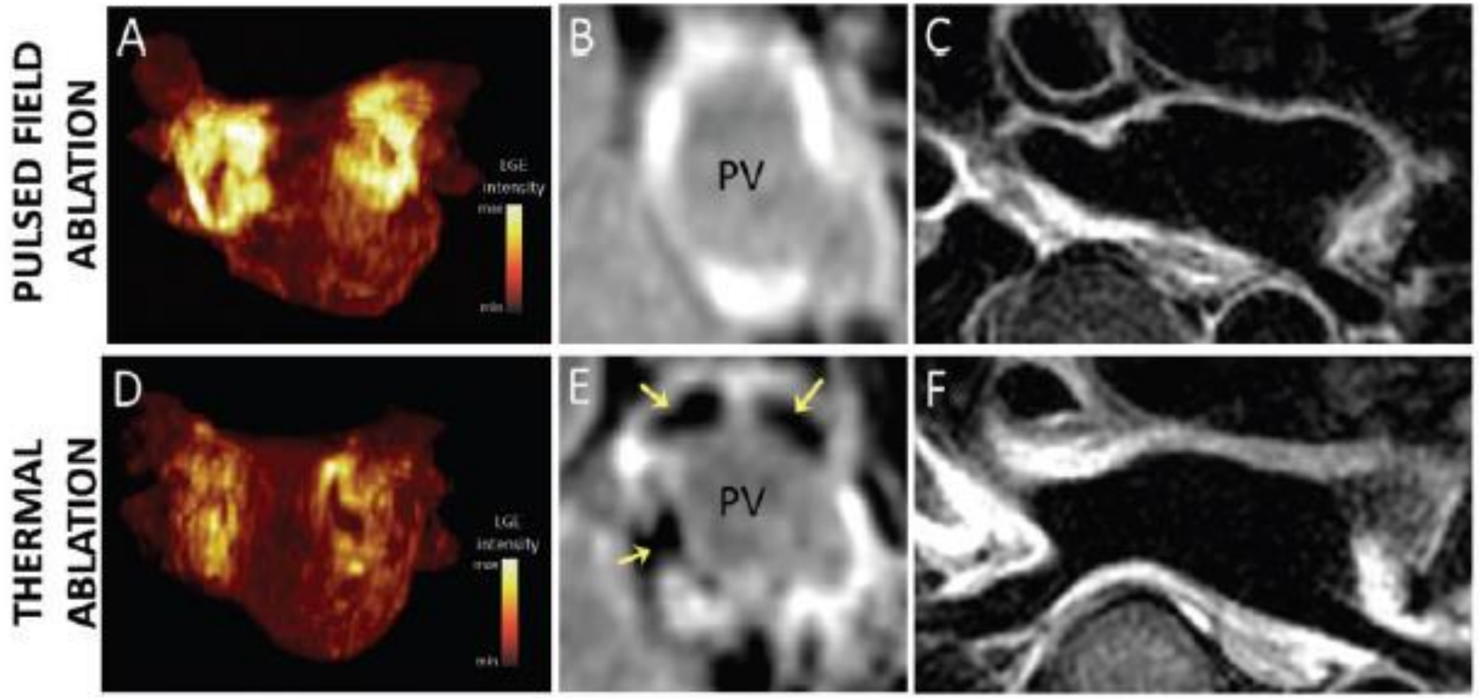
Table 2 Procedural characteristics and outcomes

	All patients (*n* = 41)	PFA group (*n* = 18)	Thermal group (*n* = 23)	P-value
Fluoroscopy time (min)	23 [18–29]	23 [17–29]	20 [18–31]	0.796
Total procedure time (min)	111 [95–146]	96 [77–111]	130 [110–200]	0.001
Total number of PFA applications	NA	32 [32–37]	NA	NA
Total ablation time (min)	NA	<1	RF 37 [26–72] CRYO 16 [15–20]	NA
Successful PV isolation	41 (100)	18 (100)	23 (100)	>0.999
Complication	3 (7)	1 (6)	2 (9)	>0.999
PV reconnection at 3 months remap	NA	0 0	NA	NA
Follow-up duration	9 ± 4	9 ± 3	9 ± 4	0.972
Arrhythmia recurrence	11 (27)	2 (11)	9 (39)	0.098

Data are median [interquartile range Q1–Q3] or number (%) of patients.
CRYO, cryoablation; PFA, pulsed field ablation; PV, pulmonary vein; RF, radiofrequency.

Europace (2021) 00, 1–10 doi:10.1093/europace/euab155





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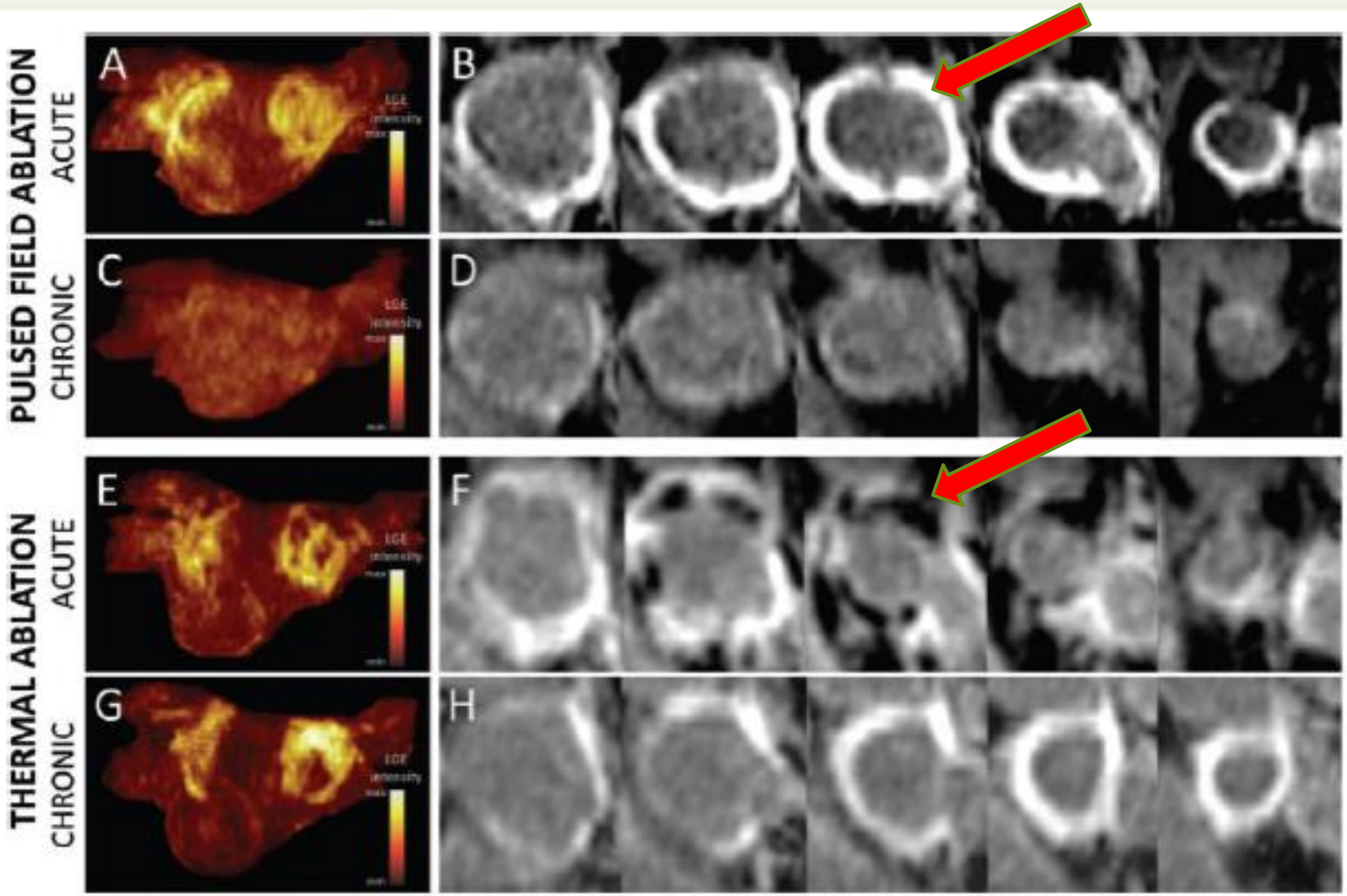

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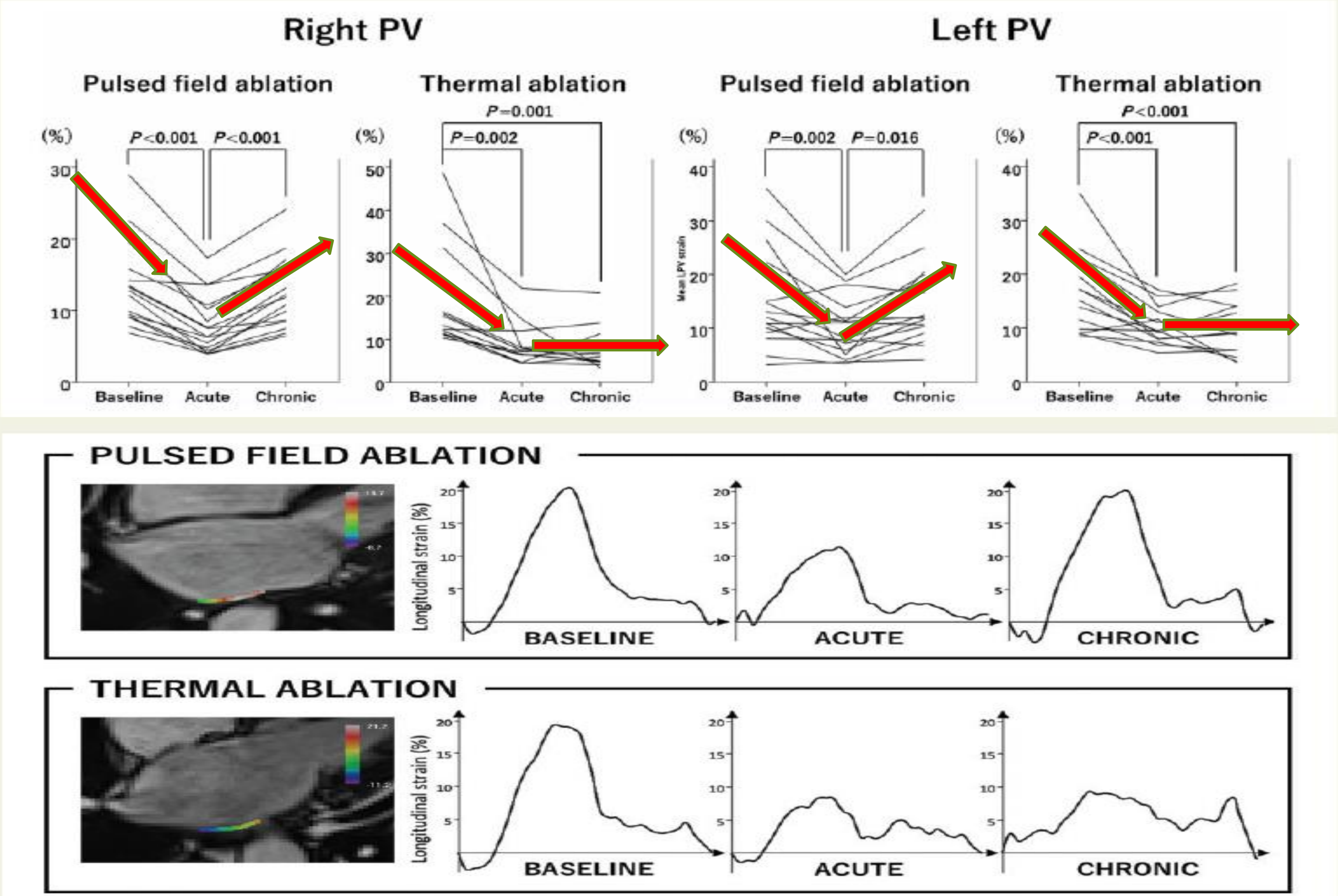

Europace (2021) 00, 1–10
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Does it work? Fast? Durable?

- 81 consecutive patients with symptomatic paroxysmal AF
- IMPULSE and PEFCAT

Pulsed Field Ablation for Pulmonary Vein Isolation in Atrial Fibrillation

Vivek Y. Reddy, MD,[a,b] Petr Neuzil, MD, PhD,[a] Jacob S. Koruth, MD,[b] Jan Petru, MD,[a] Moritoshi Funosako, MD,[a] Hubert Cochet, MD,[c] Lucie Sediva, MD,[a] Milan Chovanec, MD,[a] Srinivas R. Dukkipati, MD,[b] Pierre Jais, MD[c]

ABSTRACT

BACKGROUND Catheter ablation of atrial fibrillation using thermal energies such as radiofrequency or cryothermy is associated with indiscriminate tissue destruction. During pulsed field ablation (PFA), subsecond electric fields create microscopic pores in cell membranes—a process called electroporation. Among cell types, cardiomyocytes have among the lowest thresholds to these fields, potentially permitting preferential myocardial ablation.

OBJECTIVES The purpose of these 2 trials was to determine whether PFA allows durable pulmonary vein (PV) isolation without damage to collateral structures.

METHODS Two trials were conducted to assess the safety and effectiveness of catheter-based PFA in paroxysmal atrial fibrillation. Ablation was performed using proprietary bipolar PFA waveforms: either monophasic with general anesthesia and paralytics to minimize muscle contraction, or biphasic with sedation because there was minimal muscular stimulation. No esophageal protection strategy was used. Invasive electrophysiological mapping was repeated after 3 months to assess the durability of PV isolation.

RESULTS In 81 patients, all PVs were acutely isolated by monophasic (n = 15) or biphasic (n = 66) PFA with ≤3 min elapsed delivery/patient, skin-to-skin procedure time of 92.2 ± 27.4 min, and fluoroscopy time of 13.1 ± 7.6 min. With successive waveform refinement, durability at 3 months improved from 18% to 100% of patients with all PVs isolated. Beyond 1 procedure-related pericardial tamponade, there were no additional primary adverse events over the 120-day median follow-up, including: stroke, phrenic nerve injury, PV stenosis, and esophageal injury. The 12-month Kaplan-Meier estimate of freedom from arrhythmia was 87.4 ± 5.6%.

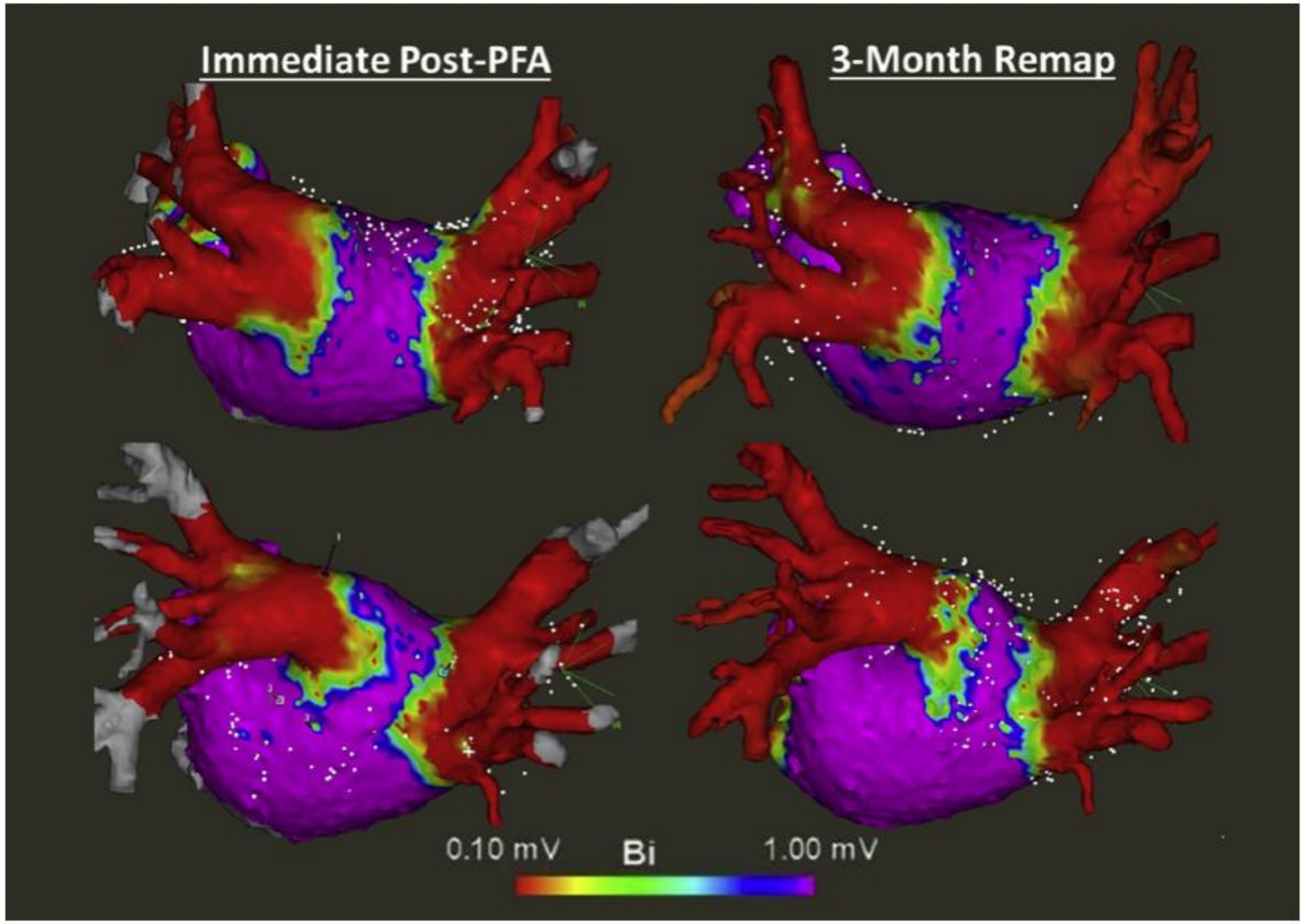
CONCLUSIONS In first-in-human trials, PFA preferentially affected myocardial tissue, allowing facile ultra-rapid PV isolation with excellent durability and chronic safety. (IMPULSE: A Safety and Feasibility Study of the IOWA Approach Endocardial Ablation System to Treat Atrial Fibrillation; NCT03700385; and PEFCAT: A Safety and Feasibility Study of the FARAPULSE Endocardial Ablation System to Treat Paroxysmal Atrial Fibrillation; NCT03714178)
(J Am Coll Cardiol 2019;74:315–26)

J Am Coll Cardiol 2019;74:315–26

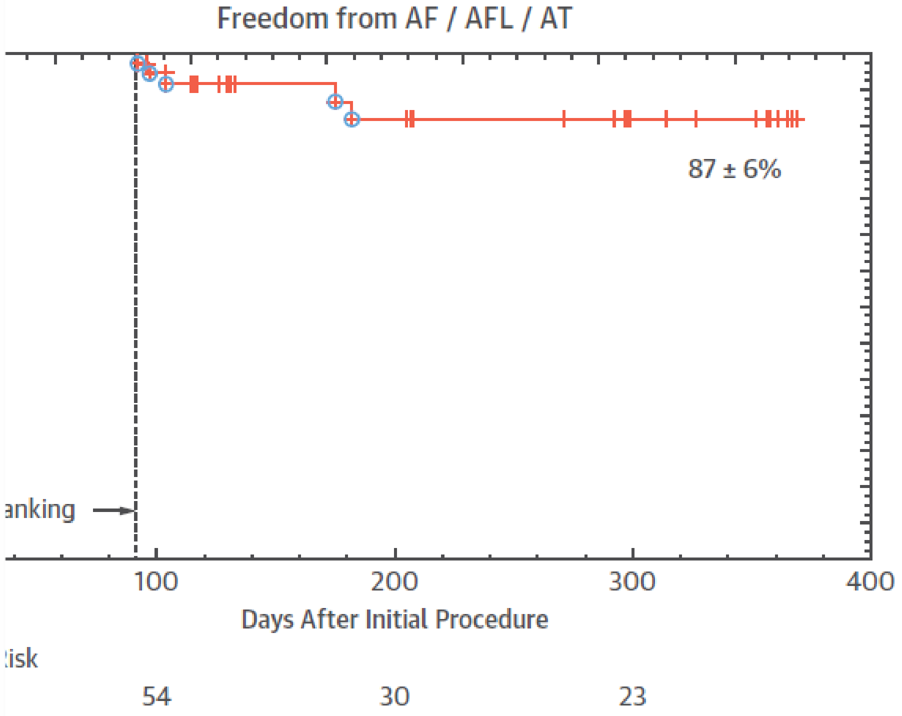
TABLE 2 Procedural Characteristics of the Total Cohort (n = 81)

Procedure time, min	92.2 ± 27.4
Mapping time	18.2 ± 10.3
Catheter dwell time	33.7 ± 16.6
Fluoroscopy time, min*	13.1 ± 7.6

FIGURE 2 Electroanatomic Voltage Mapping to Assess PV Isolation Level



of Freedom From Atrial Arrhythmias



period, shown is the freedom for atrial arrhythmias, including any atrial fibrillation (AF), atrial flutter
ode exceeding 30 s.

J Am Coll Cardiol 2019;74:315–26

FIGURE 3 Durability of PV Isolation With Successive Waveforms

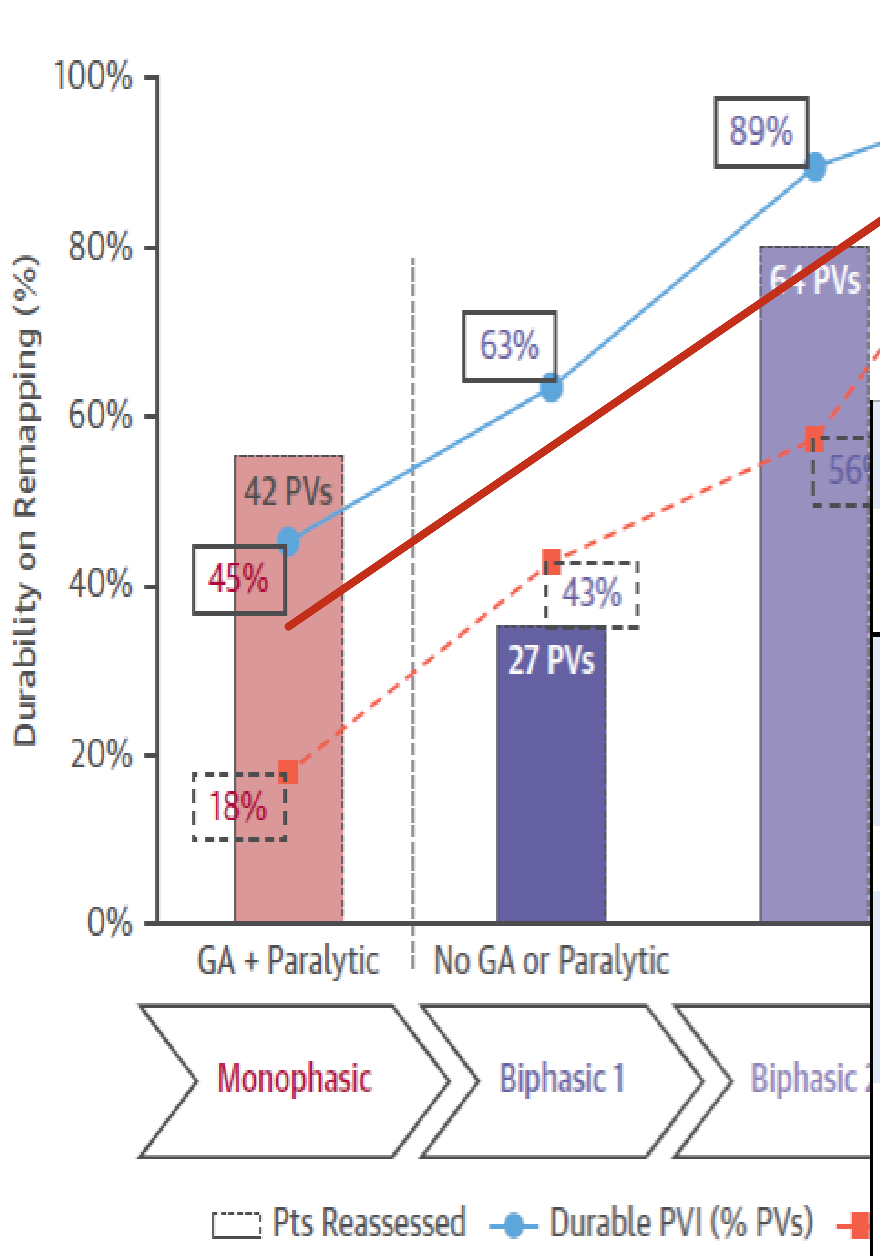


TABLE 4 Additional Safety Assessments

	Patients With Assessment	Findings
Esophageal findings		
Esophagogastroduodenoscopy	29	No esophageal lesions
Chest CMR	8	No esophageal enhancement
Brain MRI	13	Negative for DWI/FLAIR
Phrenic nerve		
Phrenic nerve assessment*	81	No paresis/palsy
Chest x-ray at 3 months	37	No paresis/palsy
Pulmonary vein stenosis		
EAM at 3 months	52	No PV stenosis/narrowing
CT scanning at 3 months	29	No PV stenosis/narrowing

What about Persistent Atrial fibrillation??

25 Patients with Persistent Atrial Fibrillation

Single arm

Bipolar Bi Phasic PFA

PVI+PWI+CTI

Pulsed Field Ablation in Patients With Persistent Atrial Fibrillation

Vivek Y. Reddy, MD,[a,b] Ante Anic, MD,[c] Jacob Koruth, MD,[b] Jan Petru, MD,[a] Moritoshi Funasako, MD,[a] Kentaro Minami, MD,[a] Toni Breskovic, MD, PhD,[c] Ivan Sikiric, MD,[c] Srinivas R. Dukkipati, MD,[b] Iwanari Kawamura, MD,[b] Petr Neuzil, MD, PhD[a]

ABSTRACT

BACKGROUND Unlike for paroxysmal atrial fibrillation (AF), pulmonary vein isolation (PVI) alone is considered insufficient for many patients with persistent AF. Adjunctive ablation of the left atrial posterior wall (LAPW) may improve outcomes, but is limited by both the difficulty of achieving lesion durability and concerns of damage to the esophagus—situated behind the LAPW.

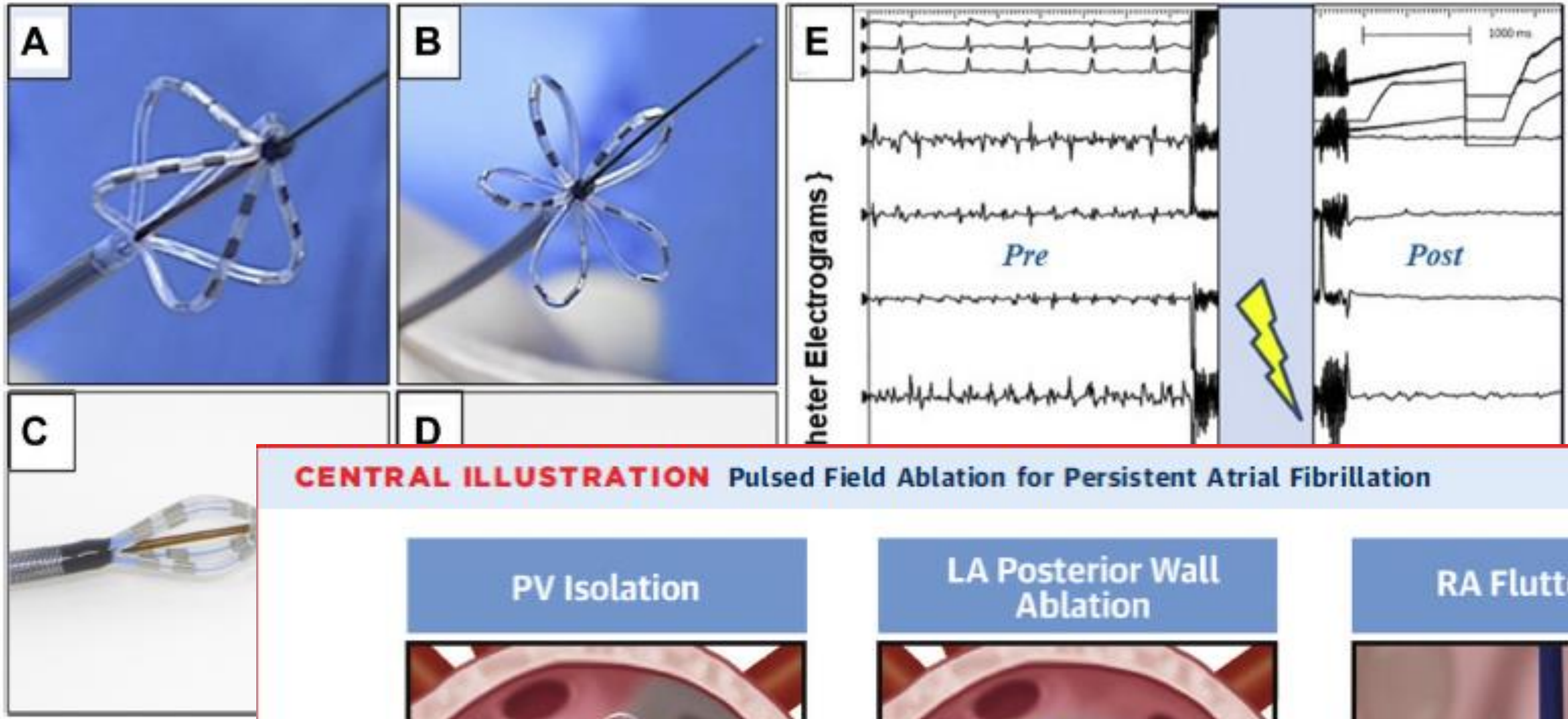
OBJECTIVES This study sought to assess the safety and lesion durability of pulsed field ablation (PFA) for both PVI and LAPW ablation in persistent AF.

METHODS PersAFOne is a single-arm study evaluating biphasic, bipolar PFA using a multispline catheter for PVI and LAPW ablation under intracardiac echocardiographic guidance. A focal PFA catheter was used for cavotricuspid isthmus ablation. No esophageal protection strategy was used. Invasive remapping was mandated at 2 to 3 months to assess lesion durability.

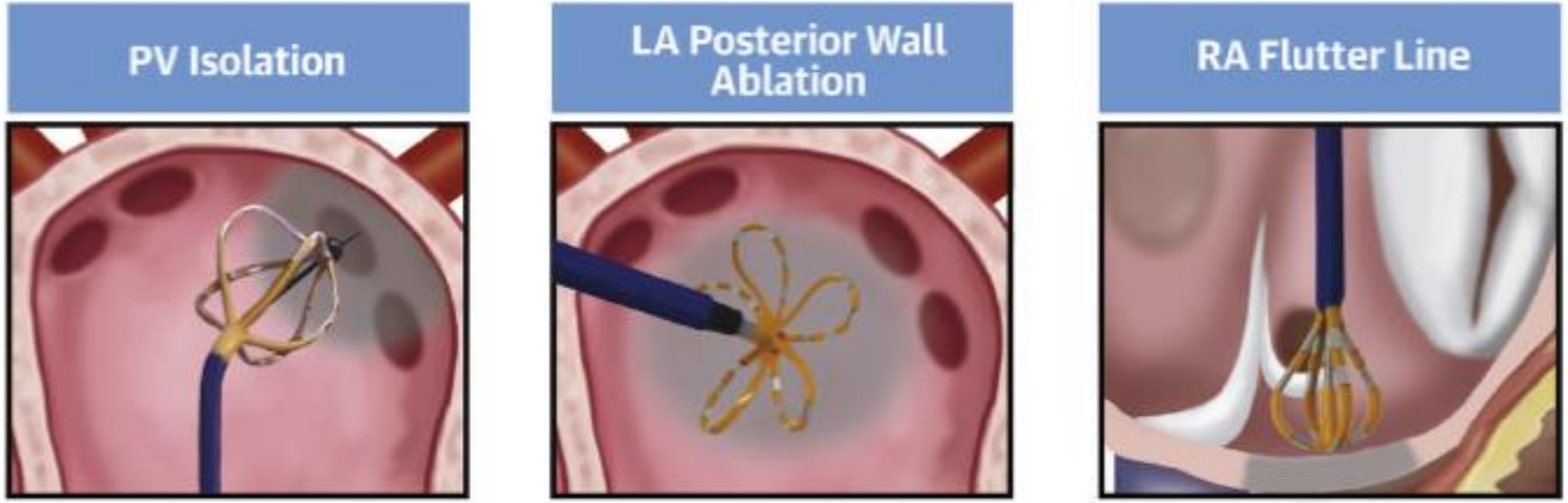
RESULTS In 25 patients, acute PVI (96 of 96 pulmonary veins [PVs]; mean ablation time: 22 min; interquartile range [IQR]: 15 to 29 min) and LAPW ablation (24 of 24 patients; median ablation time: 10 min; IQR: 6 to 13 min) were 100% acutely successful with the multispline PFA catheter alone. Using the focal PFA catheter, acute cavotricuspid isthmus block was achieved in 13 of 13 patients (median: 9 min; IQR: 6 to 12 min). The median total procedure time was 125 min (IQR: 108 to 166 min) (including a median of 28 min [IQR: 25 to 33 min] for voltage mapping), with a median of 16 min (IQR: 12 to 23 min) fluoroscopy. Post-procedure esophagogastroduodenoscopy and repeat cardiac computed tomography revealed no mucosal lesions or PV narrowing, respectively. Invasive remapping demonstrated durable isolation (defined by entrance block) in 82 of 85 PVs (96%) and 21 of 21 LAPWs (100%) treated with the pentaspline catheter. In 3 patients, there was localized scar regression of the LAPW ablation, albeit without conduction breakthrough.

CONCLUSIONS The unique safety profile of PFA potentiated efficient, safe, and durable PVI and LAPW ablation. This extends the potential role of PFA beyond paroxysmal to persistent forms of AF. (Pulsed Fields for Persistent Atrial Fibrillation [PersAFOne]; NCT04170621) (J Am Coll Cardiol 2020;76:1068-80) © 2020 The Authors. Published by Elsevier on behalf of the American College of Cardiology Foundation. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

FIGURE 1 PFA Catheters



CENTRAL ILLUSTRATION Pulsed Field Ablation for Persistent Atrial Fibrillation



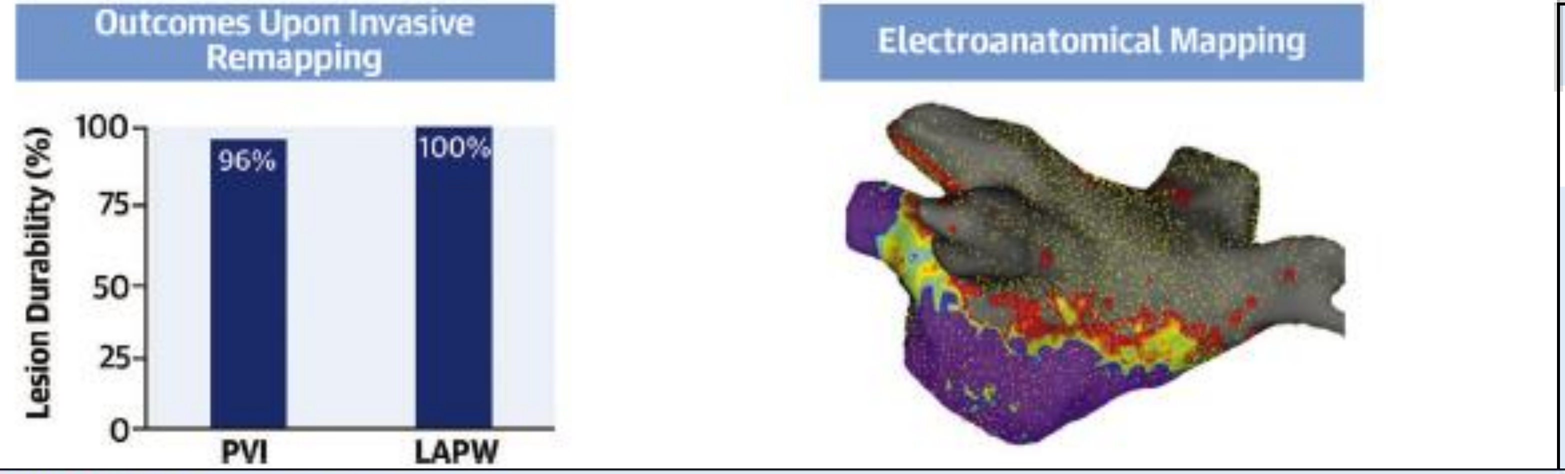


FIGURE 4 Durability of Posterior Wall PFA

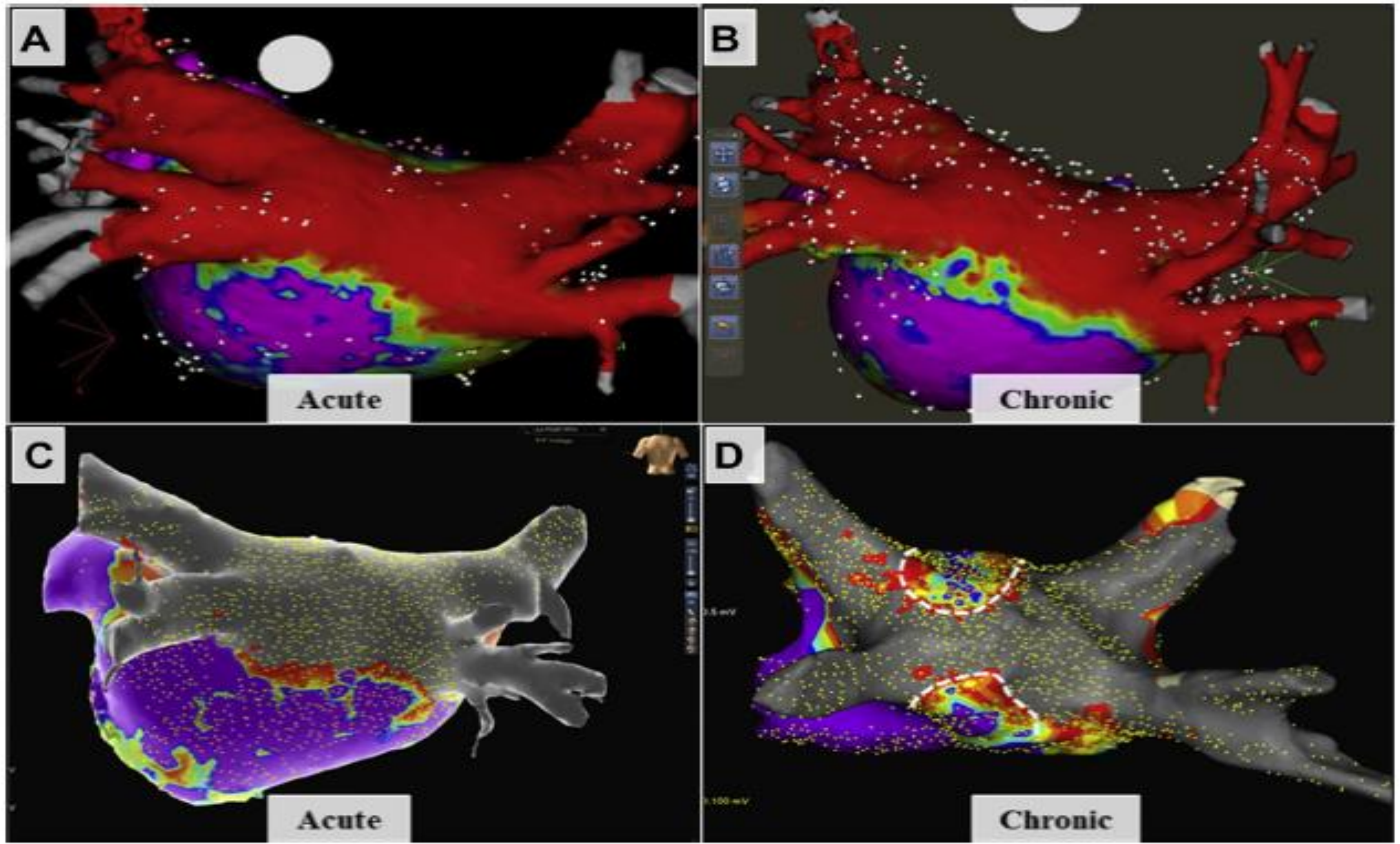


TABLE 3 Primary and Secondary Endpoints (N = 25)	
Primary feasibility endpoint (n = 25)	
Acute PV isolation	96/96 (100)
Secondary feasibility endpoints (n = 25)	
Chronic PV isolation (n = 22)	82/85 (96)
Chronic LAPW isolation (n = 22)	
Full cohort (n = 22)	21/22 (95)*
Treated using pentaspline catheter only (n = 21)	21/21 (100)*
Acute CTI block (n = 13)	13/13 (100)
Chronic CTI block (n = 12)	9/12 (75)
Primary safety endpoints	
Early onset (within 30 days of index procedure)	
Death	0/25 (0)
Myocardial infarction	0/25 (0)
Diaphragmatic paralysis	0/25 (0)
Stroke or TIA	0/25 (0)
Peripheral or organ thromboembolism	0/25 (0)
Cardiac tamponade/perforation	1/25 (4)†
Vascular access complications	0/25 (0)
Hospitalization (initial or prolonged)	0/25 (0)
Heart block	0/25 (0)
Pericarditis	0/25 (0)
Late onset (any time during follow-up)	
PV stenosis (>70% from baseline)	0/25 (0)
Atrioesophageal fistula	0/25 (0)

Reddy. J Am Coll Cardiol 2020;76:1068-80

Reddy. J Am Coll Cardiol 2020;76:1068-80

TABLE 4 Additional Safety Assessments

	Number of Patients With Assessment	Findings
Esophagogastroduodenoscopy	21	No esophageal lesions
Phrenic nerve		
Phrenic nerve assessment*	25	No paresis/palsy
Chest x-ray film at 3 months	16	No paresis/palsy
Pulmonary vein stenosis		
CT scanning at 3 months	14	No PV stenosis/narrowing

*By either observation of diaphragmatic motion with patient inspiration or by diaphragmatic capture with phrenic nerve pacing from within the superior vena cava.

CT = computed tomography.

TABLE 5 Dimensional Analysis of the PV Diameters

	n	Pre-RFA, mm	Post-RFA, mm	Change of PV Dimension, %	p Value*
LSPV					
Long axis	12	23.5 (21.6 to 25.3)	23.5 (20.7 to 26.2)	-1.7 (-6.6 to 3.0)	0.308
Short axis		16.2 (13.0 to 20.2)	15.2 (12.0 to 19.7)	-6.2 (-11.6 to 4.1)	0.158
LIPV					
Long axis	12	18.5 (16.7 to 20.7)	17.5 (14.5 to 19.4)	-5.6 (-11.6 to 2.9)	0.071
Short axis		12.9 (10.9 to 17.4)	12.5 (9.6 to 17.7)	0.6 (-5.2 to 6.8)	1.000
LCPV					
Long axis	2	32.2 (31.9 to n/a)	31.7 (30.4 to n/a)	-1.8 (-5.2 to n/a)	0.655
Short axis		19.8 (17.2 to n/a)	19.9 (18.1 to n/a)	1.1 (-2.8 to n/a)	0.655
RSPV					
Long axis	14	22.4 (19.0 to 24.0)	21.9 (18.1 to 23.9)	-1.6 (-8.4 to 2.6)	0.363
Short axis		20.7 (16.8 to 21.9)	19.0 (16.7 to 21.9)	-1.9 (-11.3 to 3.1)	0.198
RIPV					
Long axis	14	18.7 (16.8 to 22.9)	19.5 (15.5 to 20.9)	-5.2 (-11.4 to 2.3)	0.140
Short axis		16.6 (11.1 to 17.9)	16.3 (13.0 to 18.7)	2.2 (-2.5 to 9.8)	0.233

Clinical safety profile supported by real-world usage in over 40,000 patients

	RF & CRYO[1]	FARAPULSE PFA[3]
AE Fistula *Over 65% Mortality*[2]	2 to 10 in 10,000 pts	0
PV Stenosis	~1 in 250 pts	0
Permanent Phrenic Nerve Injury	~1 in 100 pts	0

***"You think about the complications the day before** you do the procedure **and the next 30 days you are still thinking about these patients.** Would there be damage to the esophagus?"*

Dr. Mattias Duytschaever, AZ Sint-Jan (Belgium)

1) Benali K, Khairy P, Hammache N, et al. Procedure-Related Complications of Catheter Ablation for Atrial Fibrillation. J Am Coll Cardiol. 2023 May, 81 (21) 2089–2099.https://doi.org/10.1016/j.jacc.2023.03.418
2) Tilz RR, Schmidt V, et al. A worldwide survey on incidence, management, and prognosis of oesophageal fistula formation following atrial fibrillation catheter ablation: the POTTER-AF study. European Heart Journal. July 2023.
3) Ekanem E, Reddy VY, et al. Multi-National Survey on the Safety of the post-approval clinical use of Pulsed Field Ablation in 17,000+ patients *(MANIFEST 17K)*. Presented at AHA 2023 on 11/12/23.

2) Tilz RR, Schmidt V, et al. A worldwide survey on incidence, management, and prognosis of oesophageal fistula formation following atrial fibrillation catheter ablation: the POTTER-AF study. European Heart Journal. July 2023.
3) Ekanem E, Reddy VY, et al. Multi-National Survey on the Safety of the post-approval clinical use of Pulsed Field Ablation in 17,000+ patients (MANIFEST 17K). Presented at AHA 2023 on 11/12/23.

Commercial Data for FARAWAVE Globally

- Efficacy rates match standard of care (80%)[1]
- Zero cases of AE Fistula, Phrenic Nerve Paralysis, or PV Stenosis in over 17k patients studied in MANIFEST 17K[2]
- < 1% adverse event rate[2]
- < 40-minute procedure times with low fluoro[3]

MANIFEST 17K Registry
106 EU centers
413 operators
17,642 patients

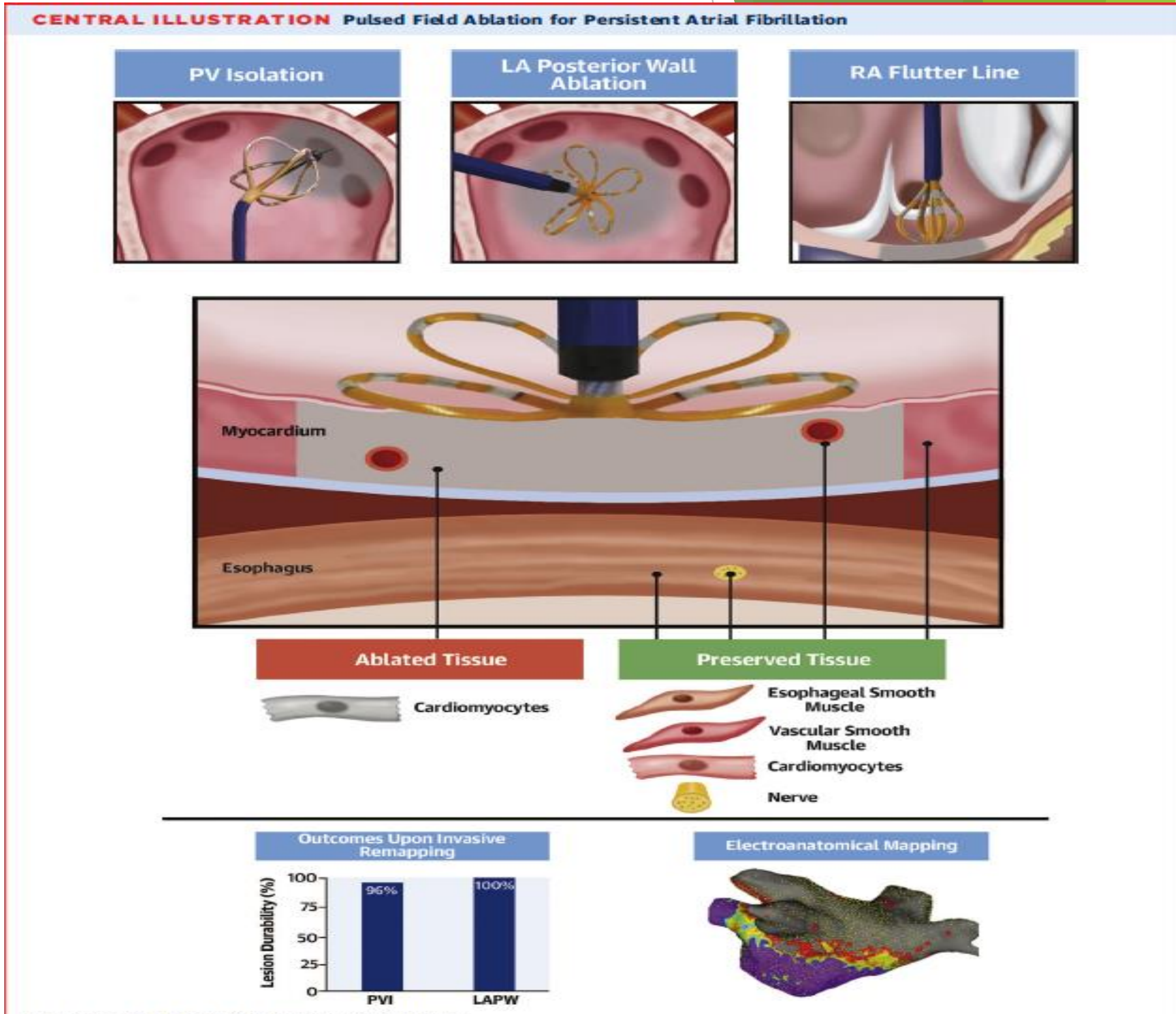
EU-PORIA Registry
7 EU centers
42 operators
1,233 patients

CCB 5S Study
Single center experience
6 operators, learning curve inclusive
191 patients treated

1. Schmidt B, Bordignon S, Neven K, et al. European real-world outcomes with Pulsed field ablation in patients with symptomatic atrial fibrillation: lessons from the multi-centre EU-PORIA registry. *Europace*. 2023. June 28.
2. Ekanem E, Reddy VY, et al. Multi-National Survey on the Safety of the post-approval clinical use of Pulsed Field Ablation in 17,000+ patients *(MANIFEST 17K)*. Presented at AHA 2023 on 11/12/23.
3. CCB 5S Study: average procedure times across 191 patients and 6 operators were 39 minutes; average fluoroscopy times across these cases averaged 9 minutes

Where Do We Go From Here?

- Non Pulmonary Vein Triggers
  - LAA
  - SVC
  - CS
- Ventricles
  - VT
  - PVCs
- Epicardial
  - VT
  - Afib



Reddy, V.Y. et al. J Am Coll Cardiol. 2020;76(9):1068-80.