Innovation in Electrophysiology: Arrhythmia Detection to Treatment and Management

Moderator:

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Center for Cardiovascular Health

Smart Devices in the Detection of Atrial Fibrillation:SHould we be Recommending a Wearable Device?

Venkata Susrut Pendyala, MD, FHRS

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- No Disclosures

INTRODUCTION

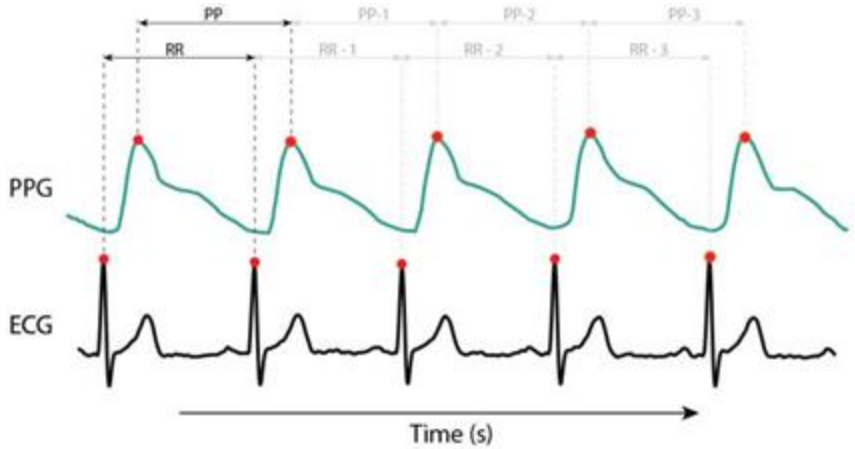
- AF is the most common sustained cardiac arrhythmia -increased risk of stroke, HF and reduced QOL.
- Early detection and Rx are critical in reducing complications.
- Traditional Dx tools(ECG, Holter,etc) require clinical settings.
- Smart devices may function as valuable tools for continuous, accessible and cost-effective AF detection.

Types of Smart Devices

- Smartwatches and Fitness Trackers(Apple Watch, Fitbit, Galaxy Watch, etc.)
- Patches(Kardia Mobile, Facelake FL10, Emay Portable ECG)

Detection Methods

- Photoplethysmography(PPG):Measures blood volume changes using optical sensors
- Electrocardiography(ECG): Direct recording of cardiac electrical activity
- Algorithmic Analysis and AI: Help differentiate AI from other arrhythmias



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WATCH-AF Trial

- **Objectives:** Comparison of diagnostic accuracy of AF detection by a smartwatch-based algorithm using PPG vs cardiologists' diagnosis by ECG.
- **Methods:** 2-center, case-control trial, PPG recording using smartwatch along with mobile ECG in 672 hospitalized subjects.
- **Results:** PPG algorithm - sensitivity of 93.7% (95% confidence interval [CI]: 89.8% to 96.4%), specificity of 98.2% (95% CI: 95.8% to 99.4%), and 96.1% accuracy (95% CI: 94.0% to 97.5%) to detect AF.
- **Conclusions:** Detection of AF using a commercially available smartwatch is in principle feasible, with very high diagnostic accuracy.

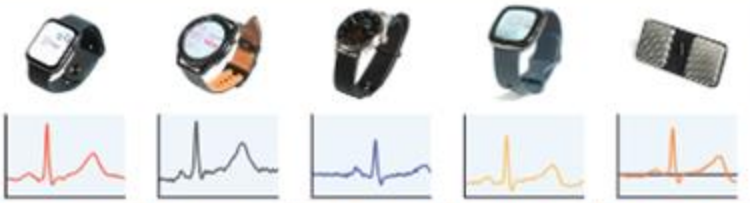
ACCURACY

- Apple Watch: Apple Heart Study - >400,000 participants without AF. People who received an irregular pulse notification had telemedicine visits with a clinician and received an ambulatory ECG monitor. Of the 2,064 patients with irregular pulse notifications, the positive predictive value (PPV) for AF was 84%.
- Fitbit: Fitbit Heart Study - >400,000 participants enrolled. Routine ambulatory ECG monitoring in patients with irregular rhythm notifications. Among 1,057 participants with an irregular heart rate notification and an analyzable confirmatory ambulatory ECG, the PPV of irregular rhythms for AF was 98.2%.

ACCURACY

BASEL Wearable Study:

CENTRAL ILLUSTRATION 5 Compared Devices



Manufacturer	Apple	Samsung	Withings	Fitbit	AliveCor
Version	Watch 6	Galaxy Watch3	ScanWatch	Sense	Kardia Mobile
Sensitivity (95% CI)	85% (72%-94%)	85% (72%-94%)	58% (42%-72%)	66% (51%-79%)	79% (64%-89%)
Specificity (95% CI)	75% (67%-83%)	75% (66%-82%)	75% (67%-83%)	79% (70%-86%)	69% (60%-77%)
Inconclusive tracings	18%	17%	24%	21%	26%
Preferred Choice*a	39%	12%	24%	15%	5%
Limit of HR interpretation*b	50-150 beats/min	50-120 beats/min	No information	50-120 beats/min	50-100 beats/min
Battery capacity*c	18 h*d	45 h*d	720 h*d	144 h*d	90 h / 2 y*e
Price*d	449	265	303	244	147

*a: Out of 165 analyzed patients, 10 patients were not able to decide between the available devices
*b: Information obtained from manufacturers website, 11/21
*c: Time with GPS disabled
*d: Information obtained on digitec.ch on 12.11.21, no discounts / special offers were included in the price, price includes tax / all prices in CHF
*e: 90 h net operating time, under regular use up to 2 years

Mannhart D, et al. J Am Coll Cardiol EP. 2023;9(2):232-242.

Comparison of analyzed devices with picture of used device and electrocardiogram as shown on the PDF produced by manufacturer's app. CHF = Swiss Franc; GPS = global positioning system; HR = heart rate.

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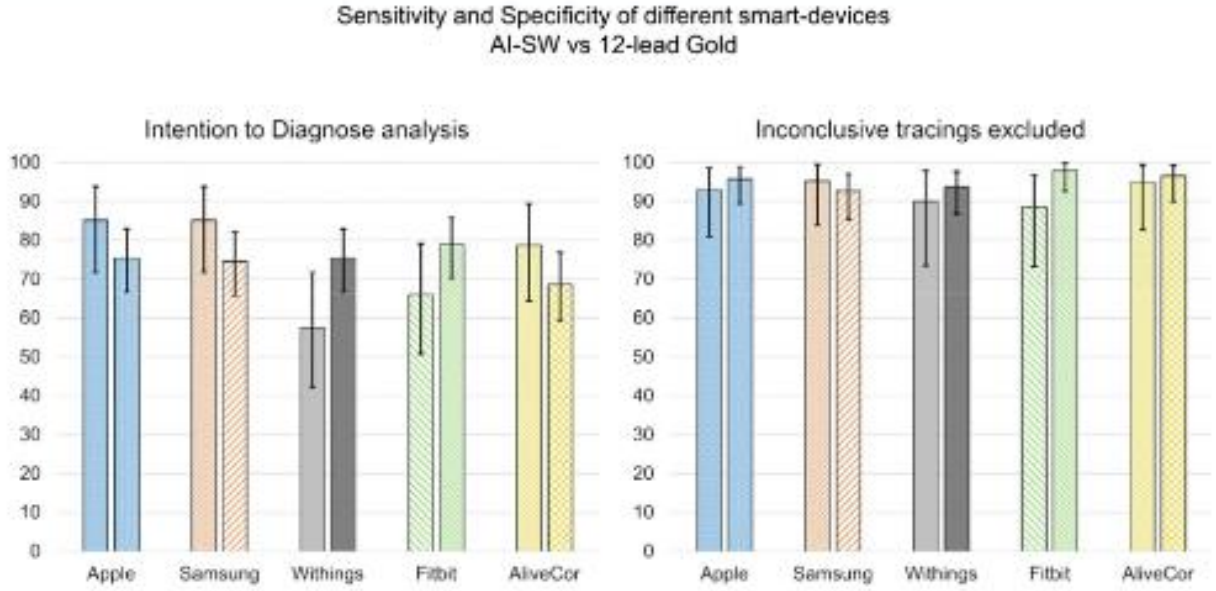
ACCURACY

FIGURE 1 **Device-Recorded Electrocardiogram AI Interpretation and 12-Lead Electrocardiogram Comparison**



Graphical illustration of sensitivity **(bar on left)** and specificity **(bar on right)** of devices and 95% CI. Only significant differences in sensitivity and specificity are reported through the intention to diagnose comparison of the device's sensitivity and specificity. *P* values were calculated using McNemar's chi-square test. 12 lead Gold = gold standard diagnosis by cardiologist from a 12 lead electrocardiogram; AI = artificial intelligence; SW = smartwatch/smart device single lead electrocardiogram.

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Artificial Intelligence

Artificial Intelligence

- **Artificial intelligence for direct-to-physician reporting of ambulatory electrocardiography**
- Beat-by-beat annotation of 14,606 individual ambulatory ECG recordings (mean duration = 14 ± 10 days) was performed by certified ECG technicians (n = 167) and an ensemble AI model, called DeepRhythmAI.

Artificial Intelligence

	Accuracy (95% CI), %		True-positive rate/sensitivity, % (95% CI)		True-negative rate/specificity, % (95%CI)		PPV, % (95% CI)		NPV, % (95% CI)		F1 score, %	
	AI	Technician	AI	Technician	AI	Technician	AI	Technician	AI	Technician	AI	Technician
Overall average critical arrhythmias	98.1 (97.9–98.2)	98.4 (98.1–98.5)	**98.6 (97.7–99.4)**	80.3 (77.3–83.3)	98.1 (97.9–98.2)	**99.2 (99.0–99.3)**	71.3 (68.5–73.9)	**82.7 (79.4–85.6)**	**99.9 (99.9–100)**	99.1 (98.9–99.2)	82.7 (80.9–84.5)	81.5 (79.0–83.6)
VT ≥ 10 s	98.2 (98.1–98.3)	99.5 (99.4–99.6)	**98.0 (94.8–100)**	64.4 (54.9–73.8)	98.2 (98.1–98.3)	**99.8 (99.7–99.8)**	27.2 (22.8–32.3)	**67.7 (58.2–76.6)**	**99.98 (99.96–100)**	99.7 (99.6–99.8)	42.6 (37.1–48.6)	**66.0 (57.4–73.2)**
AF ≥ 30 s	97.2 (96.5–97.9)	97.4 (96.6–98.0)	**99.1 (97.7–100)**	90.5 (86.8–94.0)	96.9 (96.2–97.7)	**98.4 (97.8–98.9)**	82.3 (77.8–86.8)	88.9 (84.7–92.6)	**99.9 (99.7–100)**	98.6 (98.0–99.2)	90.0 (87.1–92.7)	89.7 (86.7–92.3)
SVT ≥ 30 s	97.4 (97.1–97.9)	96.1 (95.5–96.7)	**97.3 (94.9–99.1)**	62.9 (56.6–69.3)	97.4 (97.0–97.9)	98.1 (97.7–98.4)	70.6 (65.9–75.7)	65.8 (59.3–72.2)	**99.8 (99.7–99.9)**	97.8 (97.2–98.3)	**81.8 (78.3–75.2)**	64.3 (58.7–69.8)
Asystole ≥ 3.5 s	98.5 (98.2–98.7)	**99.2 (99.0–99.4)**	**100 (100–100)**	80.6 (75.0–86.0)	98.4 (98.2–98.6)	**99.8 (99.7–99.9)**	65.7 (60.5–70.4)	**91.2 (87.8–95.6)**	**100 (100–100)**	99.4 (99.2–99.6)	79.2 (75.4–82.6)	85.8 (82.1–89.5)
Third-degree AV block	99.3 (99.2–99.4)	99.5 (99.3–99.6)	**96.4 (92.5–99.2)**	52.6 (44.0–61.6)	99.3 (99.2–99.4)	**99.9 (99.8–99.9)**	51.2 (44.6–48.2)	**76.3 (67.1–85.4)**	**100 (99.9–100)**	99.6 (99.5–99.7)	66.9 (61.2–72.8)	62.2 (53.9–70.0)

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Impact on Clinical Outcomes

- Unknown
- HEARTLINE Study : To assess if an Apple Watch with the IRN and ECG application, along with application-facilitated digital health engagement modules, improves time to AF diagnosis and cardiovascular outcomes in a real-world environment.26,485 participants. Primary end is time from randomization to clinical diagnosis of AF. Secondary endpoint are claims-based incidence of a 6-component composite cardiovascular/systemic embolism/mortality event, DOAC medication use and adherence, costs/health resource utilization, and frequency of hospitalizations for bleeding.

Utility in Monitoring AC

- REACT-AF: Multicenter prospective, randomized, open-label, blinded endpoint (PROBE design), controlled trial comparing the current standard of care of continuous DOAC use versus time-delimited (1 month) DOAC guided by an AF-sensing smart watch in participants with h/o non-permanent AF and low-to-moderate stroke risk (CHA_2DS_2-VASc score 1-4 for men, 2-4 for women). Follow-up time 3-5 years. 100 US centers targeting 2/3 academic and 1/3 private practices. Local PI: Nasir Shariff MD

Advantages

- Continuous / On-demand monitoring beyond the clinic
- Early Detection of asymptomatic or paroxysmal AF
- Possibility of integration with health systems

Limitations

- False Positives/Negatives due to artifacts or algorithmic limitations
- Regulatory Considerations
- Integration into clinical workflow can be challenging
- no guideline recommendations on what to do with information from consumer-grade devices
- Monitoring in patients with a low pretest probability of arrhythmias increases the false-positive rate.
- Physician burden increased

Thank You

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Atrial Fibrillation - New Catheter-Based Treatment Options

Ravi Kilaru, MD

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Atrial fibrillation and clinical consequences

- Stroke
- Tachycardia induced cardiomyopathy
- Congestive heart failure
- Disabling symptoms interfering with quality of life

Rhythm control

Anti arrhythmic drug therapy

Catheter AF ablation

Relationships Between Sinus Rhythm, Treatment, and Survival in the Atrial Fibrillation Follow-Up Investigation of Rhythm Management (AFFIRM) Study
Circulation 2004 Mar 30;109(12):1509-13.

Covariate	*P*	HR	HR: 99% Confidence Limits	
			Lower	Upper
*Per year of age.				
Age at enrollment*	<0.0001	1.06	1.04	1.08
Coronary artery disease	<0.0001	1.65	1.31	2.07
Congestive heart failure	<0.0001	1.83	1.45	2.32
Diabetes	<0.0001	1.56	1.22	2.00
Stroke or transient ischemic attack	<0.0001	1.54	1.17	2.05
Smoking	<0.0001	1.75	1.29	2.39
First episode of atrial fibrillation	0.0067	1.27	1.01	1.58
Sinus rhythm	<0.0001	0.54	0.42	0.70
Warfarin use	<0.0001	0.47	0.36	0.61
Digoxin use	<0.0001	1.50	1.18	1.89
Rhythm-control drug use	0.0005	1.41	1.10	1.83

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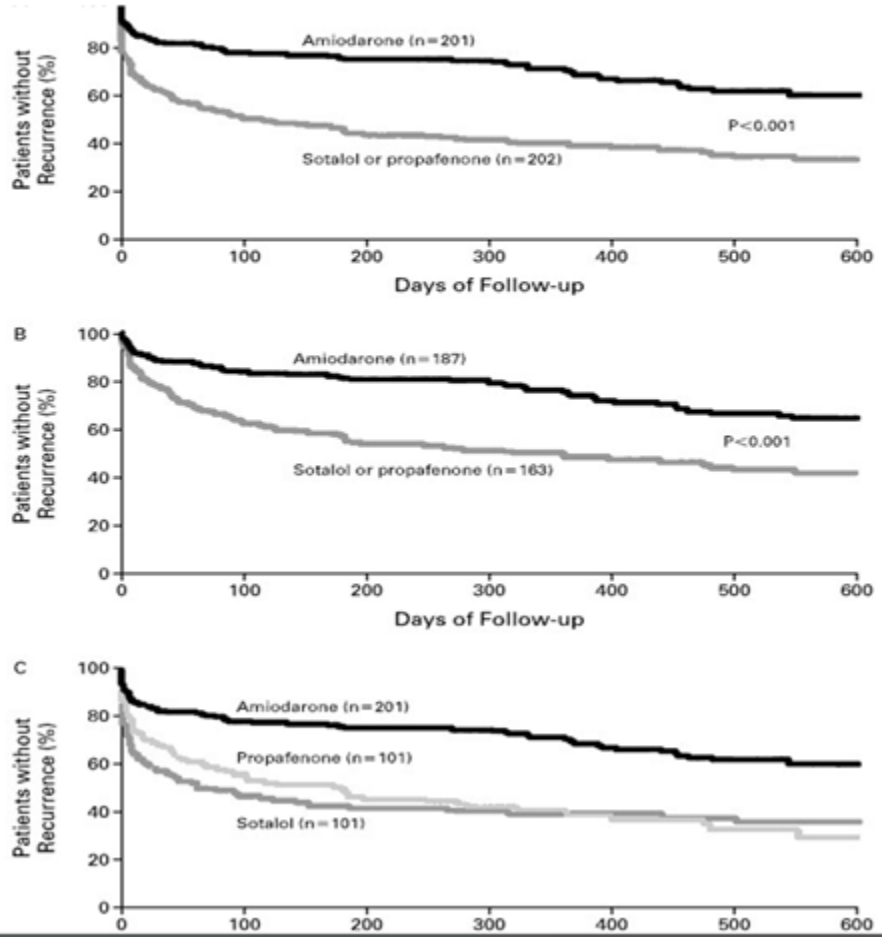
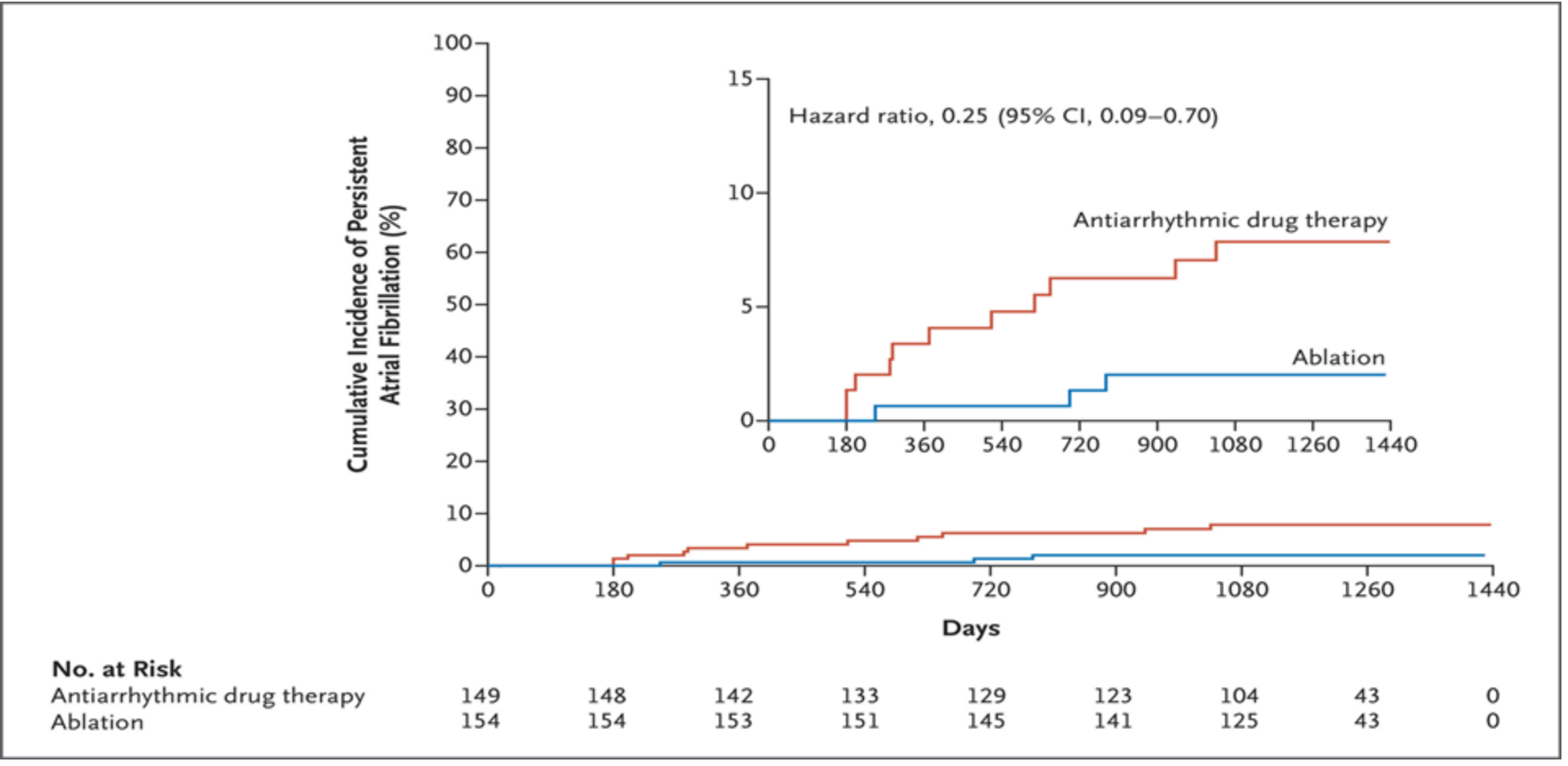
Antiarrhythmic medications include: Propafenone, Flecainide, Sotalol, Dofetilide, Amiodarone.

Amiodarone to Prevent Recurrence of Atrial Fibrillation

N Engl J Med 2000;342:913-920

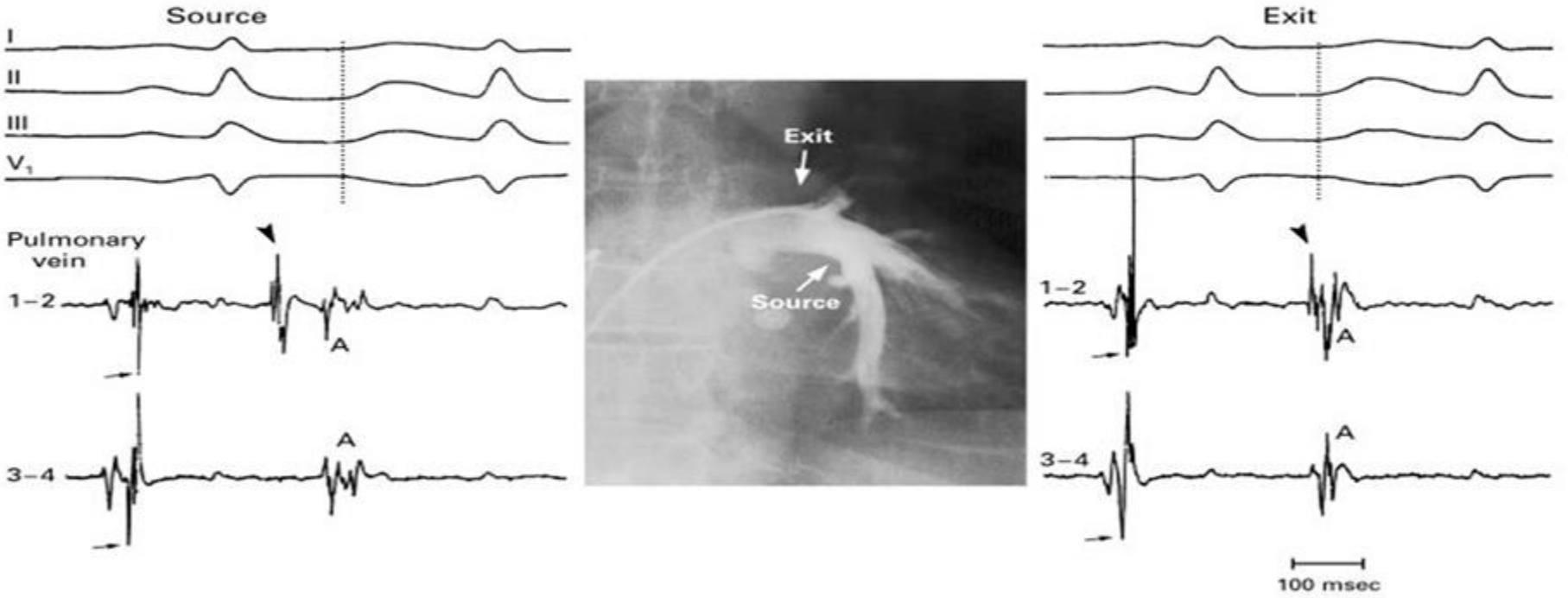


Progression of Atrial Fibrillation after Cryoablation or Drug Therapy
N Engl J Med 2023;388:105-116



Spontaneous Initiation of Atrial Fibrillation by Ectopic Beats Originating in the Pulmonary Veins

Michel Haïssaguerre, M.D. N Engl J Med 1998;339:659-666



Catheter AF ablation

- Radiofrequency ablation- High frequency alternating current generating heat at catheter tip electrode and tissue necrosis/death
- Cryoablation- Joule Thompson effect of Nitrous Oxide(N_2O) leading rapid tissue colling and ice crystal formation, leading to tissue death
- Endoscopic LASER Baloon ablation- Direct LASER heating of tissue- The only ablation technique that can be visualized directly
- Pulsed field ablation- The only non thermal ablation technique

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Thermal ablation techniques

- Include Radiofrequency ablation, Cryoablation and LASER ablation
- All these techniques cause tissue injury/ablation by tissue heating/freezing
- Collateral damage to surrounding tissue
- Atrioesophageal fistula (AEF)
- Phrenic nerve injury
- Pulmonary vein stenosis
- Cardiac perforation

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Pulsed Field ablation

- The only non thermal ablation technique
- High voltage and short duration DC electrical pulses delivered
- Cell membrane more permeable to extracellular ions and molecules- Electroporation
- Oxidation of cell membranes
- Loss of ATP and disruption of intracellular electrochemical gradient
- Loss of cellular homeostasis
- Extracellular calcium enters cell, leading apoptosis and death

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F. Guo et al., Advances in the Ablation for Arrhythmia Treatment. ***Cardiovascular Innovations and Applications*** Volume 8, Issue 1

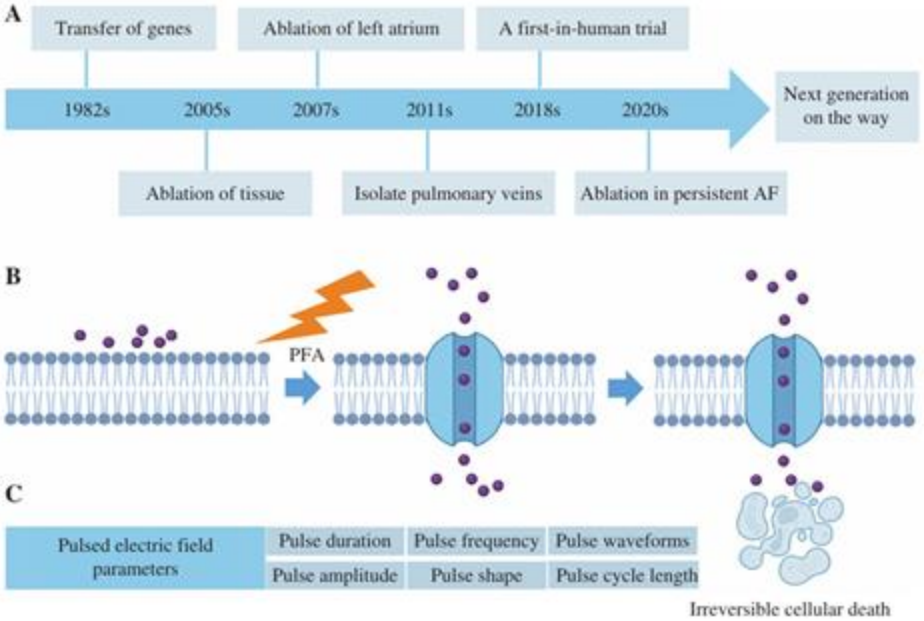

Figure 1 History and Mechanism of Pulsed Field Ablation (PFA).
(A) Milestones in the development of PFA. (B) Molecular simulation of pore formation with PFA. The cellular membrane is impermeable to ions and water, thereby enabling the establishment of a controlled intracellular environment. PFA with high energy levels induces the formation of pores in the cell membrane, thus allowing ions to freely enter the cells. Cell death results from the formation of several permanent and frequently coalescent pores with the application of sufficient energy. (C) PFA parameters influencing the observed effects on tissues.

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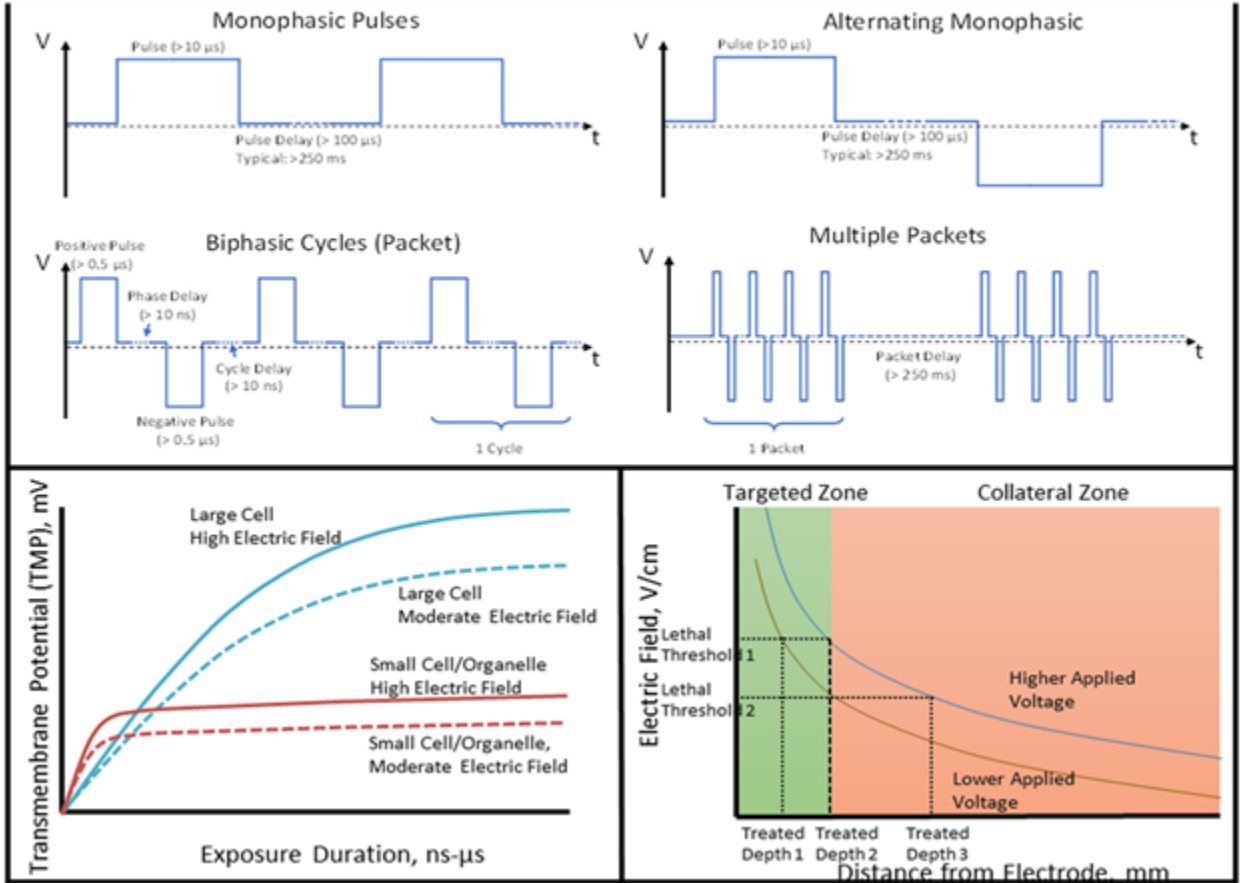
Biophysics of Pulsed field ablation

Primer on Pulsed Electrical Field Ablation: Understanding the Benefits and Limitations
Circulation: Arrhythmia and Electrophysiology Volume 14, Number 9



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Parameter	Parameter Change	Lesion Size	Muscle Contraction	Temperature Rise	Treatment Delivery Time	Gaseous Emboli Risk	Electrical Arcing Risk	Electrode Breakdown Risk	Barotrauma Risk
Voltage	↑	↑	↑	↑	=	↑	↑	↑	↑
Waveform	Monophasic	↑	↑	=	=	↑	↑	↑	↑
Fundamental Frequency	↑	↓	↓	=	=	↓	=	=	↓
Packet Duration	↑	↑	↑	↑	=	↑	↑	↑	↑
Number of Packets	↑	↑	=	↑	↑	=	=	=	=
Packet Delivery Rate	↑	=	=	↑	↓	=	=	=	=

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Why Pulsed field ablation advantageous over thermal ablation?

- Myocardium is the most sensitive tissue for pulse field ablation
- Next most sensitive cell is RBC
- Neurons and smooth muscle cells are less sensitive
- Reasons for Cardioselectivity of pulse field ablation
- Higher rate of metabolism
- More ion channels
- Larger cell diameter
- Distance from Pulse field electrodes

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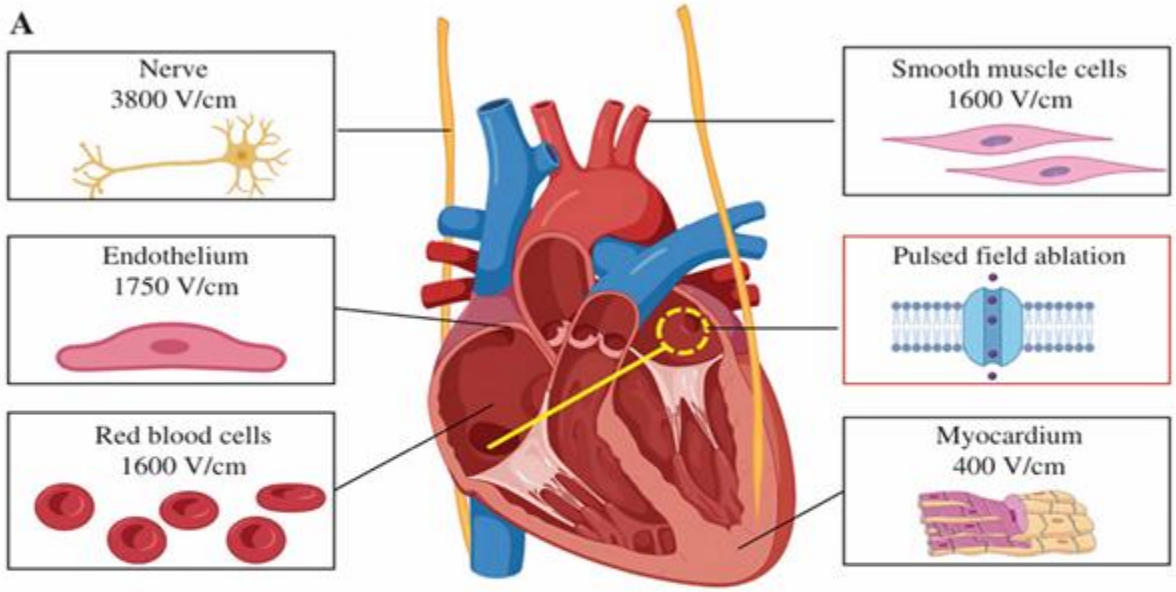
A



B

Pulsed electric field variables	Voltage	Phase (monophasic-biphasic)	Pulse frequency
	Pulse shape	Number of pulses	Catheter electrode

Figure 2 Pulsed Field Ablation (PFA) Thresholds for Various Tissues.
(A) PFA has the potential to specifically target myocardial tissue and does not affect surrounding tissues or cells [23]. (B) PFA parameters influencing the observed effects on tissue.

Catheter-Based Electroporation: A Novel Technique for Catheter Ablation of Cardiac Arrhythmias JACC: Clinical Electrophysiology
Volume 9, Issue 9, September 2023, Pages 2008-2023

TABLE 1 Electroporation Thresholds of Key Organs in Proximity of Atrial Tissue

Organ	Electroporation Threshold, V/cm
Cardiomyocytes	400
Esophagus	1,200
Pulmonary vein	1,600
Phrenic nerve	1,750

JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY VOL. 74, NO. 3, 2019

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) © 2019 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/).

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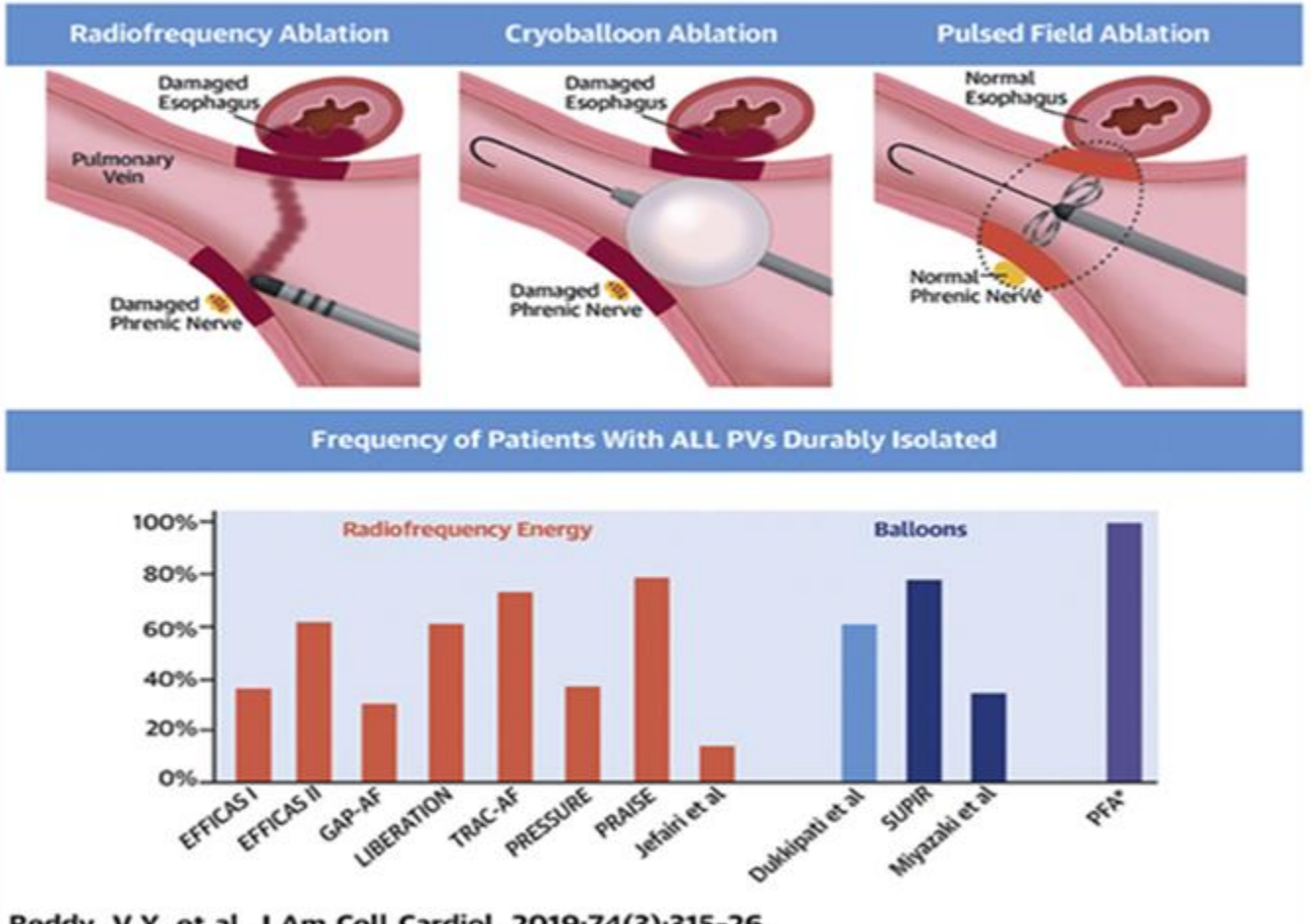
CENTRAL ILLUSTRATION: Pulmonary Vein Isolation for Atrial Fibrillation by Pulsed Field Ablation



Reddy, V.Y. et al. J Am Coll Cardiol. 2019;74(3):315-26.

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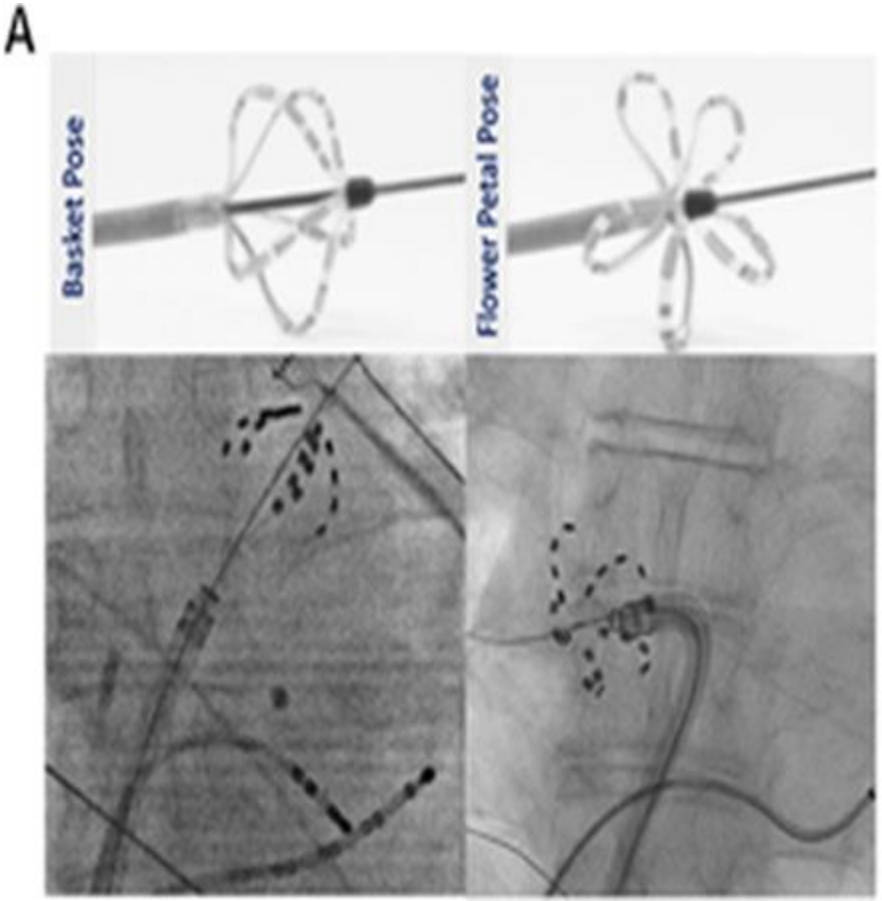
Vivek Y. Reddy et al. *JACC* 2019; 74:315-326.



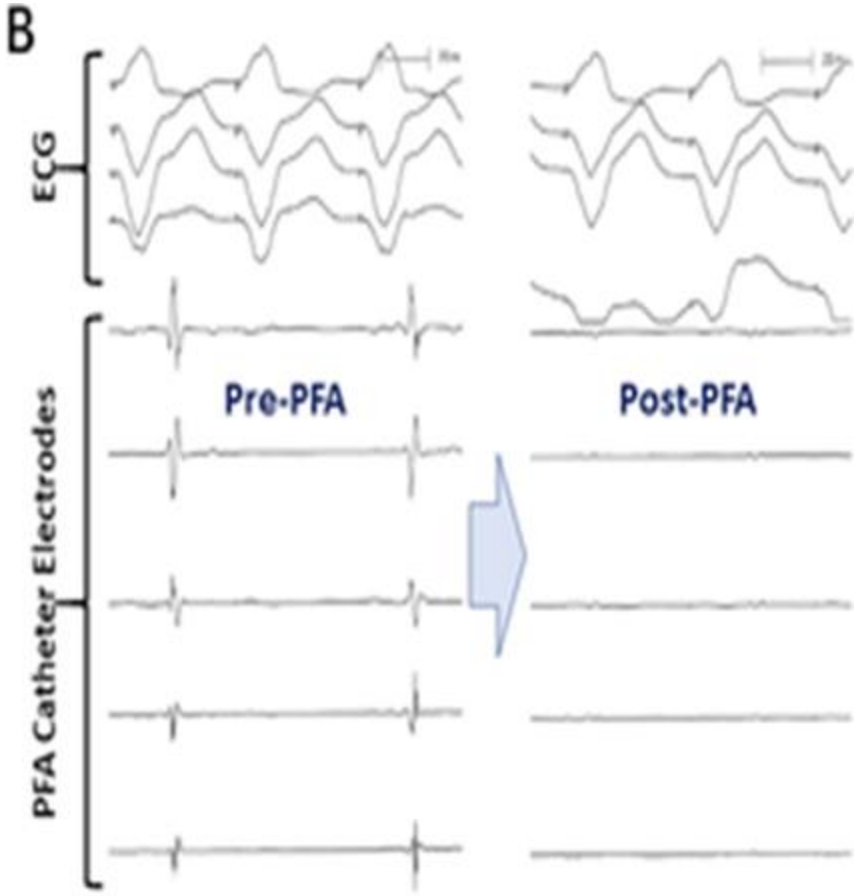
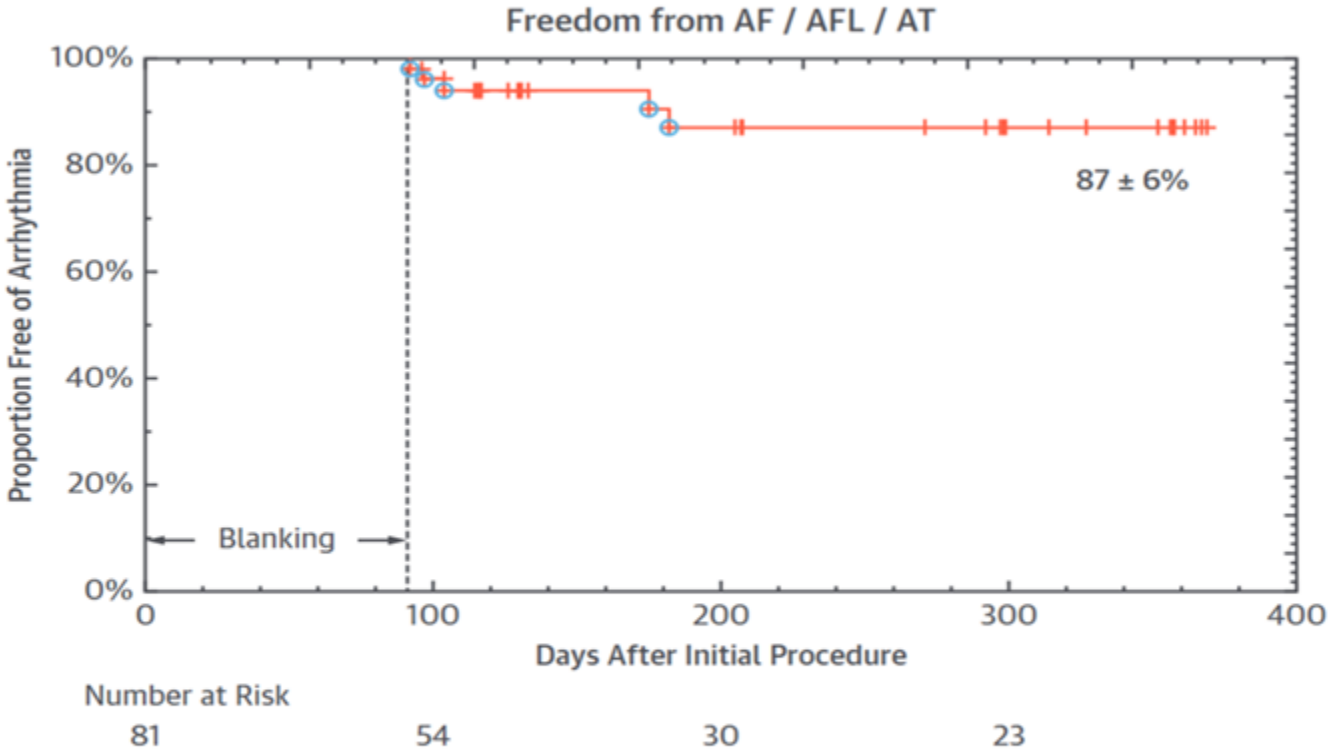


FIGURE 4 **Kaplan-Meier Analysis of Freedom From Atrial Arrhythmias**



Not including the 3-month blanking period, shown is the freedom for atrial arrhythmias, including any atrial fibrillation (AF), atrial flutter (AFL), or atrial tachycardia (AT) episode exceeding 30 s.

TABLE 3 Primary Endpoints

	IMPULSE (n = 40)	PEFCAT (n = 41)	Total Cohort (N = 81)
Primary feasibility			
Acute PV isolation	40 (100.0)	41 (100.0)	81 (100.0)
Primary safety			
Total	1 (2.5)	0 (0.0)	1 (1.2)
Death	0 (0.0)	0 (0.0)	0 (0.0)
Myocardial infarction	0 (0.0)	0 (0.0)	0 (0.0)
Diaphragmatic paralysis	0 (0.0)	0 (0.0)	0 (0.0)
Stroke or TIA	0 (0.0)	0 (0.0)	0 (0.0)
Other thromboembolism	0 (0.0)	0 (0.0)	0 (0.0)
Cardiac perforation or tamponade	1 (2.5)	0 (0.0)	1 (1.2)
Vascular complications	0 (0.0)	0 (0.0)	0 (0.0)
Prolonged or repeat hospitalization	0 (0.0)	0 (0.0)	0 (0.0)
Heart block	0 (0.0)	0 (0.0)	0 (0.0)
PV stenosis >70%	0 (0.0)	0 (0.0)	0 (0.0)
Atrioesophageal fistula	0 (0.0)	0 (0.0)	0 (0.0)
Pericarditis requiring intervention	0 (0.0)	0 (0.0)	0 (0.0)
Pneumothorax	0 (0.0)	0 (0.0)	0 (0.0)
Pulmonary edema	0 (0.0)	0 (0.0)	0 (0.0)

Values are n (%).

PV = pulmonary vein, TIA = transient ischemic attack.

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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

Values are n. *Either by observation of diaphragmatic motion with patient inspiration, or by diaphragmatic capture with phrenic nerve pacing from within the superior vena cava.

CMR = cardiac magnetic resonance; CT = computed tomography; DWI = diffusion weighted imaging; EAM = electroanatomic mapping; FLAIR = fluid-attenuated inversion recovery; MRI = magnetic resonance imaging; PV = pulmonary vein.

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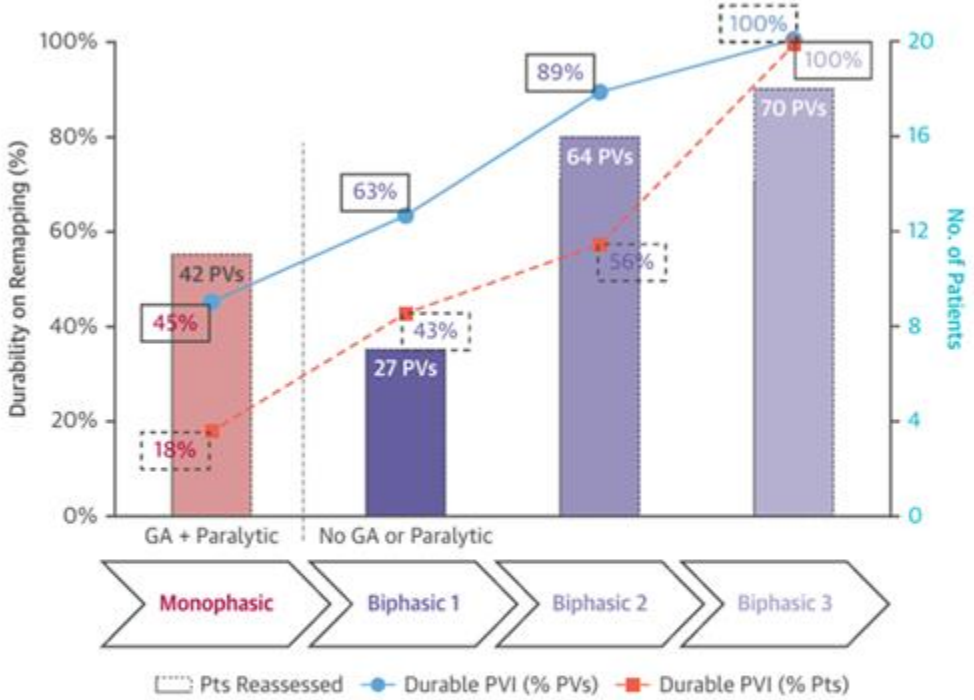
FIGURE 3 **Durability of PV Isolation With Successive Waveforms**



The bar graph demonstrates the durable pulmonary vein (PV) isolation rates during invasive electrophysiological remapping procedures. For each of the successive waveform protocols for which remapping data was obtained, shown are: 1) the number of patients (Pts) who presented for the remapping procedures **(bars)**; 2) the percentage of PVs that remained durably electrically isolated **(solid line)**; and 3) the percentage of patients with all PVs durably electrically isolated **(dashed line)**.

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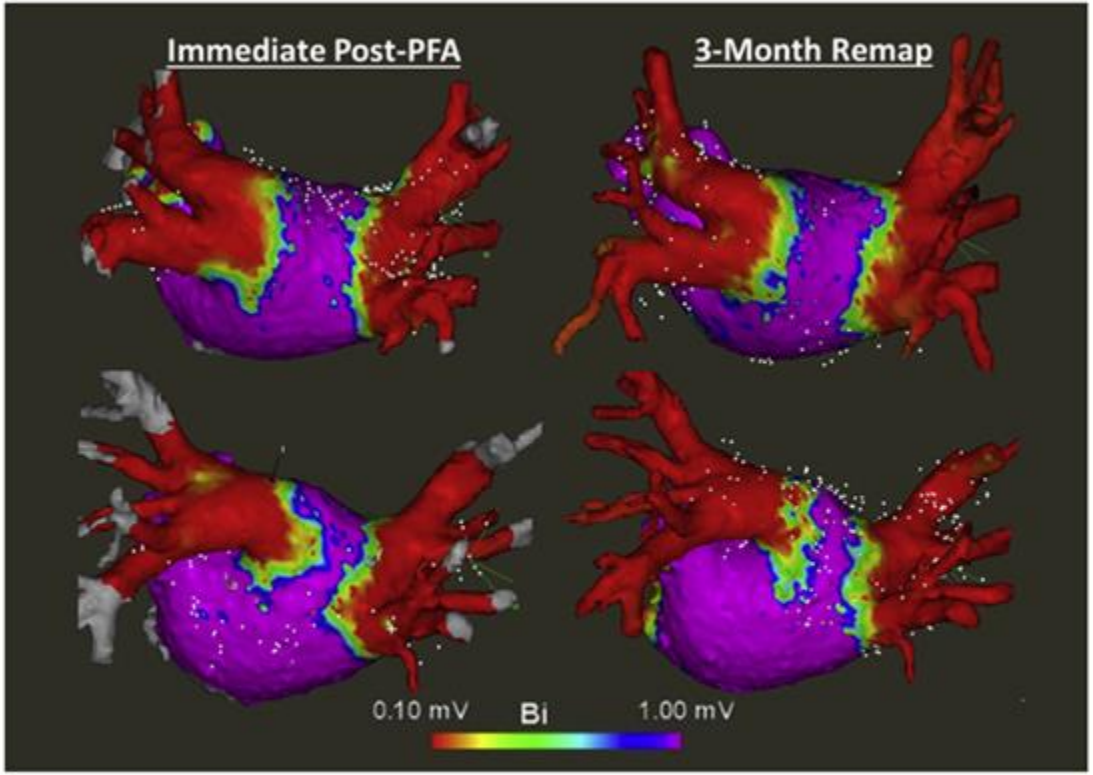
FIGURE 2 Electroanatomic Voltage Mapping to Assess PV Isolation Level



Voltage mapping was performed both at the end of the index PFA procedure **(left)** and at the time of the 3-month remapping procedure **(right)**. The color scale of the bipolar voltage values is shown at the **bottom**: values above 1 mV are considered normal atrial tissue and depicted in **purple**. Abbreviations as in Figure 1.

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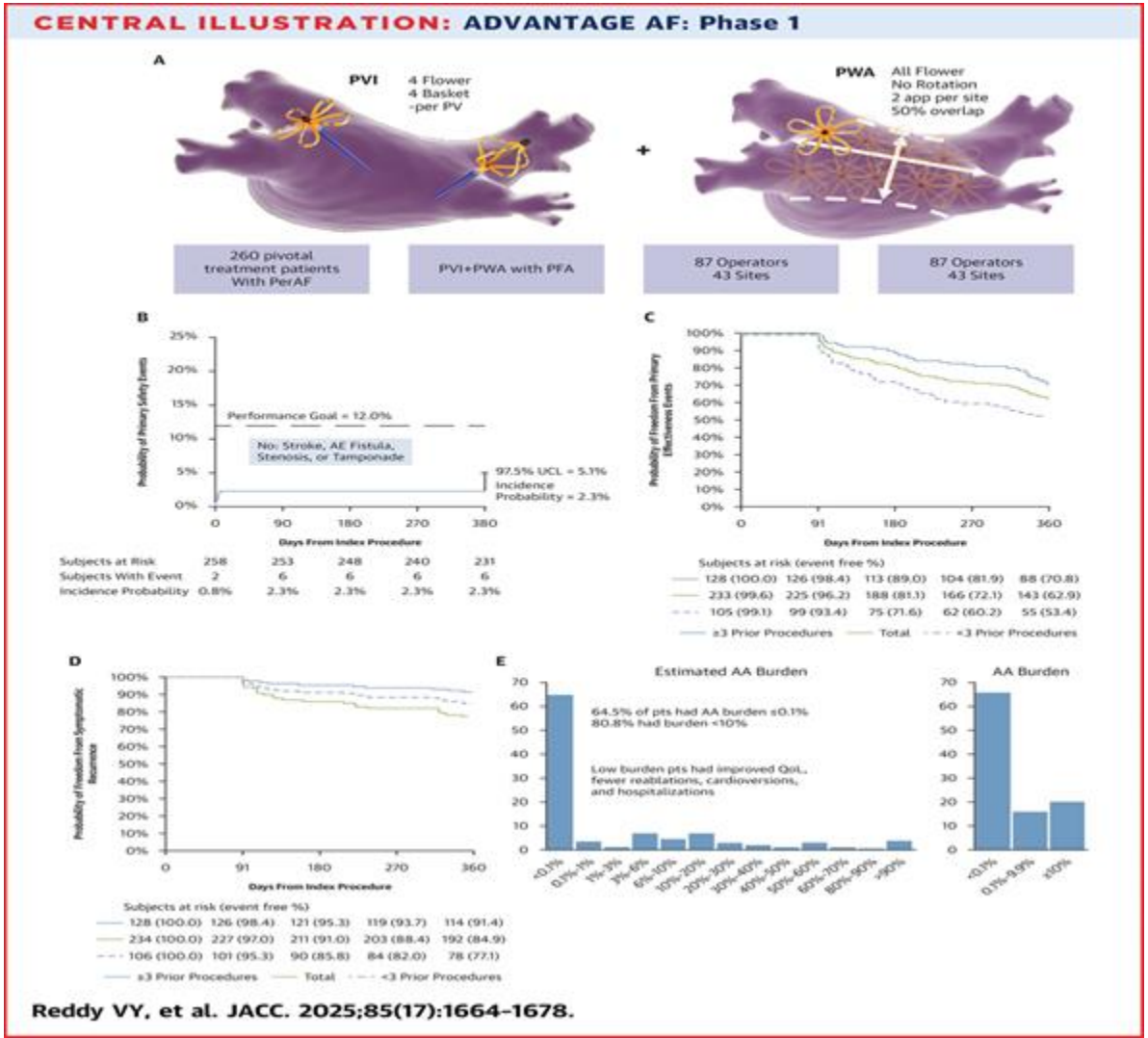
Pulsed Field Ablation for Persistent Atrial Fibrillation: 1-Year Results of ADVANTAGE AF



Reddy VY, et al. JACC. 2025;85(17):1664-1678.

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Pulsed Field or Conventional Thermal Ablation for Paroxysmal Atrial Fibrillation

November 1, 2023

DOI: 10.1056/NEJMdo007261

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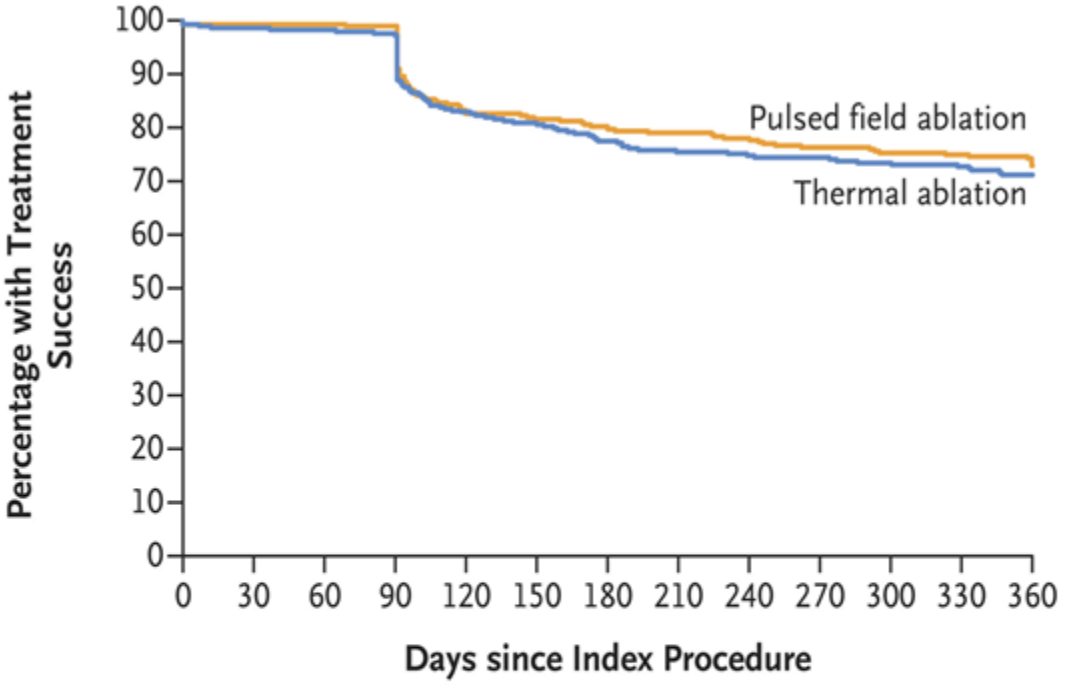


No. at Risk					
Pulsed field ablation	301	298	238	228	176
Thermal ablation	296	292	228	219	150

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

Pulsed-Field Ablation of Atrial Flutter: Insights From a Large Volume U.S. Center
Joe Demian et al. *J Am Coll Cardiol EP* 2025;

CENTRAL ILLUSTRATION: Outcomes of Atrial Flutter Ablation Using Pulsed-Field Ablation

Pulsed-Field Ablation of Atrial Flutter: Safety and Efficacy Across Different Subtrates

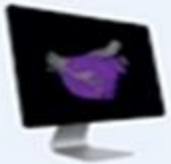
Population

311 Patients

368 Atrial Flutters

Flutter Subtypes

Procedure



Main Ablation Strategy
Pulsed-field ablation (All Flutters)

Adjunctive Radiofrequency Ablation
13 Flutters

1 CTI-dependent	12 Perimitral

ICE Guidance

Vasopressors

Nitroglycerin

Outcomes

Acute Procedural Success
96.5%

CTI-dependent 99.5%	Perimitral 82.9%

Adverse Events
1%

Major **0.64%**
Minor **0.32%**
Death **0**

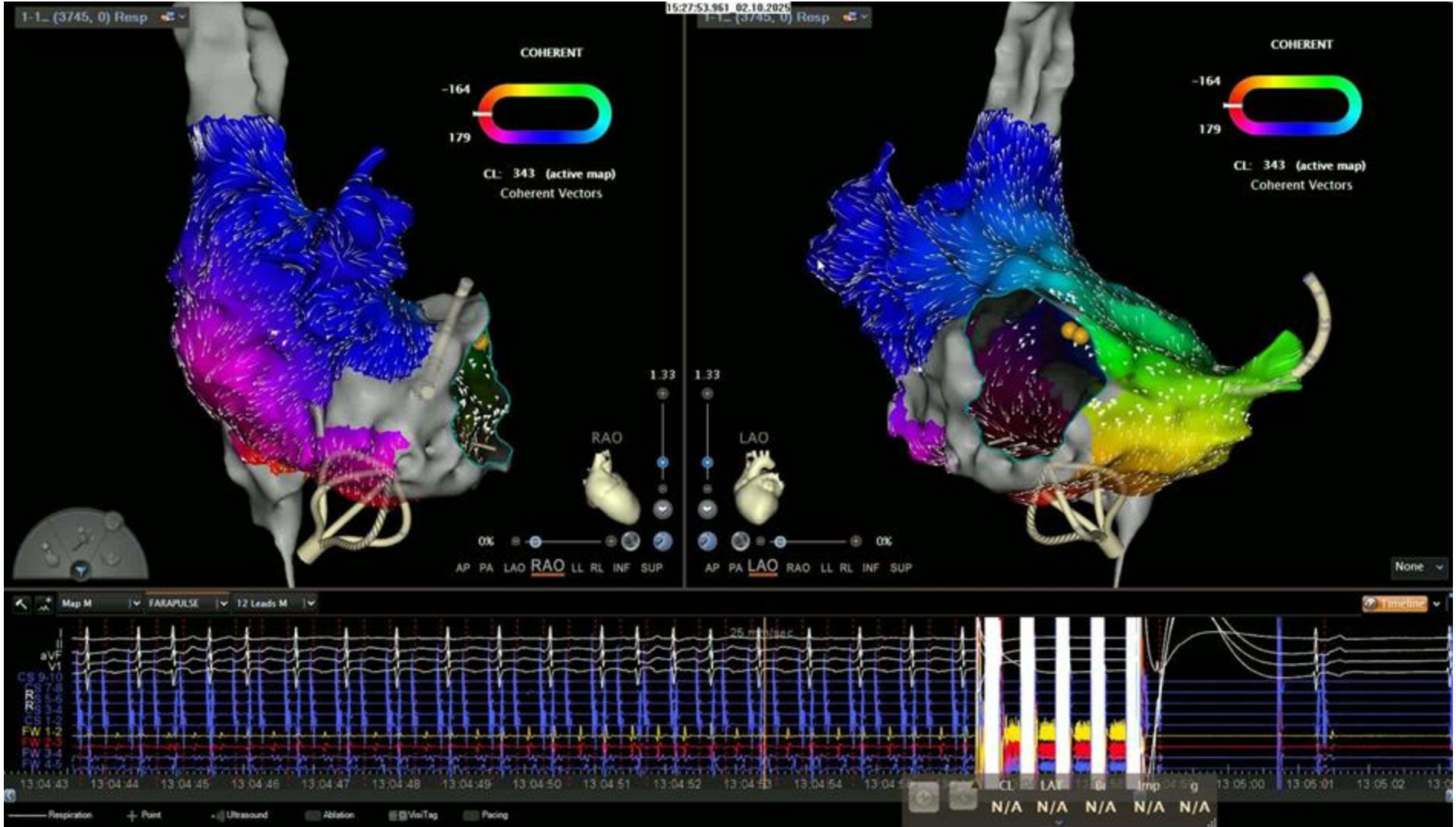
Follow-up
175 days
(IQR: 132-244)

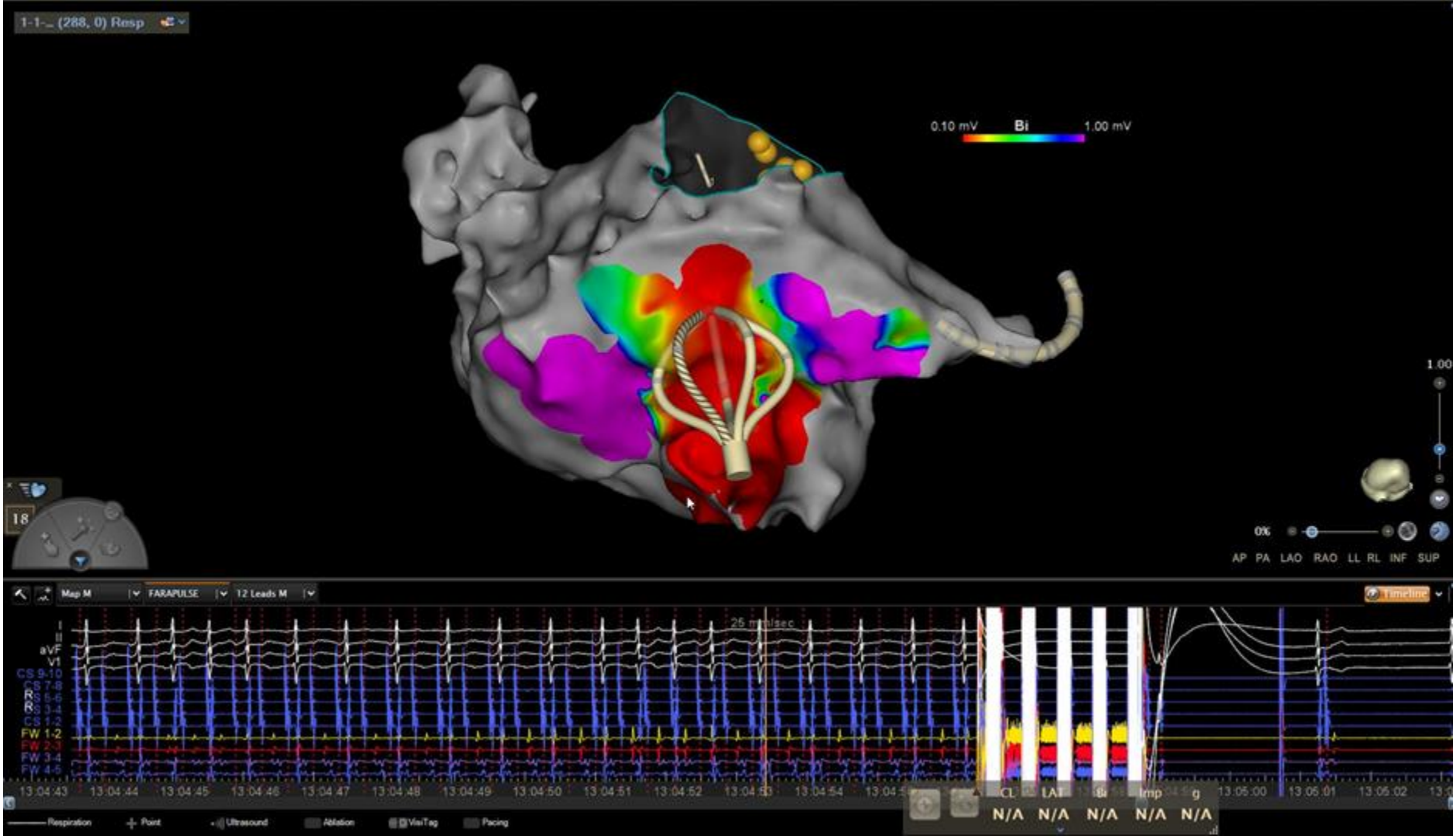
Recurrence
3.9%

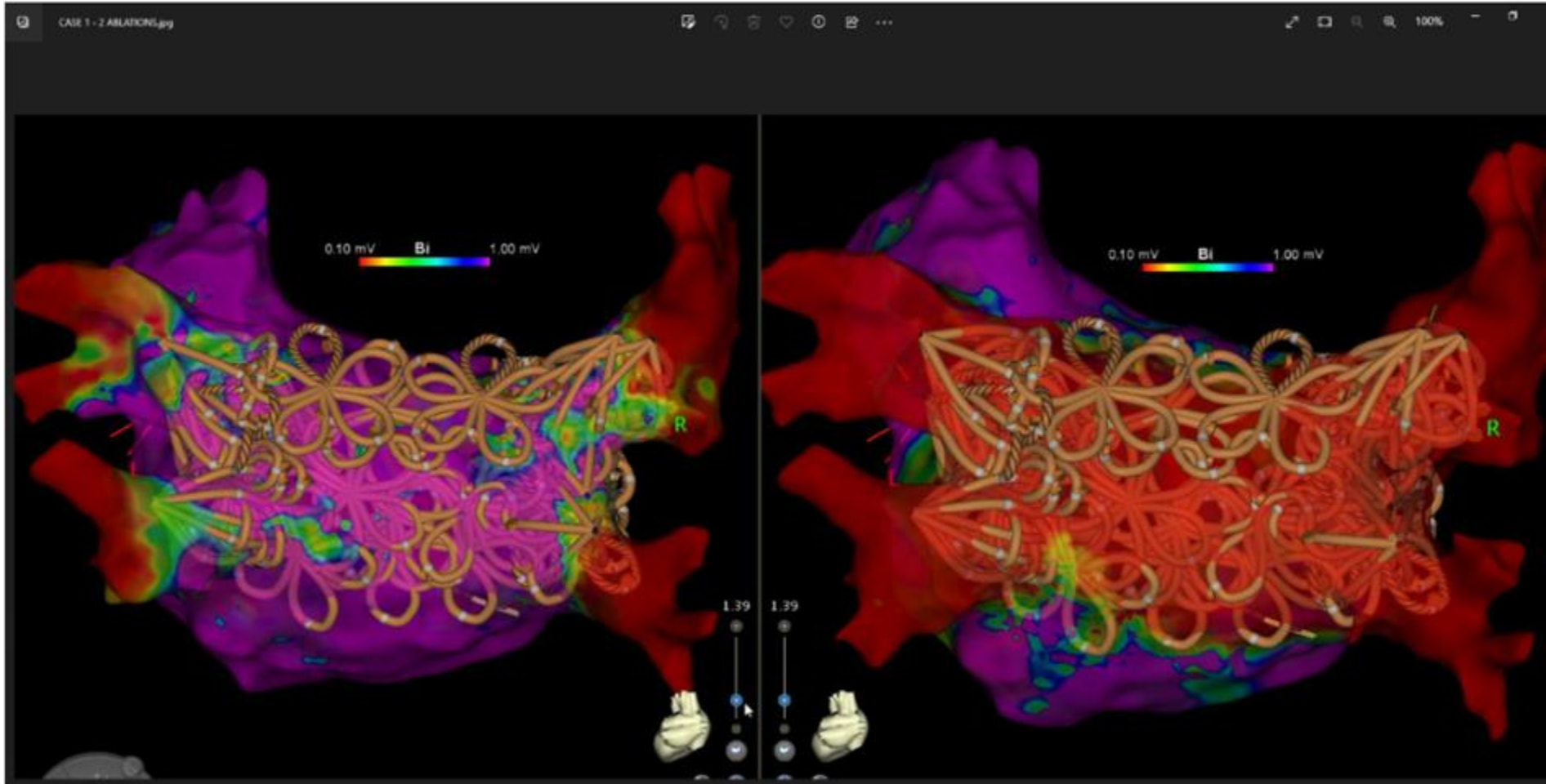
CTI-dependent **1.5%**
Perimitral **10%**

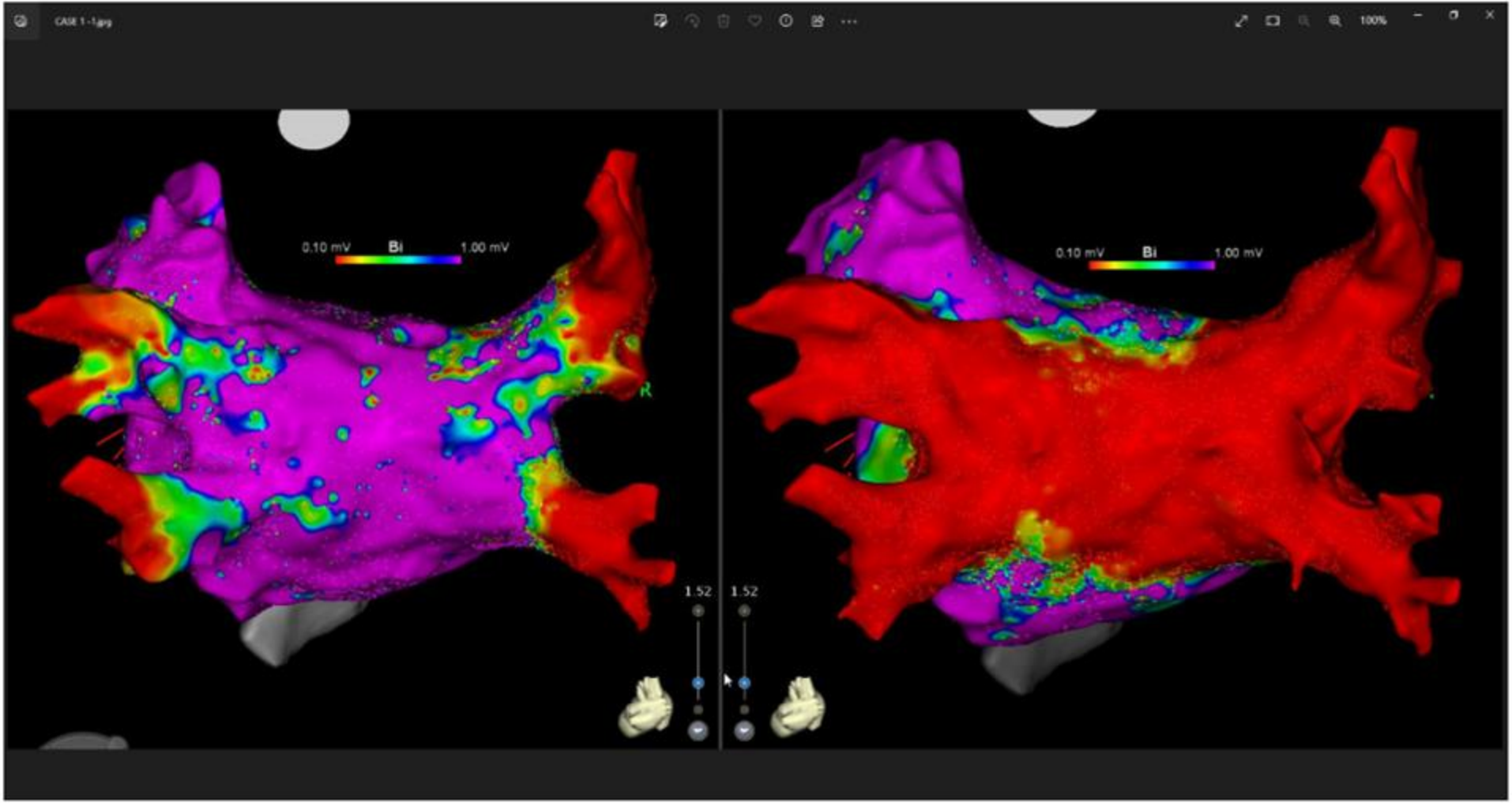
PFA is a safe and effective modality for AFL ablation, achieving high acute success rates and favorable safety outcomes.

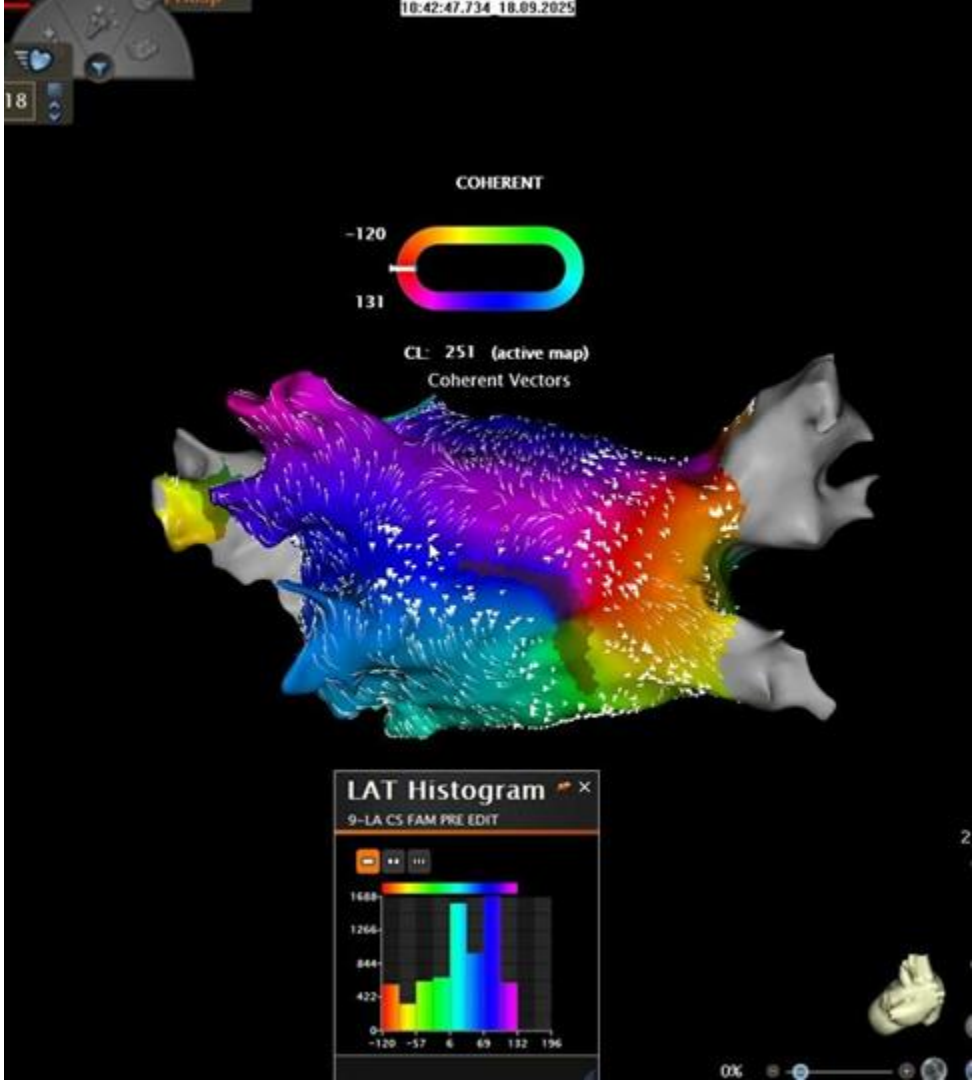
Demian J, et al. JACC Clin Electrophysiol. 2025;10.1016/j.jacep.2025.06.036


1-1_ (3745, 0) Resp
15:27:53.961 02.10.2025
COHERENT
-164
179
CL: 343 (active map)
Coherent Vectors
1.33
RAO
0%
AP PA LAO RAO LL RL INF SUP
1-1_ (3745, 0) Resp
COHERENT
-164
179
CL: 343 (active map)
Coherent Vectors
1.33
LAO
0%
AP PA LAO RAO LL RL INF SUP
None
Map M
FARAPULSE
12 Leads M
Timeline
25 mm/sec
I
II
aVF
V1
CS 9-10
CS 7-8
RS 5-6
RS 3-4
CS 1-2
FW 1-2
FW 3-4
FW 4-5
13:04:43
13:04:44
13:04:45
13:04:46
13:04:47
13:04:48
13:04:49
13:04:50
13:04:51
13:04:52
13:04:53
13:04:54
13:05:00
13:05:01
13:05:02
CL
LAT
Imp
N/A N/A N/A N/A N/A
Respiration
Point
Ultrasound
Ablation
VisiTag
Pacing


1-1-_ (288, 0) Resp
0.10 mV
Bi
1.00 mV
18
0%
AP PA LAO RAO LL RL INF SUP
Map M
FARAPULSE
12 Leads M
Timeline
25 msec
I
II
aVF
V1
CS 9-10
CS 7-8
RS 5-6
RS 3-4
CS 1-2
FW 1-2
FW 2-3
FW 3-4
FW 4-5
13:04:43
13:04:44
13:04:45
13:04:46
13:04:47
13:04:48
13:04:49
13:04:50
13:04:51
13:04:52
13:04:53
13:04:54
13:05:00
13:05:01
13:05:02
CL
LAT
Imp
N/A
N/A
N/A
N/A
N/A
Respiration
Point
Ultrasound
Ablation
VisiTag
Pacing


CASE 1 - 2 ABLATIONS.jpg
100%
0.10 mV
BI
1.00 mV
R
1.39
1.39
0.10 mV
BI
1.00 mV
R


CASE 1 -1.jpg
100%
0.10 mV
Bi
1.00 mV
R
1.52
1.52
0.10 mV
Bi
1.00 mV



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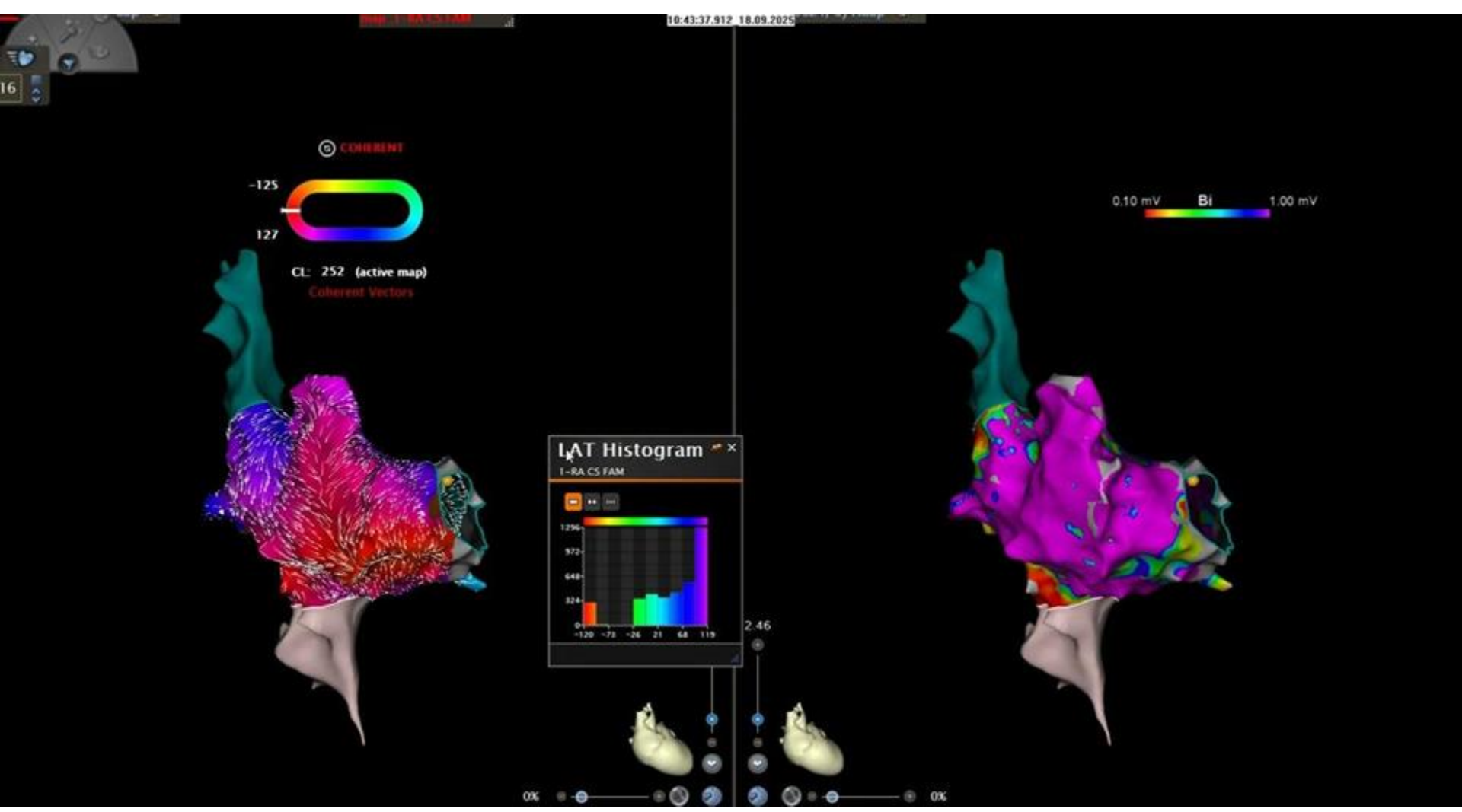
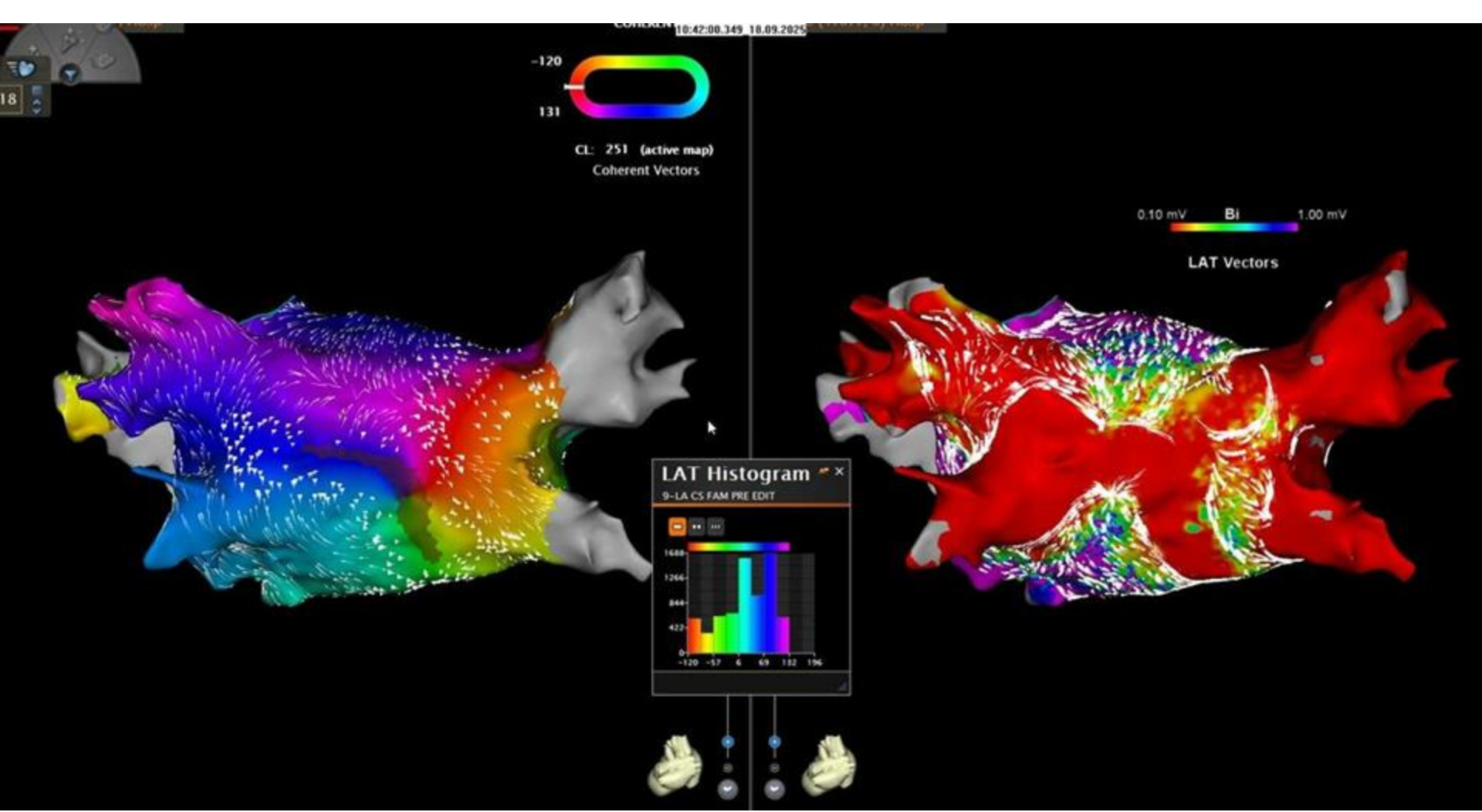
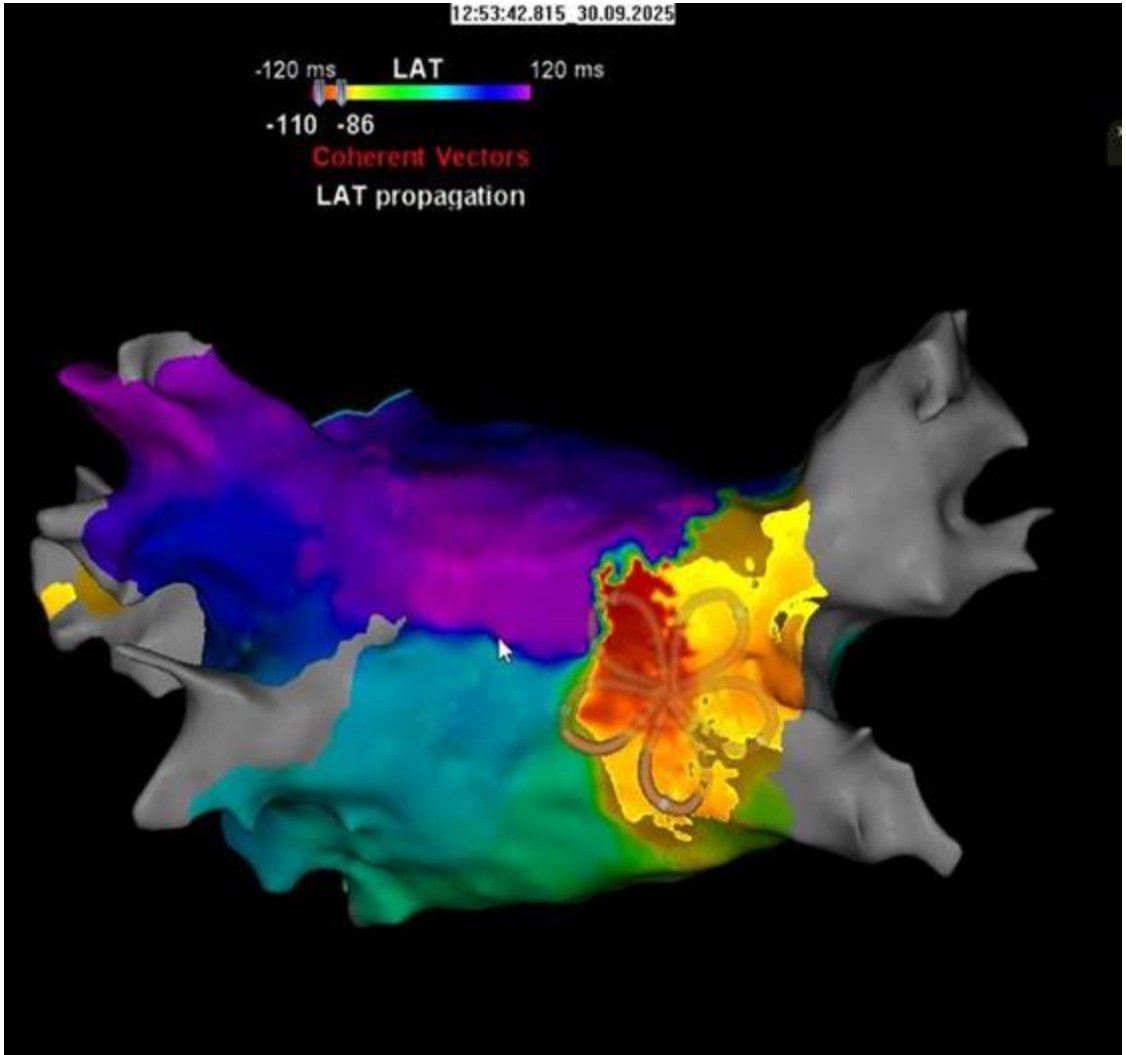

10:43:37.912 18.09.2025
COHERENT
-125
127
CL: 252 (active map)
Coherent Vectors
0.10 mV
Bi
1.00 mV
LAT Histogram
1-RA CS FAM
1296
972
648
324
0
-120
-73
-26
21
68
119
2.46
0%
0%


-120
131
CL: 251 (active map)
Coherent Vectors
0.10 mV
Bi
1.00 mV
LAT Vectors
LAT Histogram
9-LA CS FAM PRE EDIT
1688
1266
844
422
0
-120
-57
6
69
132
196



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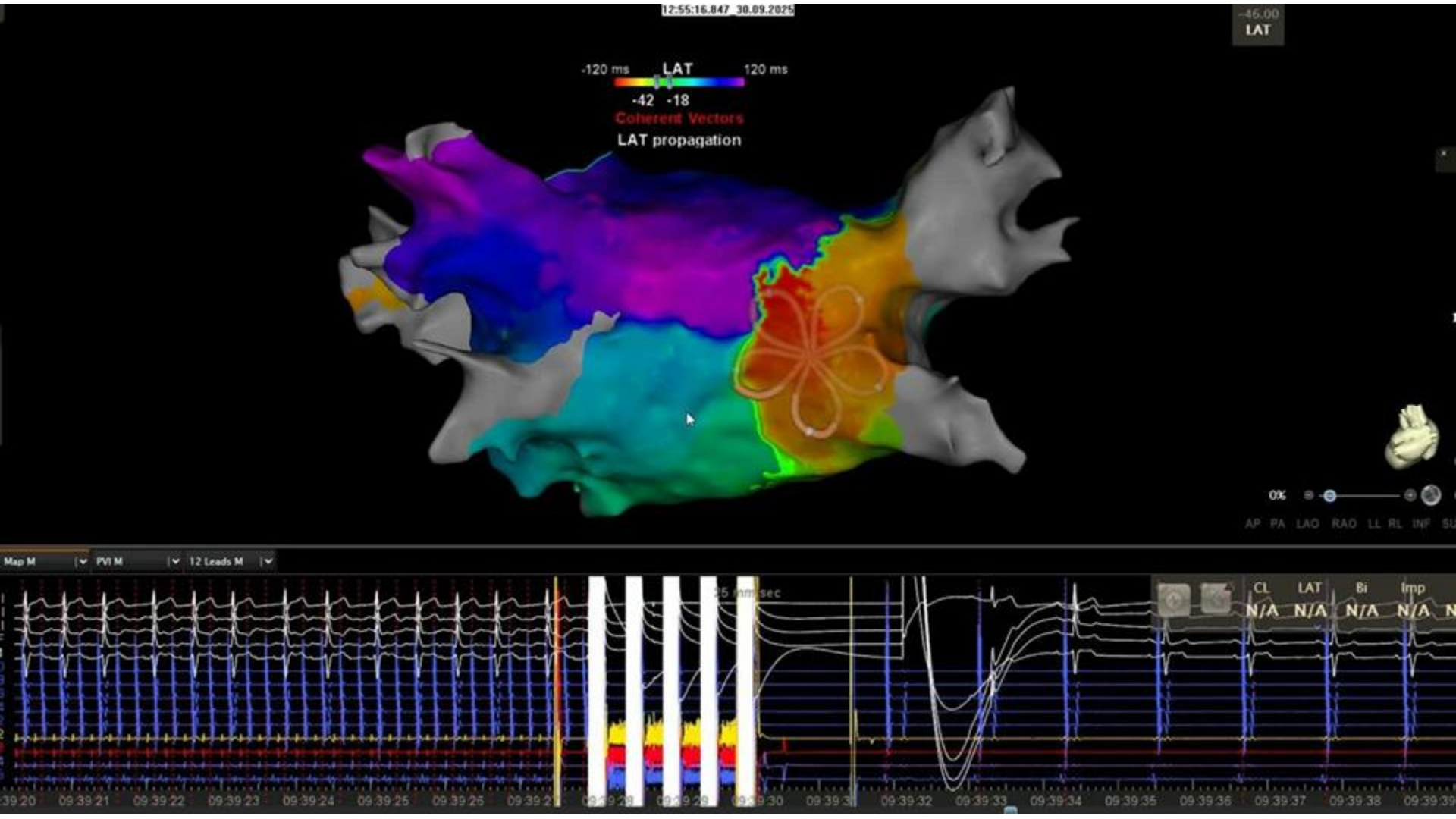
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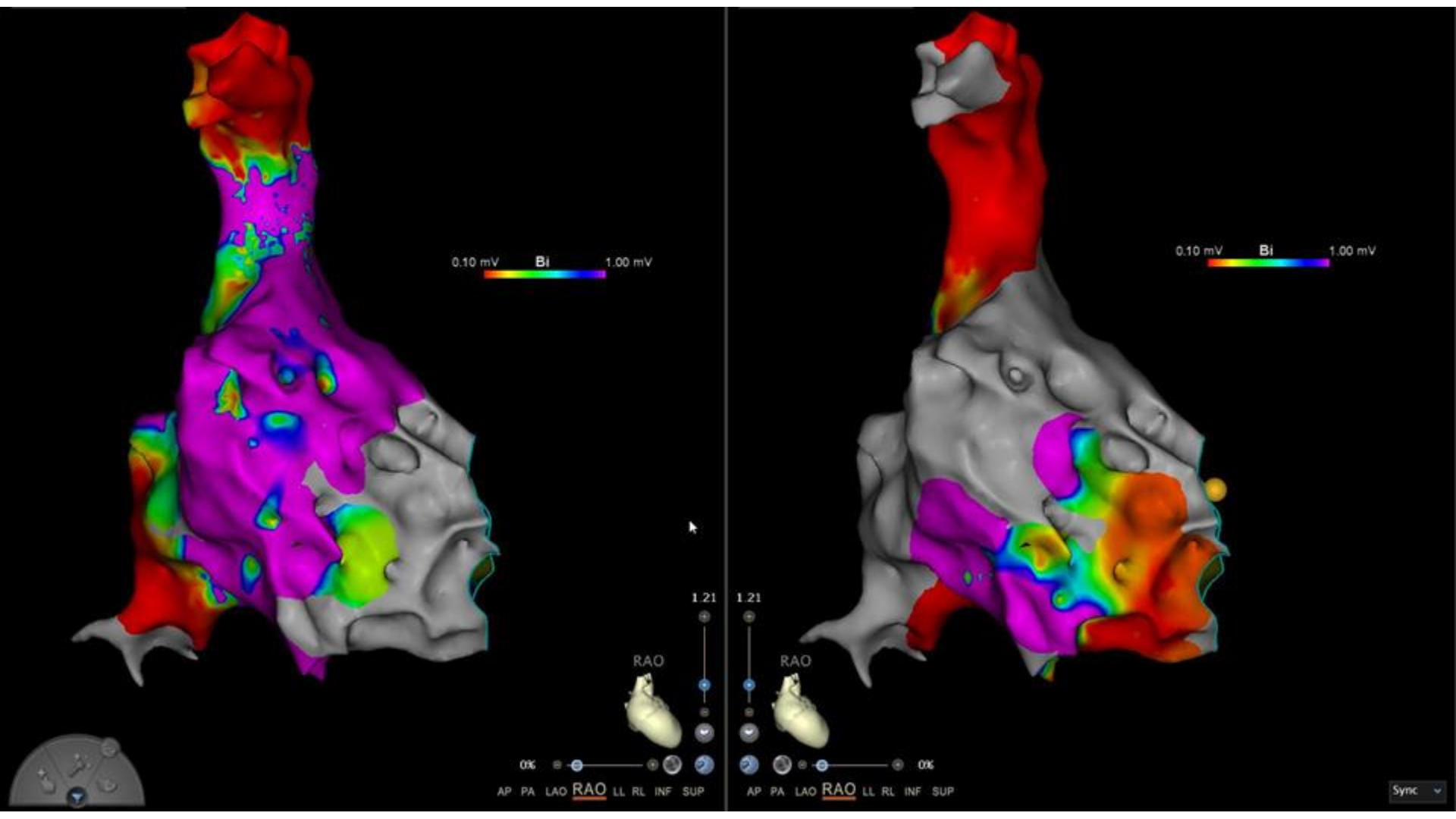
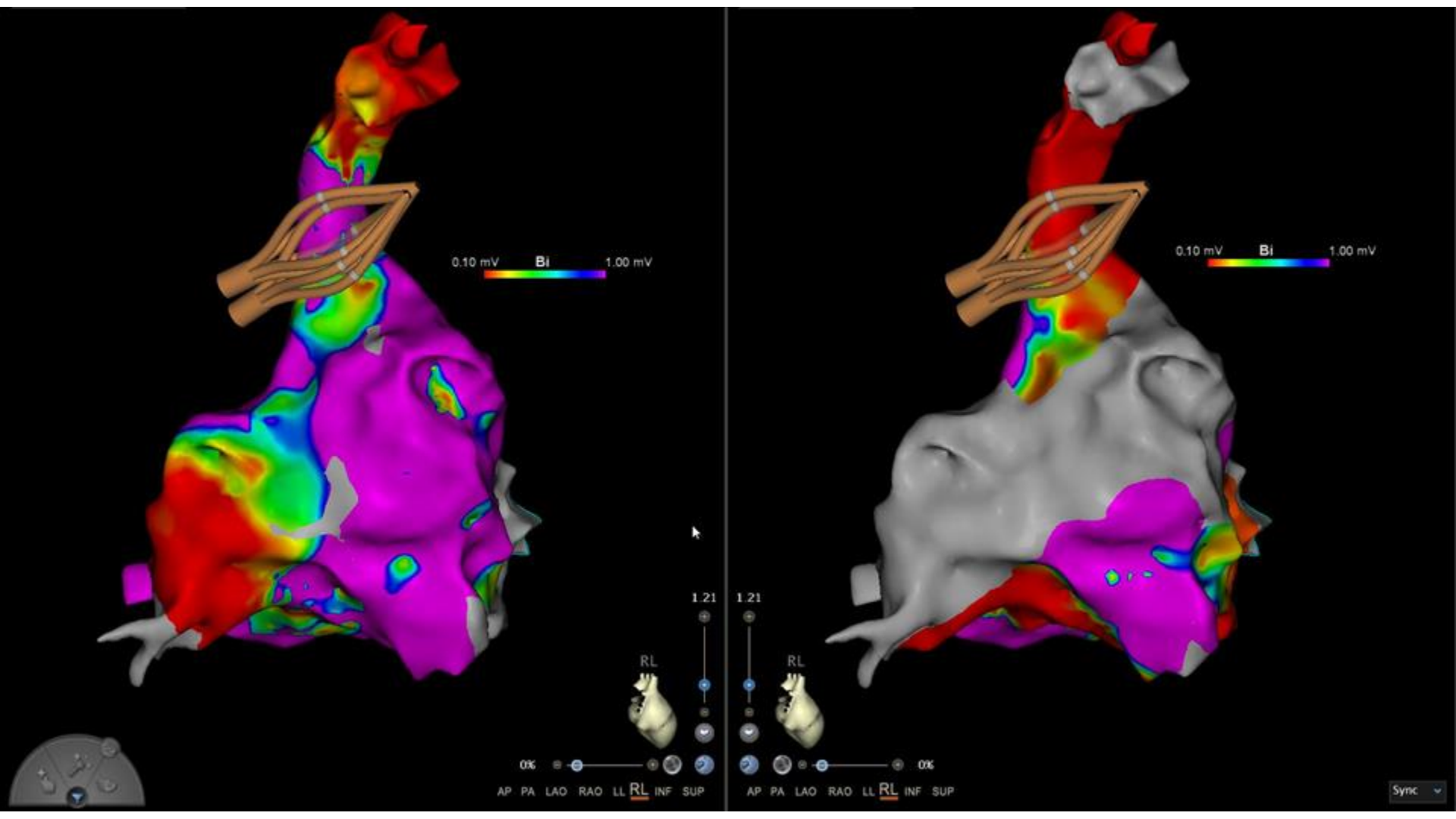
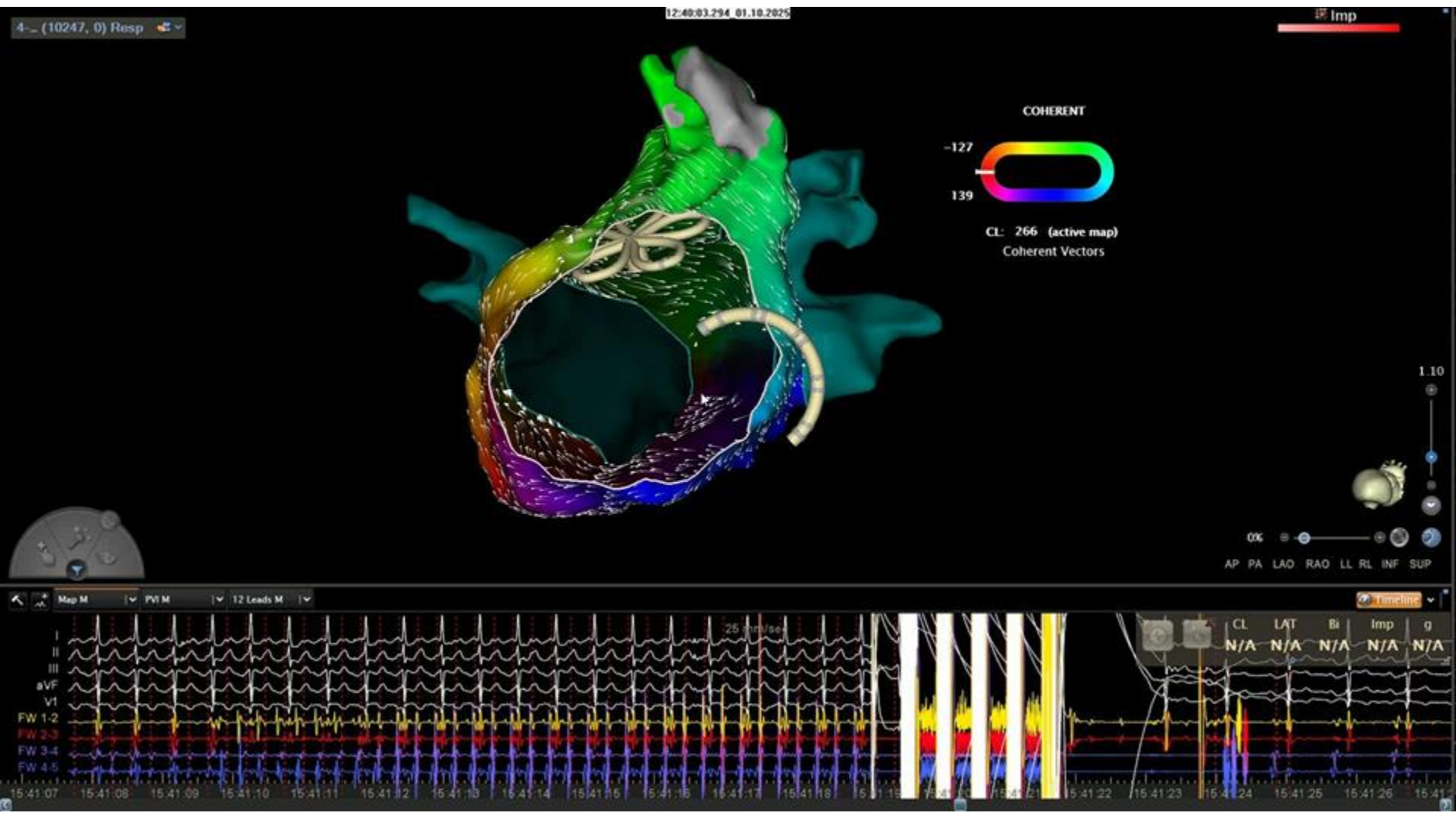
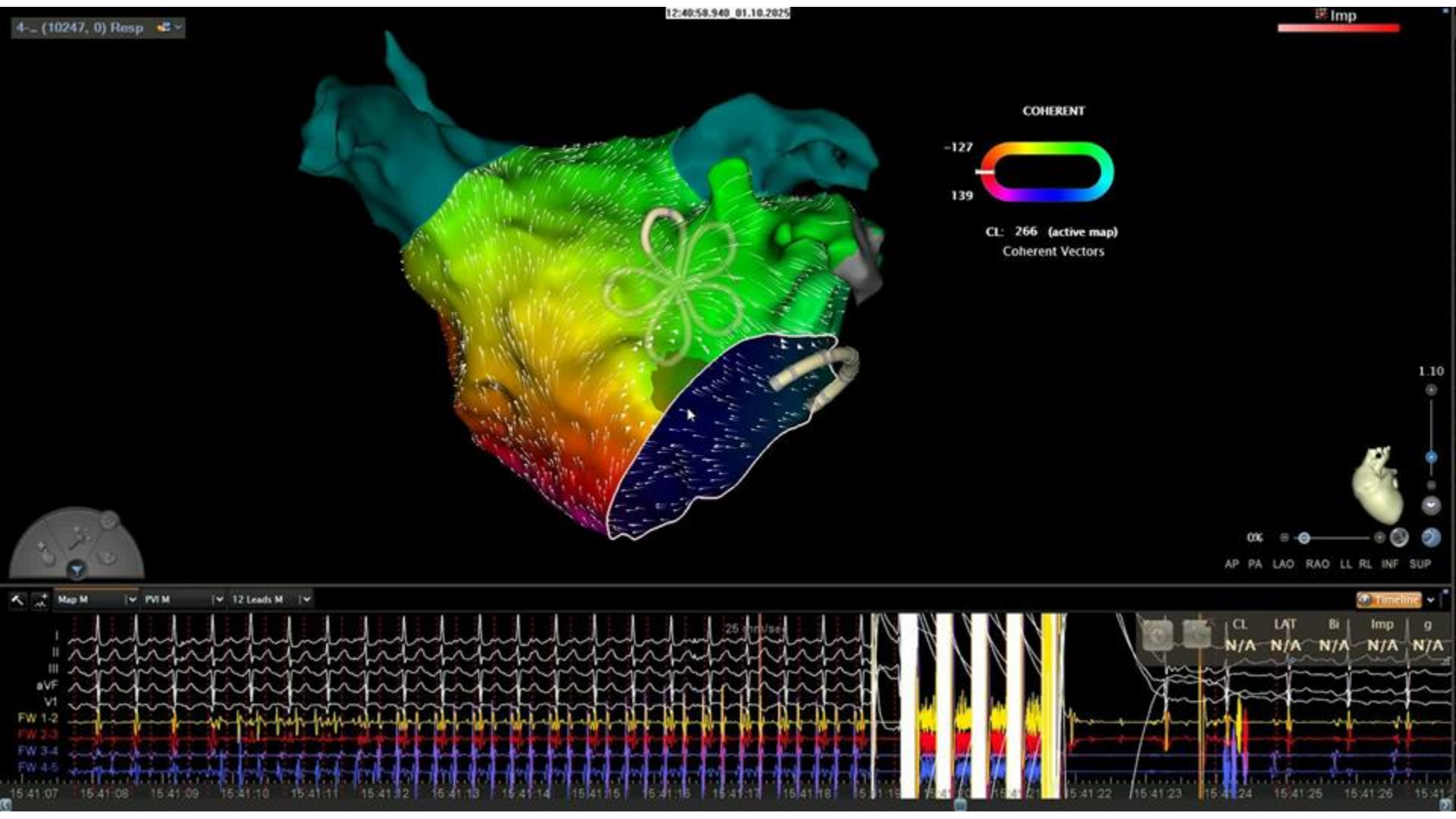
-46.00
LAT
-120 ms
LAT
120 ms
-42 -18
Coherent Vectors
LAT propagation
0%
AP PA LAO RAO LL RL INF SU
Map M
PVI M
12 Leads M
25 mm/sec
CL LAT Bi Imp
N/A N/A N/A N/A N
09:39:20 09:39:21 09:39:22 09:39:23 09:39:24 09:39:25 09:39:26 09:39:32 09:39:33 09:39:34 09:39:35 09:39:36 09:39:37 09:39:38


0.10 mV
Bi
1.00 mV
1.21
RAO
0%
AP PA LAO RAO LL RL INF SUP
0.10 mV
Bi
1.00 mV
1.21
RAO
0%
AP PA LAO RAO LL RL INF SUP
Sync


0.10 mV
Bi
1.00 mV
1.21
RL
0%
AP PA LAO RAO LL RL INF SUP
0.10 mV
Bi
1.00 mV
1.21
RL
0%
AP PA LAO RAO LL RL INF SUP
Sync


4-_ (10247, 0) Resp
12:40:03.294 01.10.2025
Imp
COHERENT
-127
139
CL: 266 (active map)
Coherent Vectors
1.10
0%
AP PA LAO RAO LL RL INF SUP
Map M
PVI M
12 Leads M
Timeline
CL LAT Bi Imp g
N/A N/A N/A N/A N/A
I
II
III
aVF
V1
FW 1-2
FW 2-3
FW 3-4
FW 4-5
15:41:07 15:41:08 15:41:09 15:41:10 15:41:11 15:41:12 15:41:13 15:41:14 15:41:15 15:41:16 15:41:17 15:41:18 15:41:22 15:41:23 15:41:24 15:41:25 15:41:26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Imp
COHERENT
-127
139
CL: 266 (active map)
Coherent Vectors
1.10
0%
AP PA LAO RAO LL RL INF SUP
Map M
PVI M
12 Leads M
Timeline
CL LAT Bi Imp g
N/A N/A N/A N/A N/A
I
II
III
aVF
V1
FW 1-2
FW 2-3
FW 3-4
FW 4-5
15:41:07 15:41:08 15:41:09 15:41:10 15:41:11 15:41:12 15:41:13 15:41:14 15:41:15 15:41:16 15:41:17 15:41:18 15:41:22 15:41:23 15:41:24 15:41:25 15:41:26

2023 ACC/AHA/ACCP/HRS Guideline for the Diagnosis and Management of Atrial Fibrillation: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines

AF Stroke prevention

Anticoagulation is the primary way of AF stroke prevention irrespective of rate or rhythm control approach.

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Recommendations for Antithrombotic Therapy
Referenced studies that support the recommendations are summarized in the Online Data Supplement.

COR	LOE	Recommendations
1	A	1. For patients with AF and an estimated annual thromboembolic risk of ≥2% per year (eg, CHA_2DS_2-VASc score of ≥2 in men and ≥3 in women), anticoagulation is recommended to prevent stroke and systemic thromboembolism.[1–7]
1	A	2. In patients with AF who do not have a history of moderate to severe rheumatic mitral stenosis or a mechanical heart valve, and who are candidates for anticoagulation, DOACs are recommended over warfarin to reduce the risk of mortality, stroke, systemic embolism, and ICH.[1–7]
2a	A	3. For patients with AF and an estimated annual thromboembolic risk of ≥1% but <2% per year (equivalent to CHA_2DS_2-VASc score of 1 in men and 2 in women), anticoagulation is reasonable to prevent stroke and systemic thromboembolism.[1,3]
3: Harm	B-R	4. In patients with AF who are candidates for anticoagulation and without an indication for antiplatelet therapy, aspirin either alone or in combination with clopidogrel as an alternative to anticoagulation is not recommended to reduce stroke risk.[8,9]
3: No Benefit	B-NR	5. In patients with AF without risk factors for stroke, aspirin monotherapy for prevention of thromboembolic events is of no benefit.[10,11]

Long-Term Anticoagulation Contraindicated	Long-Term Anticoagulation Is Still Reasonable
Severe bleeding due to a nonreversible cause involving the gastrointestinal, pulmonary, or genitourinary systems Spontaneous intracranial/intraspinal bleeding due to a nonreversible cause Serious bleeding related to recurrent falls when cause of falls is not felt to be treatable	Bleeding involving the gastrointestinal, pulmonary, or genitourinary systems that is treatable Bleeding related to isolated trauma Bleeding related to procedural complications

Nonpharmacological Stroke Prevention

Recommendations for Percutaneous Approaches to Occlude the LAA
Referenced studies that support the recommendations are summarized in the Online Data Supplement.

COR	LOE	Recommendations
2a	B-NR	1. In patients with AF, a moderate to high risk of stroke (CHA_2DS_2-VASc score ≥2), and a contraindication (Table 14) to long-term oral anticoagulation due to a nonreversible cause, percutaneous LAAO (pLAAO) is reasonable.[1–4]
2b	B-R	2. In patients with AF and a moderate to high risk of stroke and a high risk of major bleeding on oral anticoagulation, pLAAO may be a reasonable alternative to oral anticoagulation based on patient preference, with careful consideration of procedural risk and with the understanding that the evidence for oral anticoagulation is more extensive.[1–3,5,6]

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Left Atrial Appendage Closure after Ablation for Atrial Fibrillation

N Engl J Med 2025;392:1277-87

Virginia Mason Franciscan Health

Table 2. Primary and Secondary End Points at 36 Months (Kaplan–Meier Estimates).*

End Point	Analysis	Device Group (N=803)	Anticoagulation Group (N=797)	Difference (one-sided 97.5% upper confidence limit)	P Value
		no. of patients (%)		*percentage points*	
Primary end points					
Safety: non–procedure-related bleeding†	Superiority	65 (8.5)	137 (18.1)	—	<0.001
Efficacy: death from any cause, stroke, or systemic embolism‡	Noninferiority, with 5.0-percentage-point margin	41 (5.3)	44 (5.8)	−0.5 (1.8)	<0.001
Secondary end point					
Major bleeding event§	Noninferiority, with 5.25-percentage-point margin	30 (3.9)	38 (5.0)	−1.1 (1.0)	<0.001

* The analyses were performed in the intention-to-treat population, which included all patients who underwent randomization, grouped according to their assigned treatment group; the start time of follow-up for the intention-to-treat analysis was the day of randomization. Testing was performed in a hierarchical manner, with each step needing to reject the null hypothesis in order to proceed to the next step. Step 1 was superiority testing of the primary safety end point and noninferiority testing of the primary efficacy end point, step 2 was noninferiority testing of the secondary end point, step 3 was superiority testing of the secondary end point, and step 4 was superiority testing of the primary efficacy end point. The trial was considered to be successful if the criteria were met for both superiority regarding the primary safety end point and noninferiority regarding the primary efficacy end point.

† Non–procedure-related bleeding was a composite of ISTH major bleeding or clinically relevant nonmajor bleeding. Non–procedure-related events were those that occurred after 3 days following the procedure in the device group. The P value was calculated with the use of the log-rank test and is based on the Kaplan–Meier estimation for the superiority testing.

‡ The P value for the primary efficacy end point (a composite of stroke, all-cause death, or systemic embolism) was calculated with the use of the z test and is based on the standard normal distribution for the noninferiority testing and log-rank test for the superiority testing.

§ Major bleeding was defined as ISTH major bleeding, including procedure-related bleeding. The P value was calculated with the use of the z test and is based on the standard normal distribution for the noninferiority testing and log-rank test for the superiority testing.

Conclusions

- Among patients who underwent catheter-based atrial fibrillation ablation, left atrial appendage closure was associated with a lower risk of non–procedure-related major or clinically relevant nonmajor bleeding than oral anticoagulation and was noninferior to oral anticoagulation with respect to a composite of death from any cause, stroke, or systemic embolism at 36 months.

Thank you

Ravi Kilaru MD

Clinical Cardiac Electrophysiologist

St. Michael Medical Center

Silverdale , WA

Virginia Mason Franciscan Health

Thank You

Virginia Mason Franciscan Health
Center for Cardiovascular Health

To Lead or be Leadless: Risks and Benefits of Leadless Pacemakers

Michael Eskander, MD, FACC, FHRS

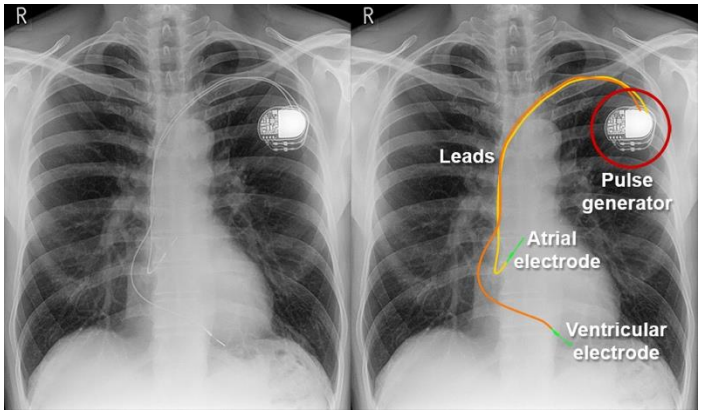
Virginia Mason Franciscan Health
Center for Cardiovascular Health

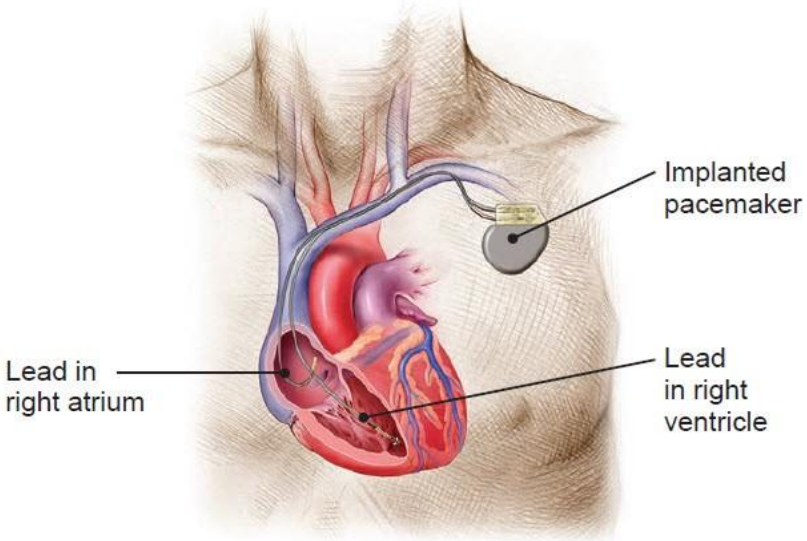
Disclosures

- NO RELEVANT DISCLOSURES

Introduction

- Traditional transvenous pacemakers have been in use for over 60 years
- Long history of safety and reliability
- Inserted via small incision in the chest





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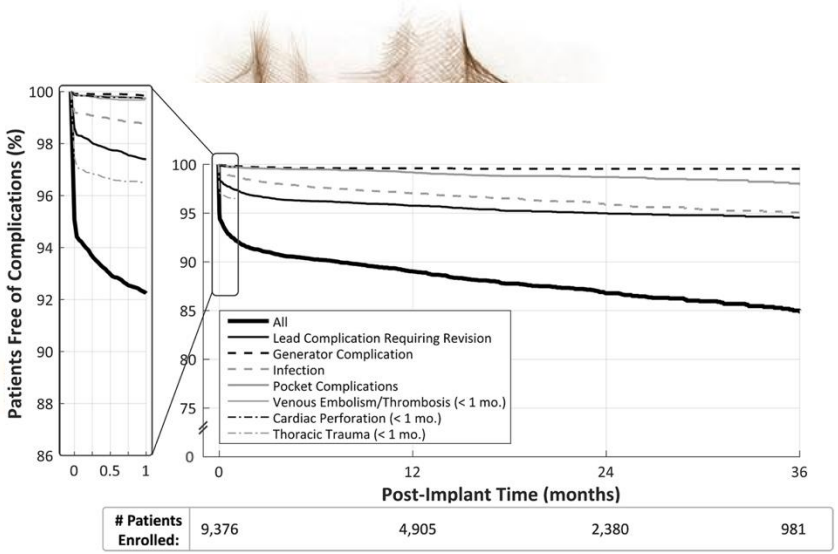
Introduction

- Traditional transvenous pacemakers effective but limited
- Lead/pocket complications are common
- Create additional costs to healthcare system
- Leadless systems developed to overcome these issues



Cantillon, DJ, et al. JACC: Clinical Electrophysiology. 2017

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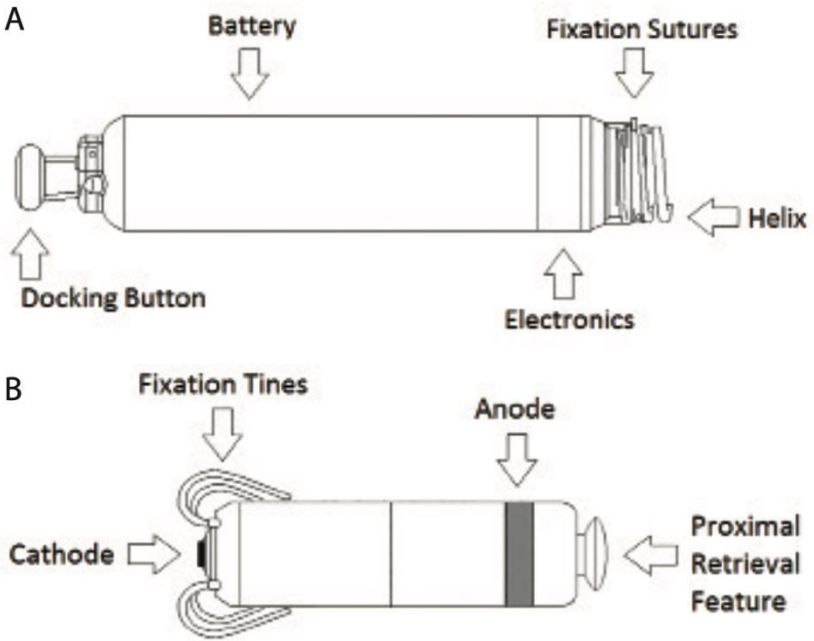
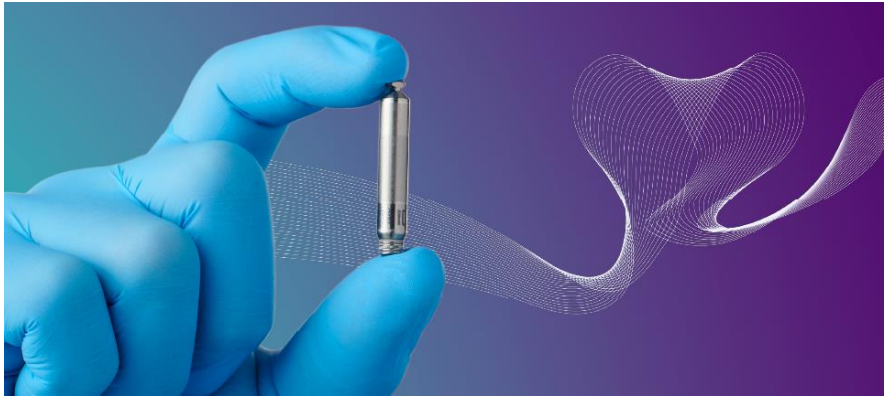
Leadless Pacemakers

- Capsule-like devices delivered via the femoral or jugular vein
- Fixation through tines or helix
- Growing indications: initially single, ventricular pacing; now also dual chamber pacing



Leadless Pacemakers



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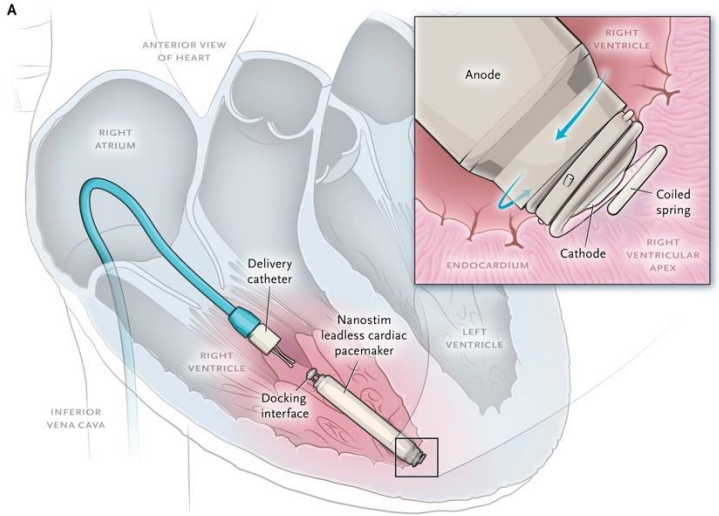
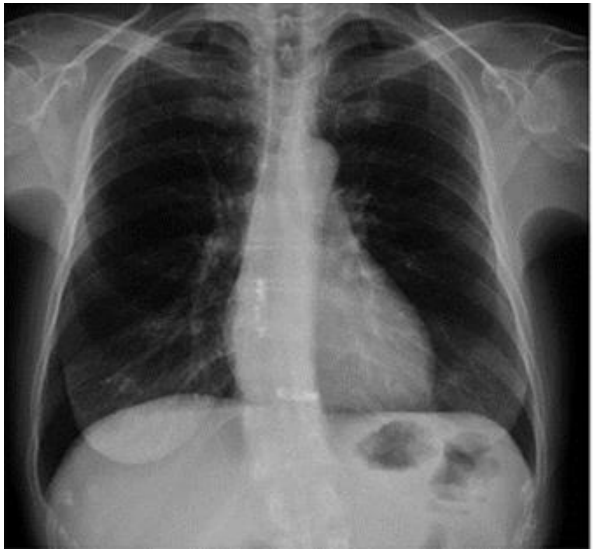
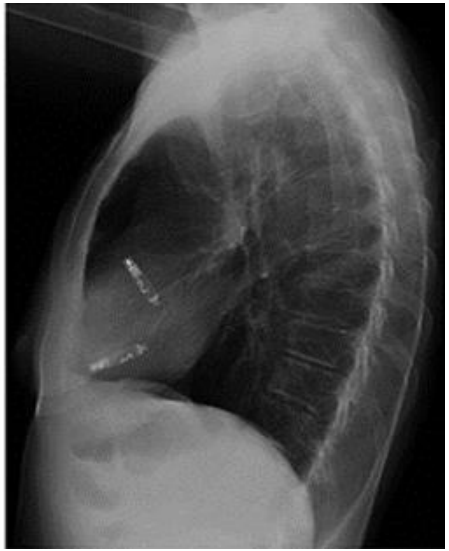
Leadless Pacemakers - Implant







Reddy, VY. et al. NEJM. 2015

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Leadless Pacemakers: Benefits

- No leads or pockets
- Eliminates pocket complications (infection, hematoma, erosion)
- Less components (single device vs. multiple leads/connections)
- No venous obstruction
- Useful in patients with limited access (dialysis/ports)
- Low infection risk

Infection Risks

How Frequent is LP Infection?

Event no	Days post-implant	Event	Major Complication	Outcome
1	0	Sepsis	Yes	Resolved, IV antibiotics
2	7	Hematoma infection	Yes	Resolved, IV antibiotics
3	7	Puncture site infection	No	Resolved, oral antibiotics
4	13	Groin infection	No	Resolved, oral antibiotics
5	17	Groin infection	No	Resolved, oral antibiotics
6	20	Catheter site infection	Yes	Resolved, IV antibiotics
7	25	Abdominal wall infection	Yes	Resolved, IV antibiotics
8	29	Postoperative wound infection	No	Resolved, no action taken
9	390	Device related infection	Yes	Resolved, IV antibiotics

James Porterfield, M.D., James E. Ip, M.D., and Srinivas R. Dukkipati, M.D.,
for the LEADLESS II Study Investigators*

Clinical Trial

Reynolds D, et al. A leadless intracardiac transcatheter pacing system. *N Engl J Med*. 2016;374(6):533–541.

Reddy VY, et al. Percutaneous implantation of an entirely intracardiac leadless pacemaker. *N Engl J Med*. 2015;373(12):1125–1135.

El-Chami MF, et al. Updated performance of the Micra transcatheter pacemaker in the real-world setting: A comparison to the investigational study and a transvenous historical control. *Heart Rhythm*. 2018;15(12):1800–1807

Reddy VY, et al. Primary results on safety and efficacy from the LEADLESS II-Phase 2 worldwide clinical trial. *J Am Coll Cardiol EP*. 2018;4(12):1512–1519

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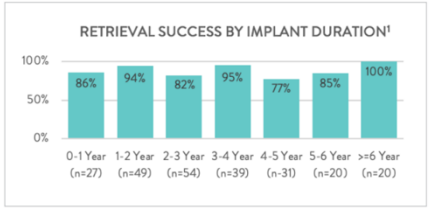
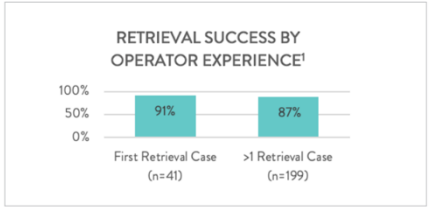
Leadless Pacemakers: Risks

- Femoral vascular injuries; hematoma
- Cardiac perforation/tamponade (~<1-1.5%)
- Device embolization/dislodgement (rare)
- Some devices may not retrievable after endothelialization

Retrieval success rates remained high through 241 retrieval attempts, regardless of implant duration or operator experience.[1]





Most unsuccessful retrieval attempts (84%) were attributed to an inability to access the docking button or an inability to deliver the retrieval catheter.

REASONS FOR UNSUCCESSFUL RETRIEVAL ATTEMPTS - 29 out of 241 (12%)*	n (%)
Docking Button Could Not be Accessed	22 (75.9%)
Inability to Deliver Retrieval Catheter to LP	3 (10.3%)
Detachment of Docking Button During Retrieval	2 (7.0%)
Inability to Remove Snare (broken)	1 (3.4%)
Inability to Unscrew LP from RV wall	1 (3.4%)
Total	**29 (100%)**

The percentage of pericardial effusion or cardiac tamponade with attempted retrievals was 0.83% (2 out of 241 attempts).

1. Reddy, VY, et al. Worldwide Experience with Leadless Pacemaker Retrievals: A Worldwide Nanostim Experience out of 9y. Presented at: APHRS 2022; Nov 18-20, 2022; Singapore.
2. AVEIR™ VR Leadless Pacemaker and Delivery Catheter IFU. ARTEN600175956

* Limited data is available for AVEIR VR LP

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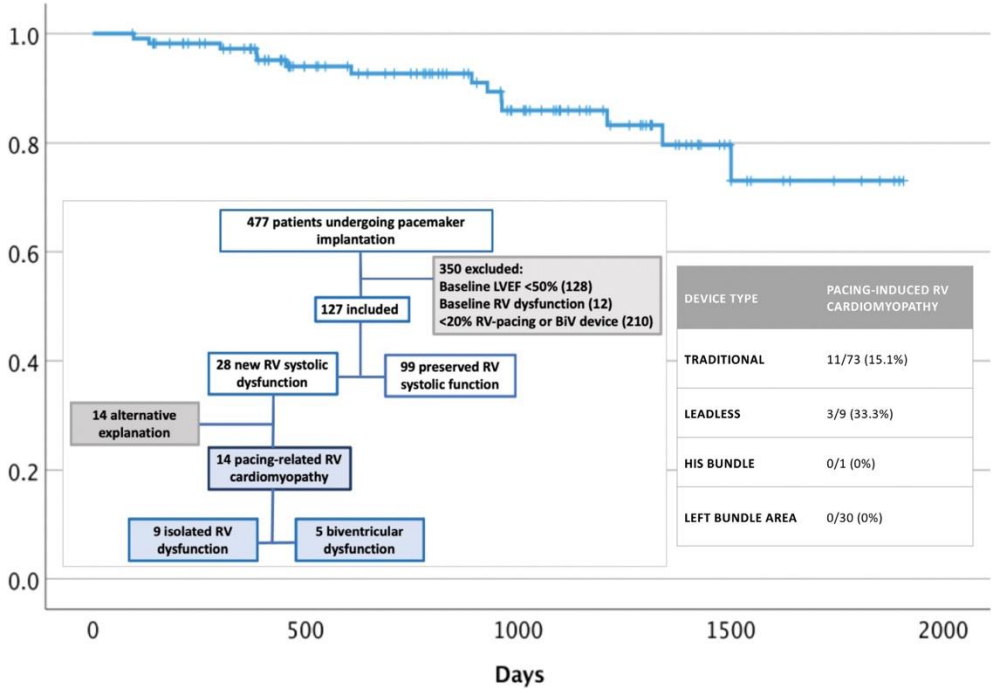
Leadless Pacemakers: Long-Term Limitations

- Single-chamber pacing (certain devices)
- Limited extraction/replacement
- Battery longevity 8-12 years; newer generation devices up to 15 years
- Atrioventricular synchrony
- Pacing-induced cardiomyopathy risk similar to transvenous right ventricular apical pacing



DEVICE TYPE	PACING-INDUCED RV CARDIOMYOPATHY
TRADITIONAL	11/73 (15.1%)
LEADLESS	3/9 (33.3%)
HIS BUNDLE	0/1 (0%)
LEFT BUNDLE AREA	0/30 (0%)

Boyle, TA, et al. Circ: Arrhy and Elect. 2024

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Special Considerations/Future Directions

- Ideal for elderly, dialysis patients, high infection risk
- Less ideal for younger patients, those requiring resynchronization devices (biventricular pacers)
- Improved longevity
- Potential for modular, wireless pacing networks (working alongside defibrillators)
- Conduction system pacing

VMFH Experience

- 360 pacemaker implants at SJMC and >1200 pacemaker implants across all VMFH sites 2024
- On track for 1300 implants this fiscal year
- 187 leadless pacer implants

Summary

- Leadless pacemakers is a useful tool but not for everyone
- Benefits: fewer complications, minimally invasive, now can be used in patients requiring dual chamber pacing
- Risks: Perforation, vascular injury, limited options, less reliable atrioventricular synchrony
- Technology is improving quickly with more innovation in the industry to meet current limitations

Thank You

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