

Nuove frontiere e vecchie sfide nell'ablazione della fibrillazione atriale

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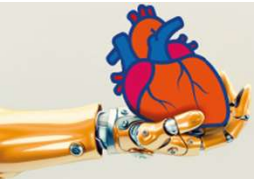
Lucca, 22-24 Giugno 2023
Centro Congressi Auditorium San Francesco

Antonio Di Monaco



Ente Ecclesiastico
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MIULLI



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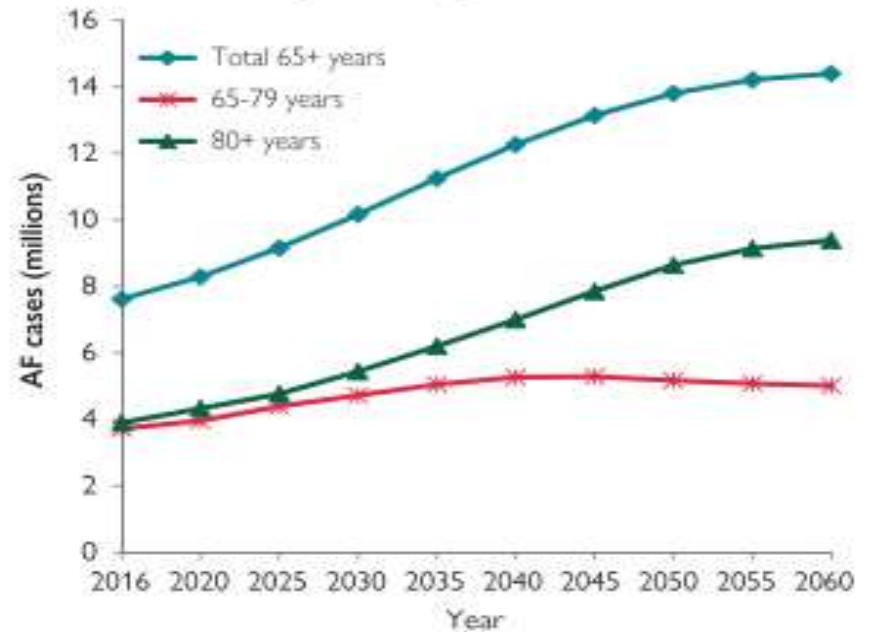
Fibrillazione atriale: epidemiologia

GLOBAL PREVALENCE OF AF

(globally, 43.6 million individuals had prevalent AF/AFL in 2016)



Projected increase in AF prevalence among elderly in EU 2016-2060



ESC guidelines



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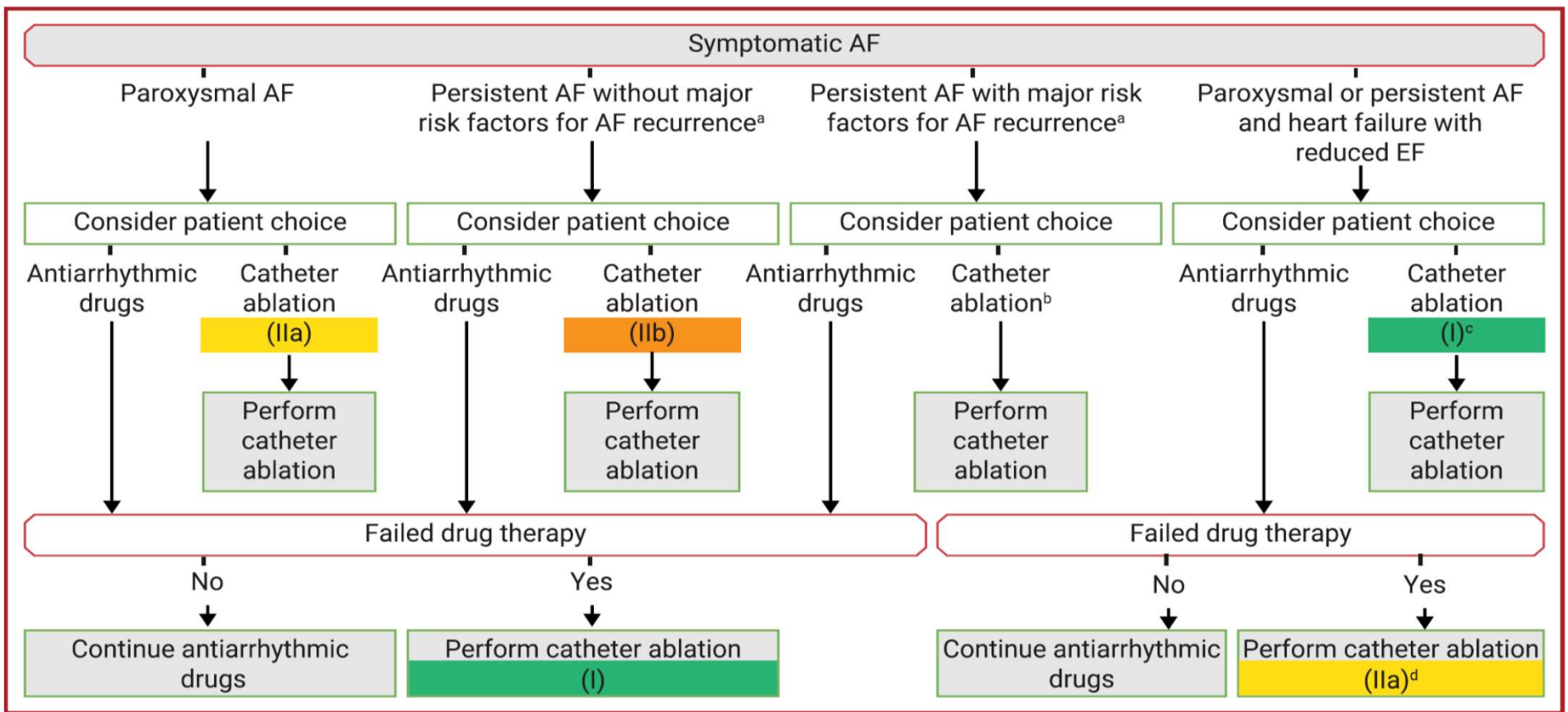
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Linee Guida ESC sulla Fibrillazione atriale





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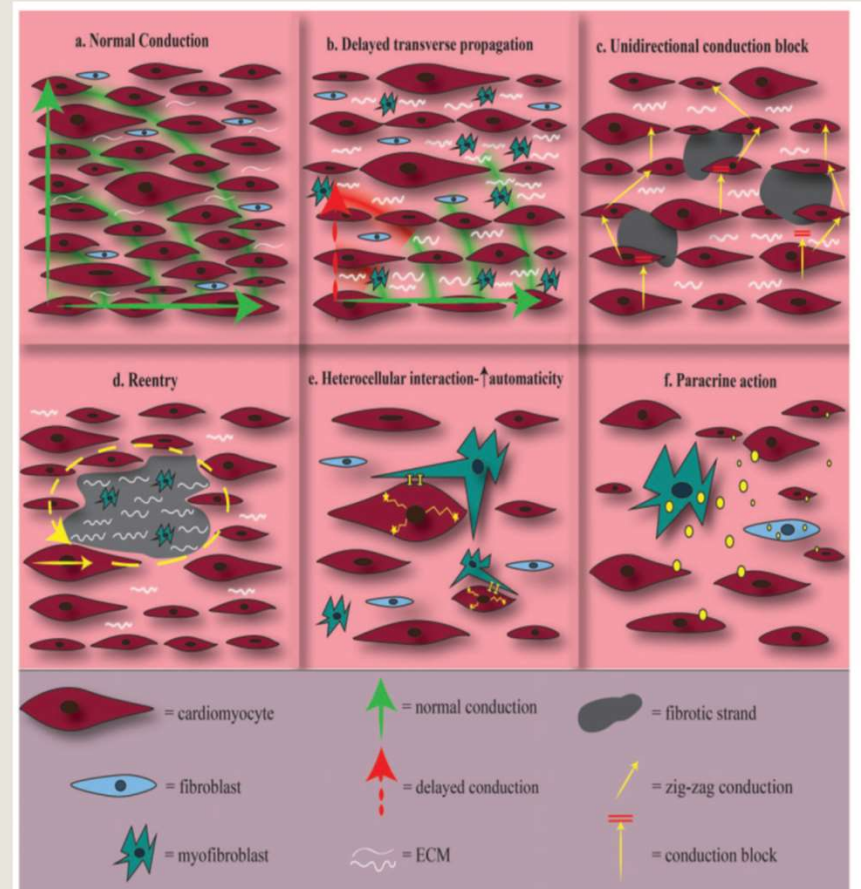
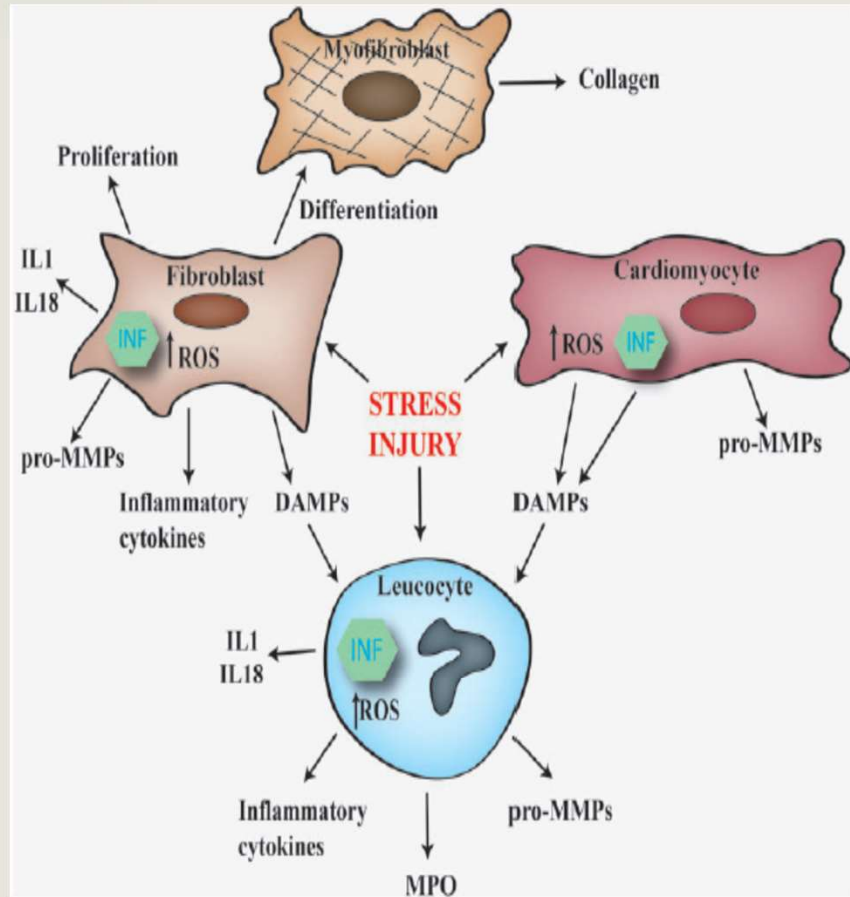
Fibrillazione atriale Potenziali elettrici delle Vene Polmonari



Haissaguerre M, N Engl J 1998



Atrial fibrosis as a dominant factor for the development of atrial fibrillation: facts and gaps





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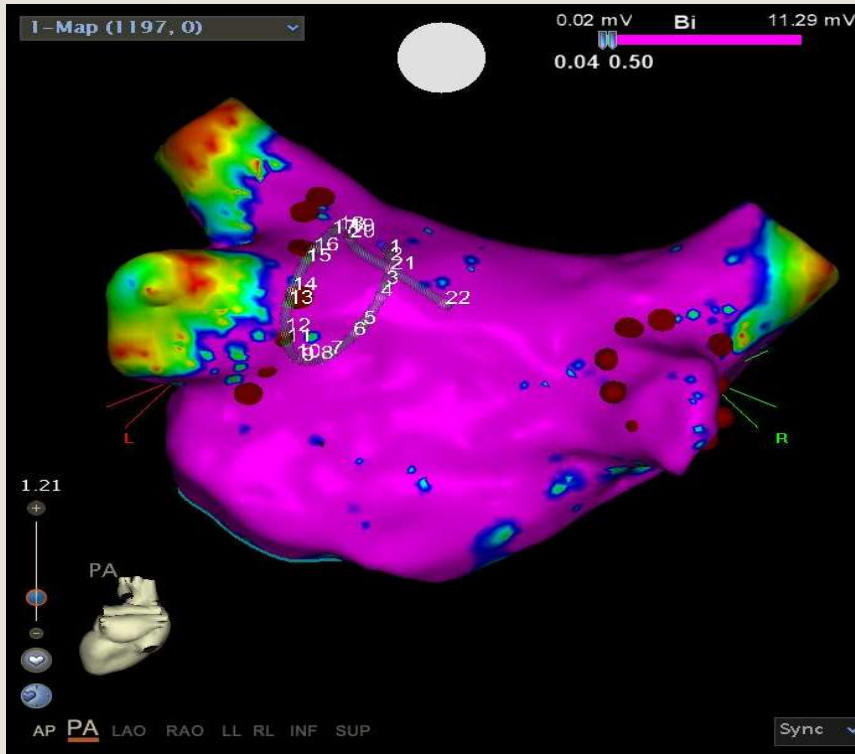
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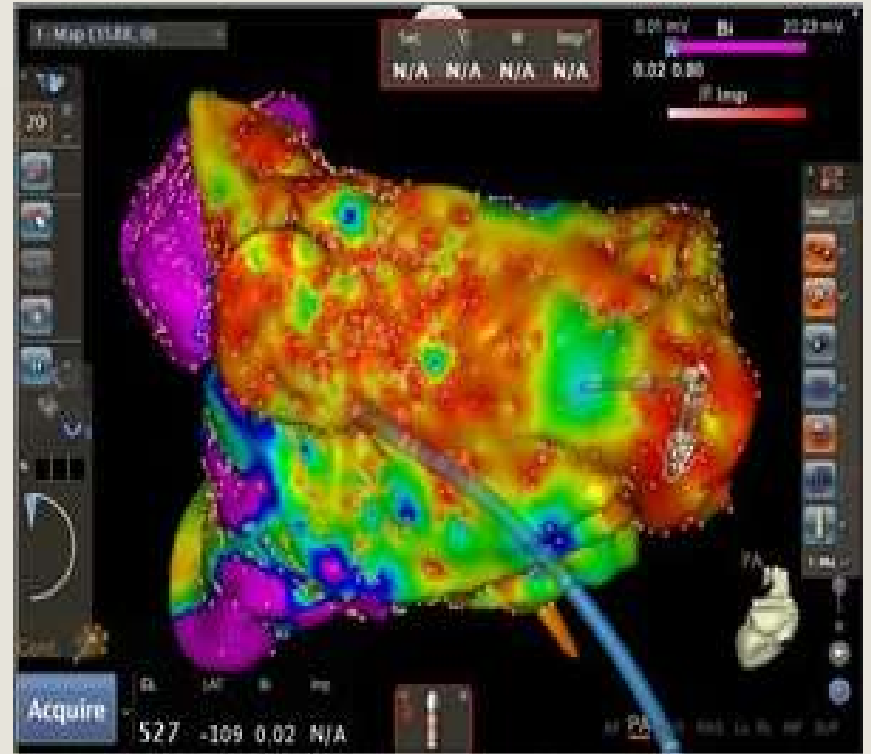
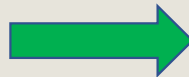


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Fibrillazione atriale parossistica



Fibrillazione atriale persistente



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Nuove tecnologie

**Isolamento elettrico delle vene
polmonari**

Analisi substrato aritmico

Lesioni transmurali e continue

Lesioni permanenti

Complicanze





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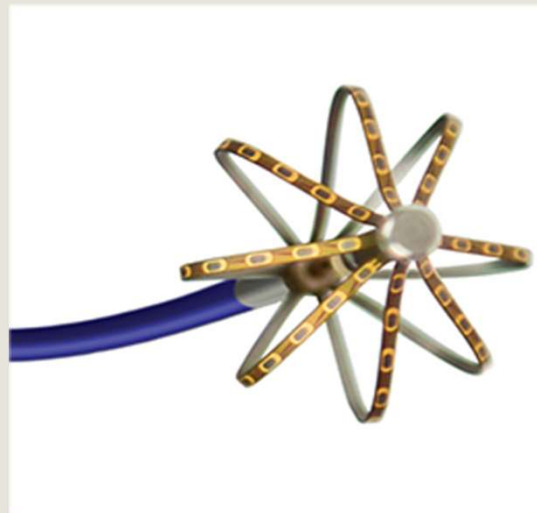
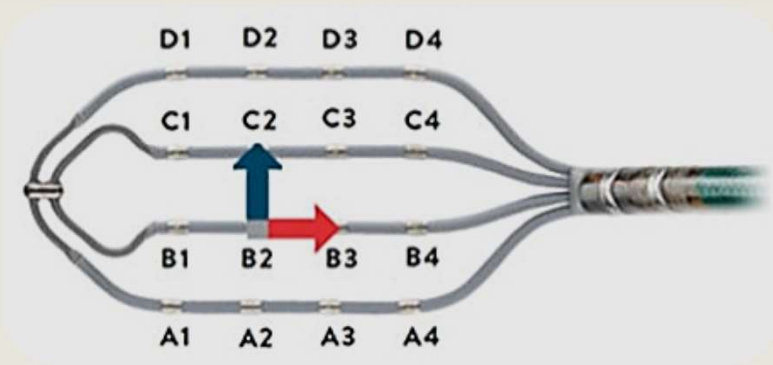
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Mappaggio multielettrodo





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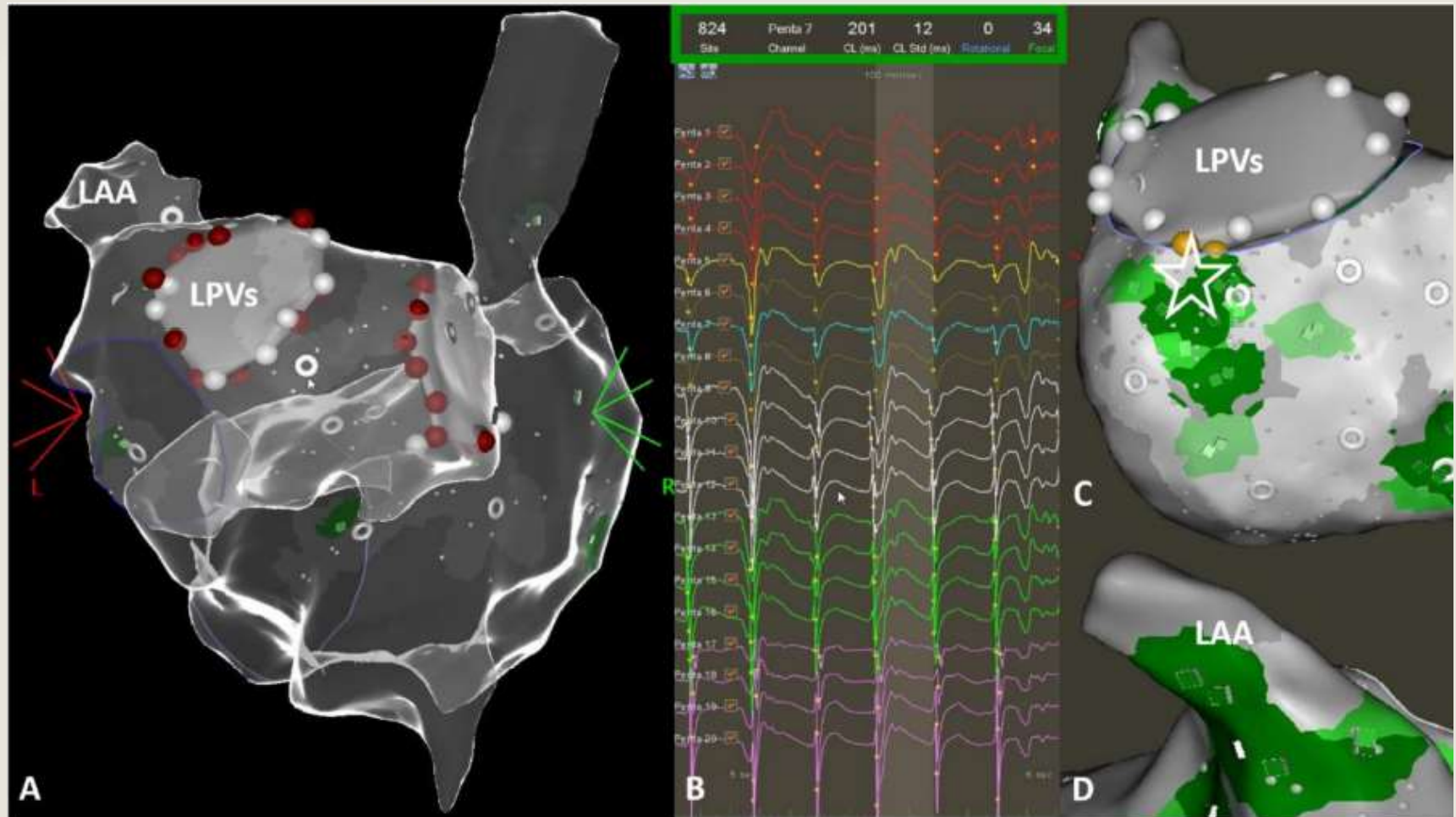
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CARTOFINDER





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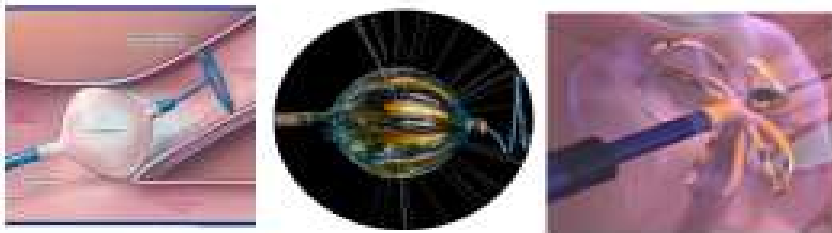


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Ablazione

One shot



Less operator dependent

✓

Fast

✓

AF as «gym» for young electrophysiologists

✓

Ability to treat unexpected arrhythmias

✓

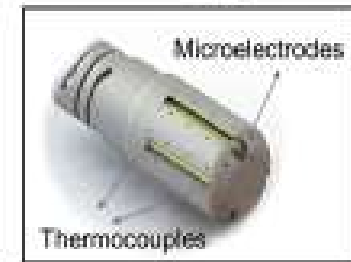
Carto guided transeptal puncture

✓

Fits all PV anatomies

✓

Point by point





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VOL. 5, NO. 7, 2019

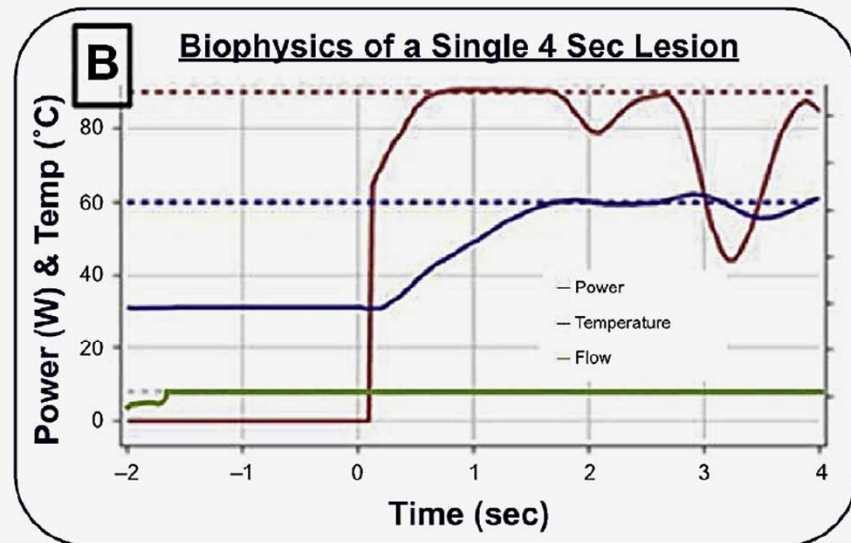
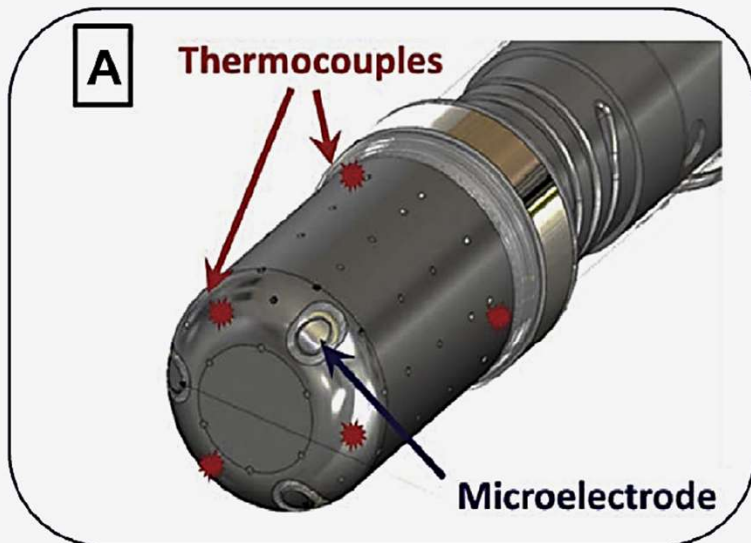
Pulmonary Vein Isolation With Very High Power, Short Duration, Temperature-Controlled Lesions

The QDOT-FAST Trial

Vivek Y. Reddy, MD,^{a,b} Massimo Grimaldi, MD,^c Tom De Potter, MD,^d Johan M. Vijgen, MD,^e Alan Bulava, MD, PhD,^f Mattias Francis Duytschaever, MD,^g Martin Martinek, MD,^h Andrea Natale, MD,ⁱ Sebastien Knecht, MD, PhD,^g Petr Neuzil, MD, PhD,^b Helmut Pürerfellner, MD^h



FIGURE 1 The vHPSD Catheter





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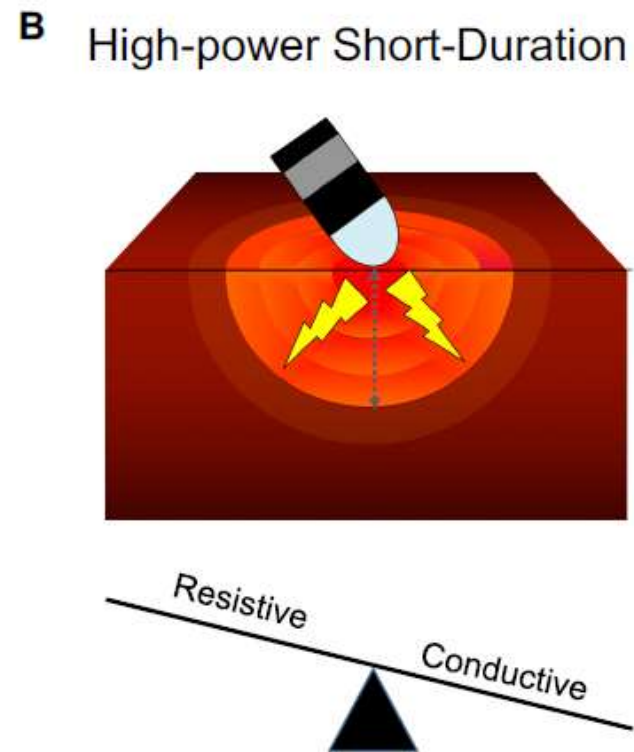
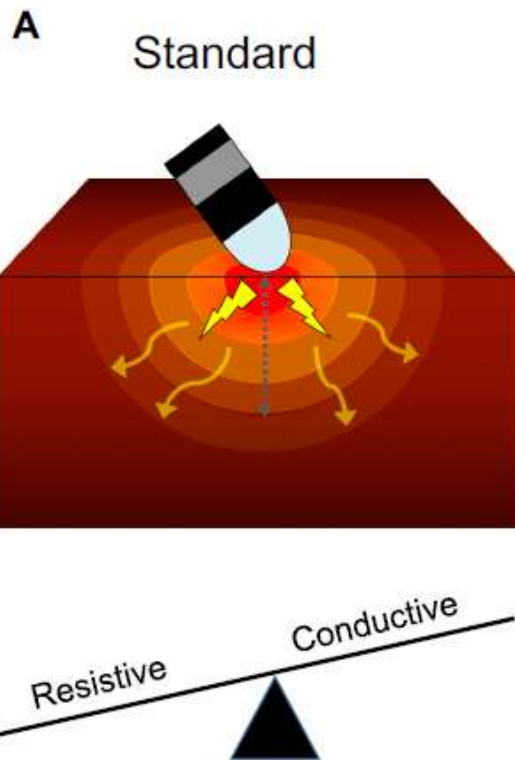
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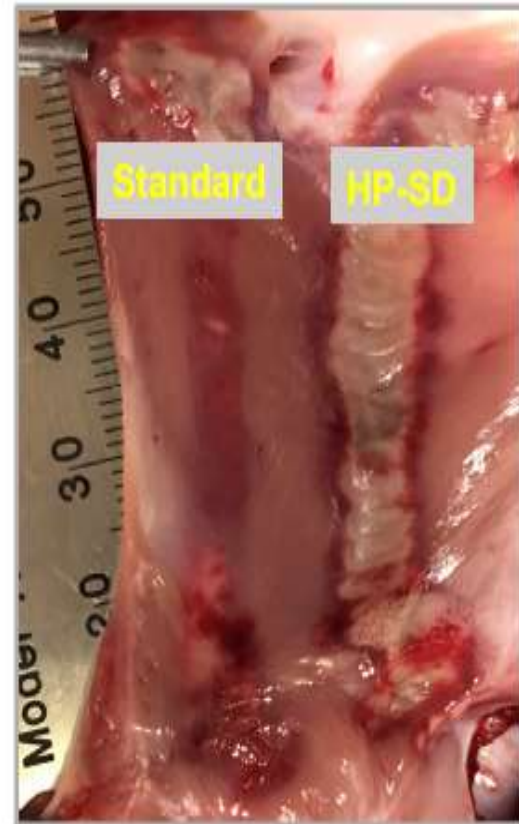
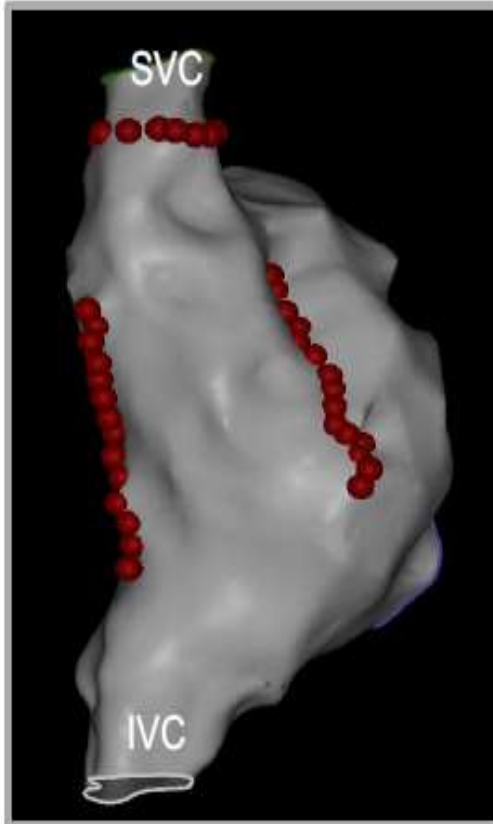
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High-Power and Short-Duration Ablation for Pulmonary Vein Isolation



Biophysical Characterization





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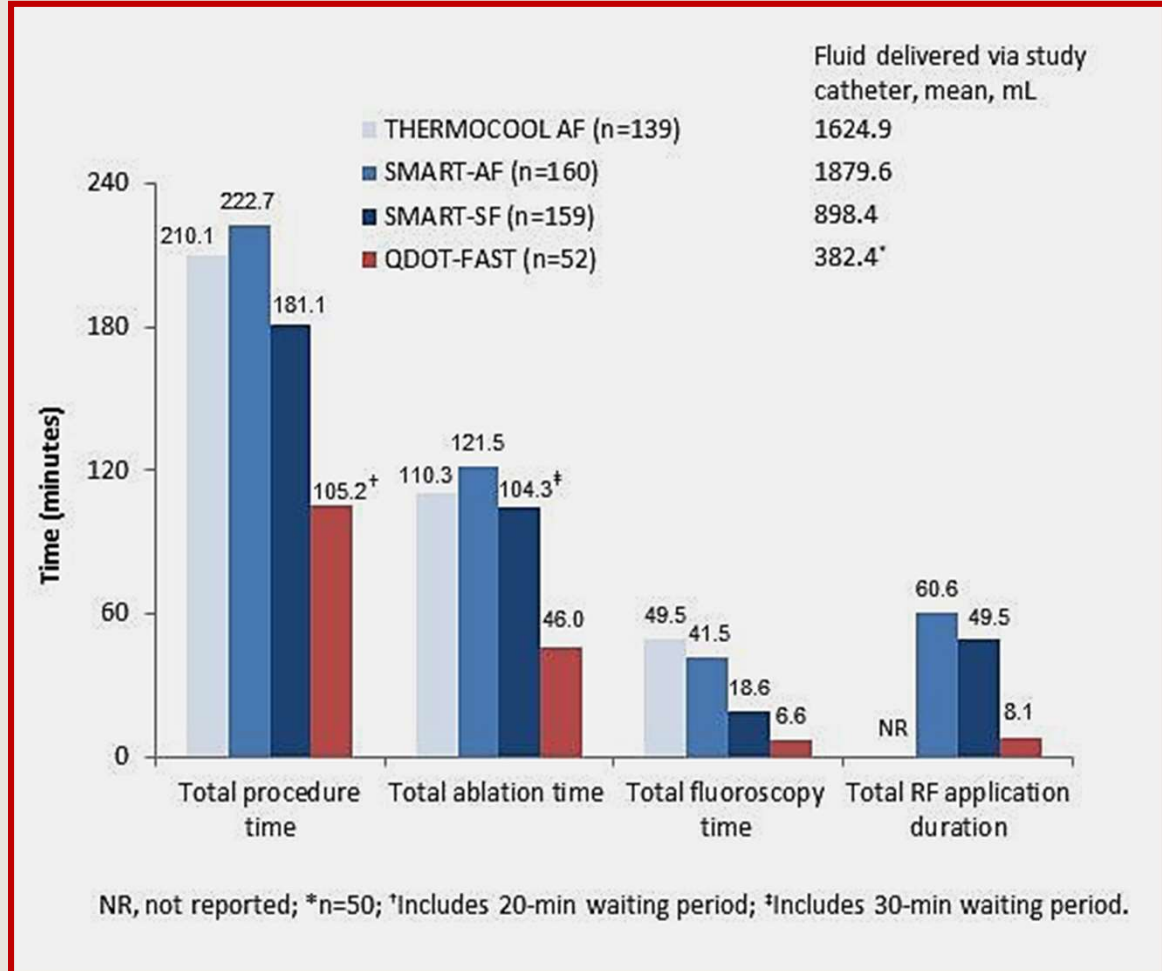
VOL. 5, NO. 7, 2019

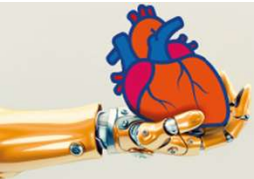
Pulmonary Vein Isolation With Very High Power, Short Duration, Temperature-Controlled Lesions



The QDOT-FAST Trial

Vivek Y. Reddy, MD,^{a,b} Massimo Grimaldi, MD,^c Tom De Potter, MD,^d Johan M. Vijgen, MD,^e Alan Bulava, MD, PhD,^f
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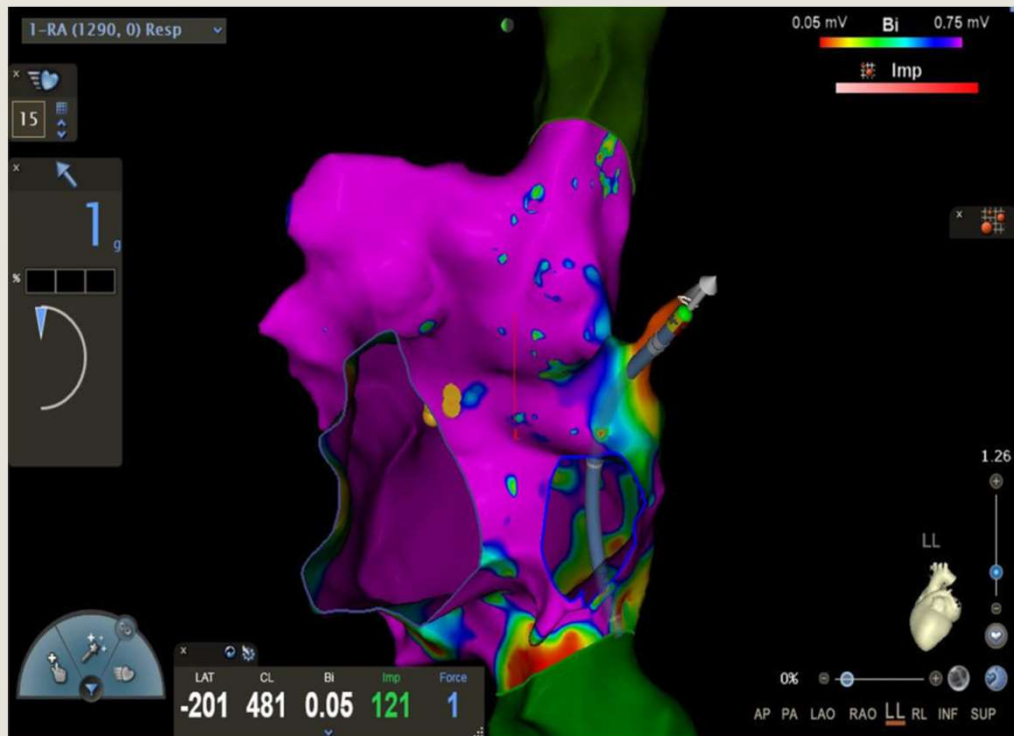
Received: 14 February 2020 | Revised: 23 June 2020 | Accepted: 6 July 2020
DOI: 10.1111/jce.14683

ORIGINAL ARTICLES

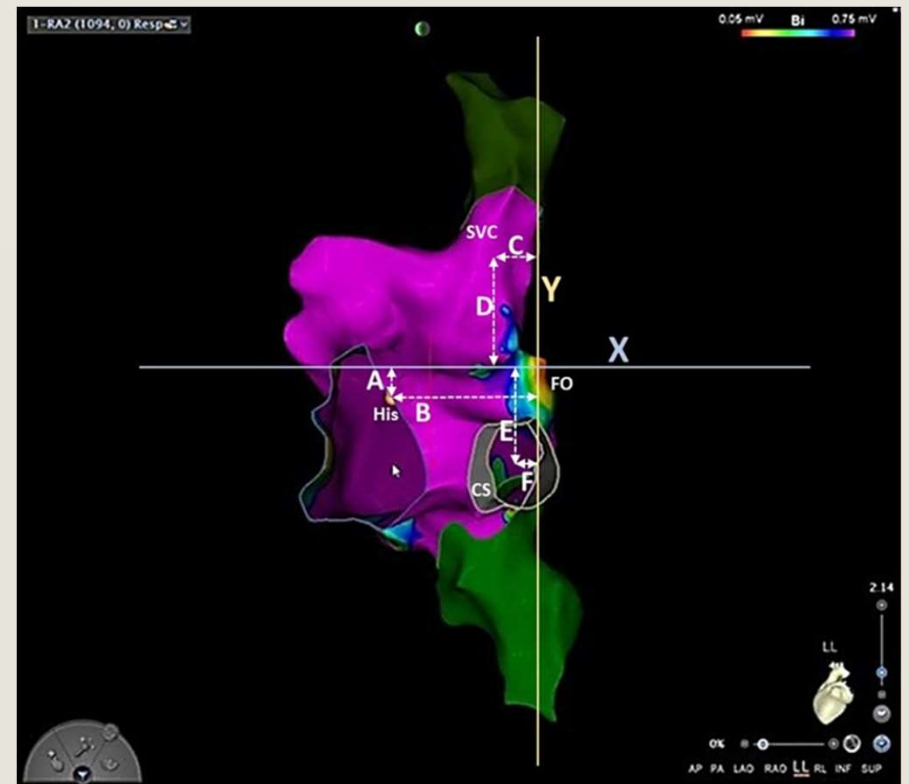
WILEY

Electroanatomic guidance versus conventional fluoroscopy during transeptal puncture for atrial fibrillation ablation

Federica Troisi MD, PhD | Federico Quadrini MD | Antonio Di Monaco MD |
Nicola Vitulano MD | Rosa Caruso DNP | Pietro Guida PhD |
Tommaso Langialonga MD | Massimo Grimaldi MD, PhD



J Cardiovasc Electrophysiol. 2020;31:2607–2613





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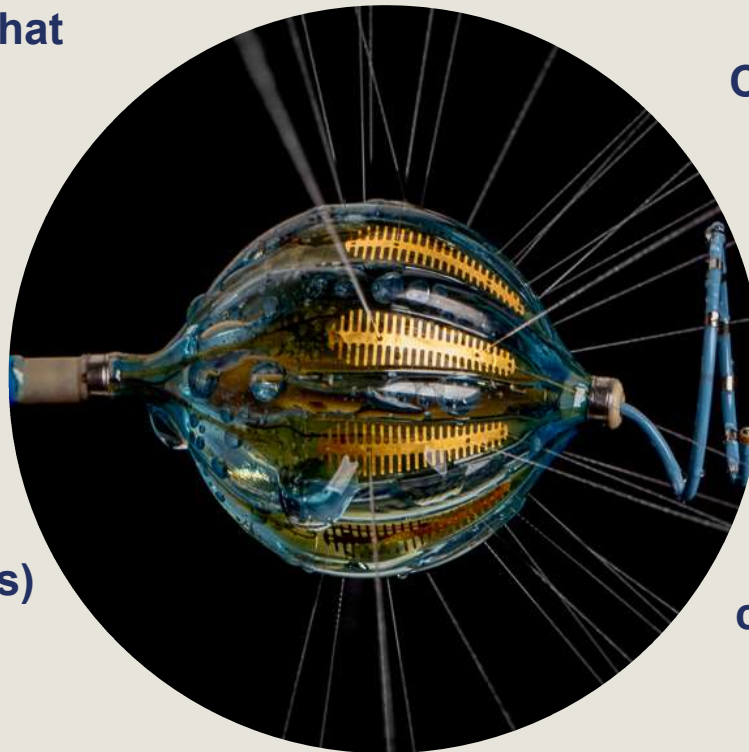
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Multi-electrode RF balloon

Spherical, compliant balloon that conforms to varied PV anatomy

10 irrigated electrodes to deliver customized RF energy from all or selected electrode(s) enabling 'single shot' or segmental ablation



Compatible with CARTO®3 Mapping System to reduce fluoroscopy

Over-the-wire 3F diagnostic catheter for real time PVI validation

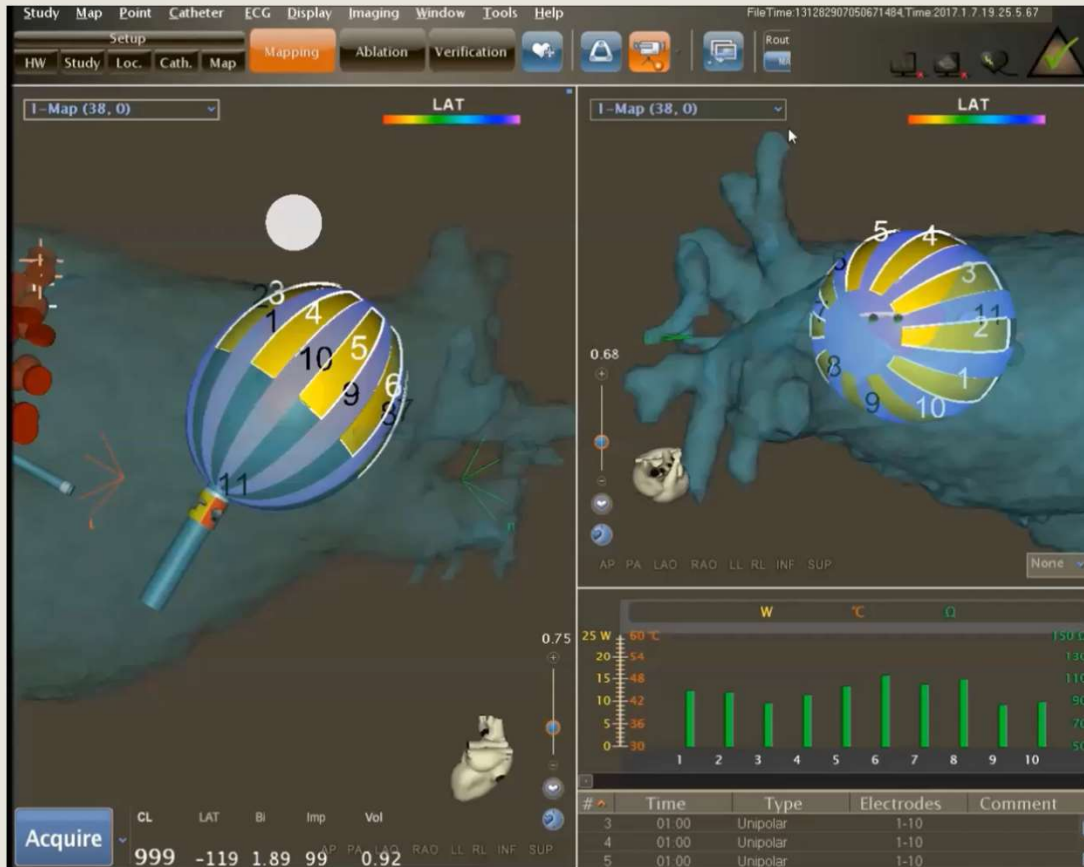


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Radiance: First in human study



- **40 patients** enrolled and **39** treated by 9 operators (5 EU and 4 USA)
 - 4 sites in UK, Italy and Czech Republic
- **100% isolation of PVs with balloon only** (no focal touch-up needed)
 - 79.6% one shot isolation of targeted PVs
- 40.5 min balloon dwell time in left atrium
- 17.5 min fluoro time
- 4.6% (7/150 PVs) reconnection rate



Pulmonary Vein Isolation with the Novel Radiofrequency Balloon in Paroxysmal Atrial Fibrillation Patients - The Multicentre SHINE Study

PATIENT ENROLLMENT	PULMONARY VEIN ISOLATION (PVI)	12 MONTHS FOLLOW-UP				
<p>MULTICENTRE</p>  <p>6</p> <p>EUROPEAN HOSPITALS</p>	<table border="1"><thead><tr><th>CIRCUMFERENTIAL</th><th>SEGMENTAL</th></tr></thead><tbody><tr><td></td><td></td></tr></tbody></table> <p>OR</p>	CIRCUMFERENTIAL	SEGMENTAL			<p>SAFETY PROFILE</p> <p>1.2%</p> <p>PRIMARY ADVERSE EVENT (n=1 Retroperitoneal bleed)</p>
CIRCUMFERENTIAL	SEGMENTAL					
						
<p>PATIENT INCLUSION</p>  <p>85</p> <p>PATIENTS WITH SYMPTOMATIC PAROXYSMAL ATRIAL FIBRILLATION</p> <p>Age 18-75 years First-time ablation LA diameter ≤50 mm, LVEF ≥40%</p>	 <p>PROCEDURAL EFFICIENCY</p> <hr/> <table border="1"><tbody><tr><td>99.7% PVI WITH BALLOON ALONE</td><td>40.3MIN BALLOON DWELL TIME, MEAN</td></tr><tr><td>87.6MIN PROCEDURE TIME, MEAN</td><td>10.9MIN FLUOROSCOPY TIME, MEAN</td></tr></tbody></table>	99.7% PVI WITH BALLOON ALONE	40.3MIN BALLOON DWELL TIME, MEAN	87.6MIN PROCEDURE TIME, MEAN	10.9MIN FLUOROSCOPY TIME, MEAN	<p>12-MONTH EFFECTIVENESS</p>  <p>72.2%</p> <p>12-MONTH FREEDOM FROM SYMPTOMATIC ATRIAL ARRHYTHMIA RECURRENCE*</p> <p>No significant site variation in 12-month freedom from symptomatic atrial arrhythmia recurrence</p> <p>38.0% of patients on Class I/III AAD at 12 months, corresponding to a 32.8% decrease from baseline</p> <p>*Based on binomial analysis with stringent arrhythmia monitoring</p>
99.7% PVI WITH BALLOON ALONE	40.3MIN BALLOON DWELL TIME, MEAN					
87.6MIN PROCEDURE TIME, MEAN	10.9MIN FLUOROSCOPY TIME, MEAN					



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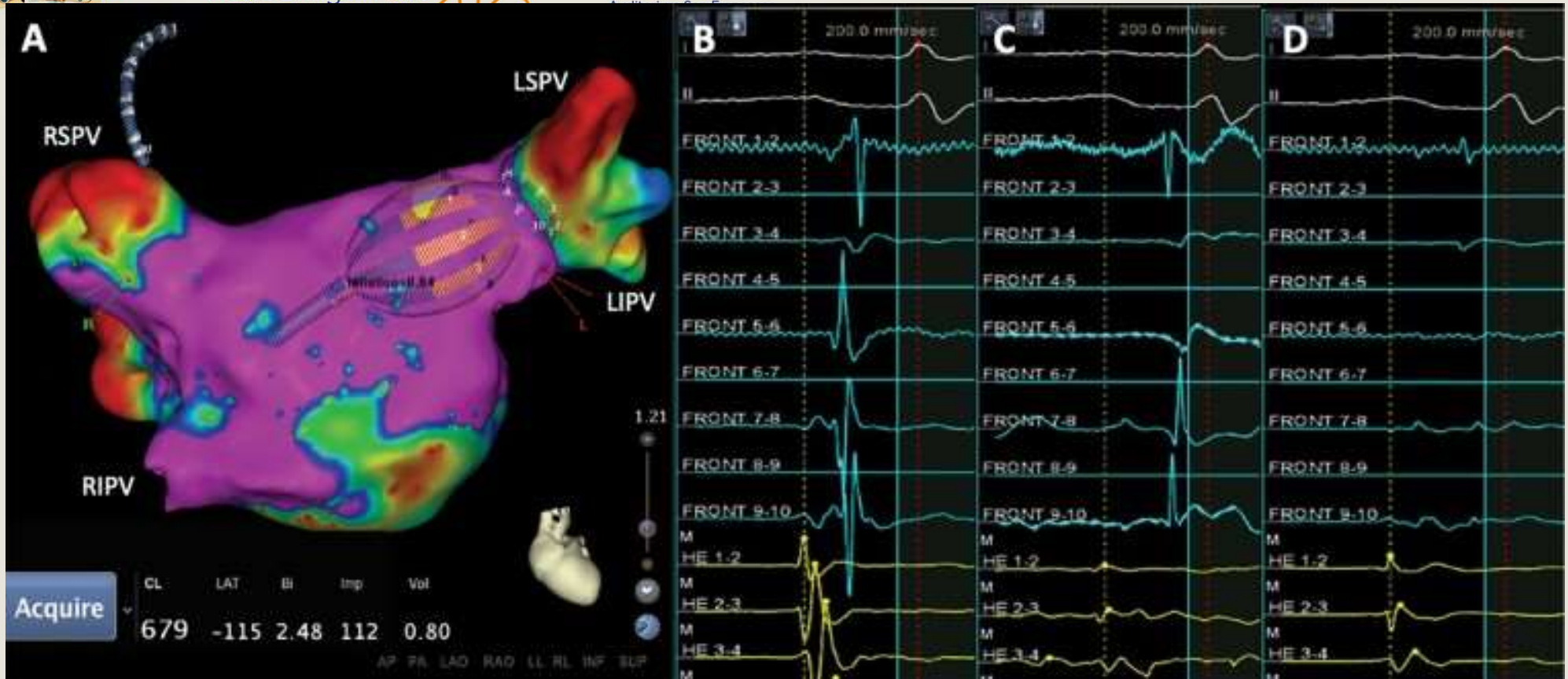
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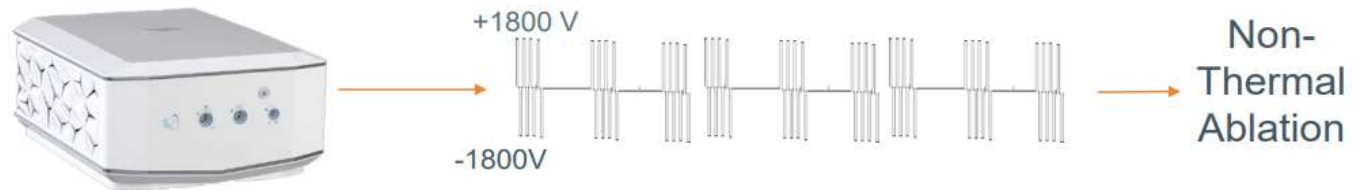


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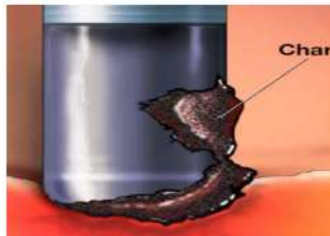
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Irreversible electroporation

PEF Energy is delivered in a series of short, high-voltage, bipolar, biphasic pulses lasting fractions of a second



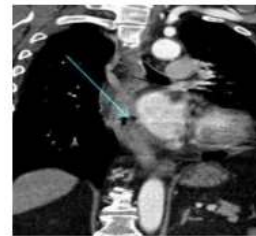
Non-Thermal ablation minimizes the risk of typically thermal induced risks and harms



Char



Steam Pop



AEF



Phrenic Nerve
Palsy



PV Stenosis



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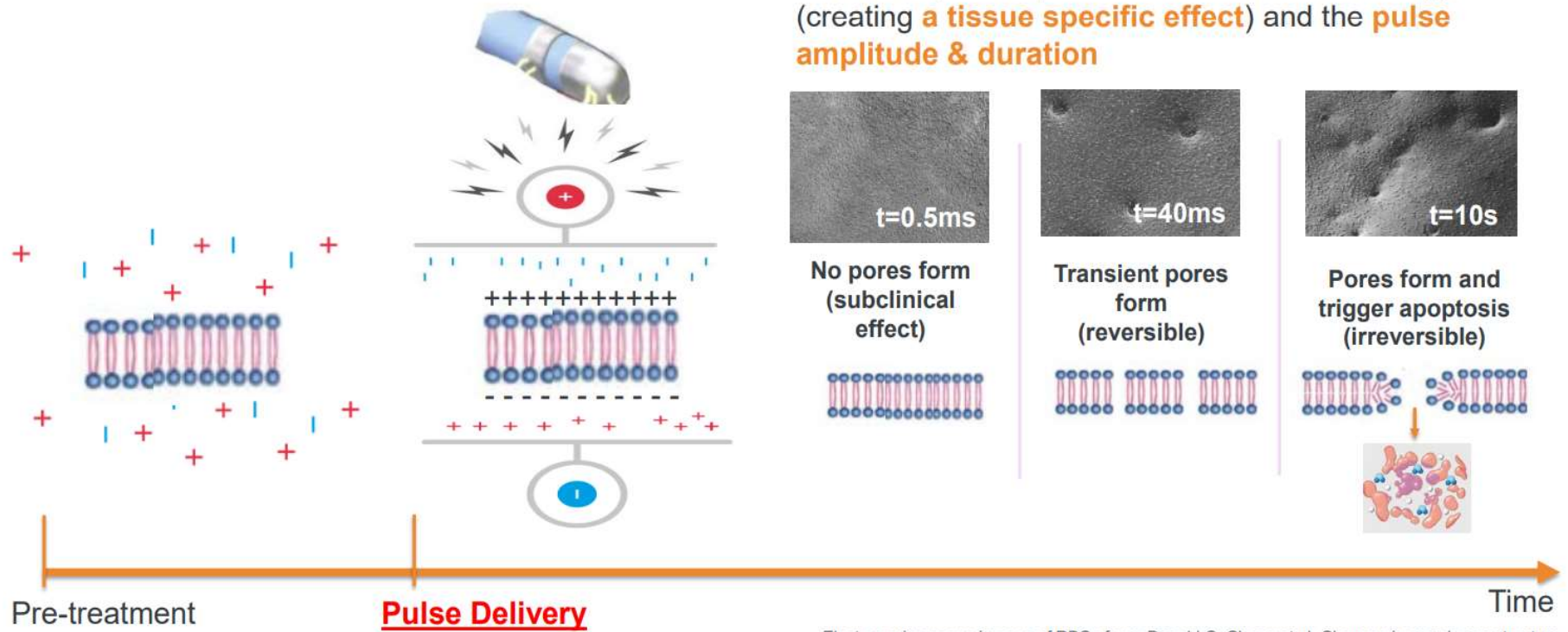
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Electron microscope images of RBCs from: Donald C. Chang et al, Changes in membrane structure induced by electroporation as revealed by rapid-freezing electron microscopy, Biophys. J. 1990



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Time Course of Irreversible Electroporation Lesion Development Through Short- and Long-Term Follow-Up in Pulsed-Field Ablation-Treated Hearts

Massimo Grimaldi , MD, PhD; Antonio Di Monaco , MD; Tara Gomez , PhD; Dror Berman, BS; Keshava Datta, PhD; Tushar Sharma, MD; Assaf Govari, PhD; Andres Altmann , MSc; Luigi Di Biase , MD

Circ Arrhythm Electrophysiol. 2022;15:e010661. |



Table 2. Study Results Summary

	Subacute; n=6	Chronic study; n=4
Mean survival time, d, \pm SD	9 \pm 0	28.5 \pm 0.5
Mean PV diameter change, %, \pm SD	14.5 \pm 12.0%	11.8 \pm 13.3%
Mean lesion depth, mm, \pm SD	3.2 \pm 0.9	2.8 \pm 0.8
Mean lesion width, mm, \pm SD	16.1 \pm 3.6	17.1 \pm 8.9
Acute PV isolation (RIPV and RSPV)	12/12 (100%)	7/7(100%)*
Follow-up PV isolation	12/12 (100%)	6/6 (100%)
Acute SVC isolation	6/6 (100%)	4/4 (100%)
Follow-up SVC isolation	6/6 (100%)	4/4(100%)

PV indicates pulmonary vein; RIPS, right inferior pulmonary vein; RSPV, right superior pulmonary vein; and SVC, superior vena cava.

*RSPV isolation was not performed for one swine, resulting in 7 evaluable veins for the chronic cohort.



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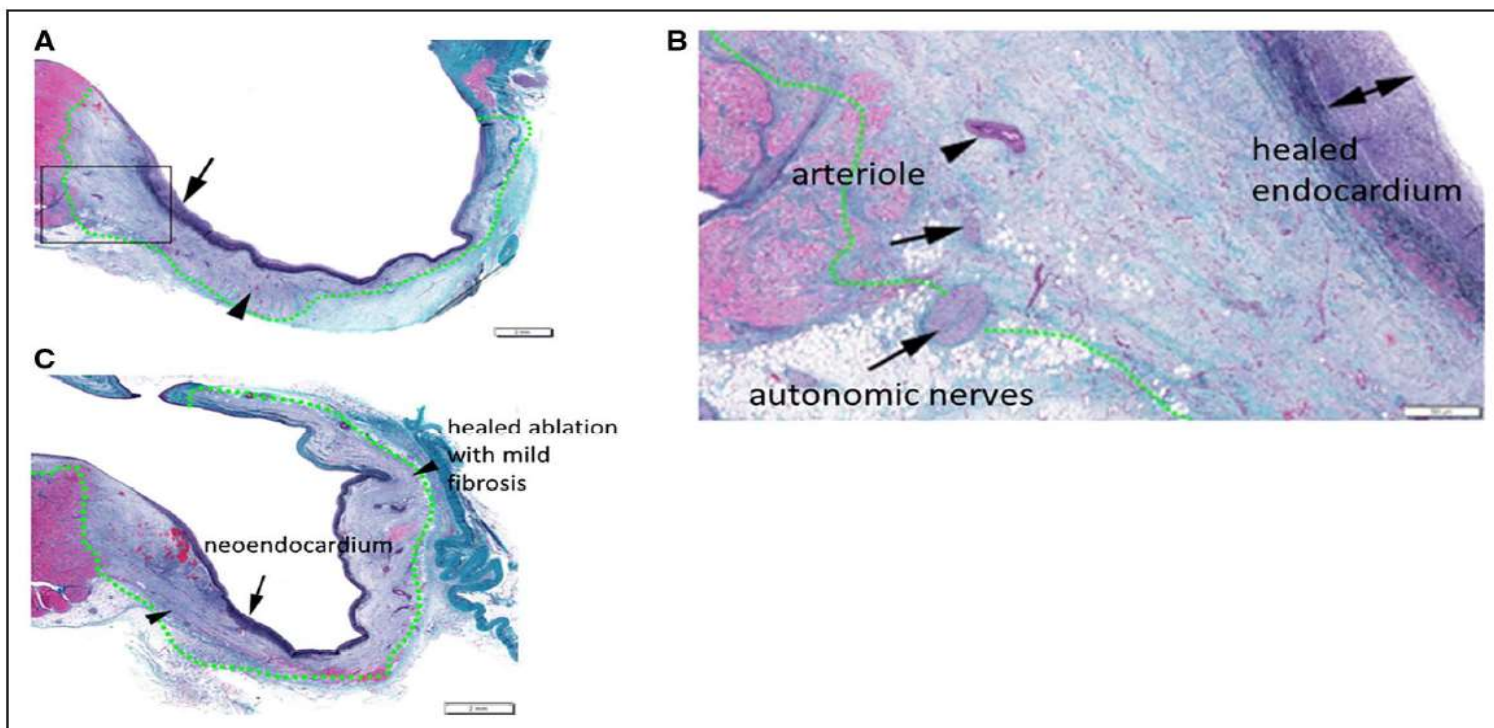


Figure 4. Histological analysis of chronic cohort.

A **Posterior wall**. Green dotted line denotes healed ablated area showing no adverse changes, arrow denotes thin neoendocardium, arrowhead denotes healed ablation with mild fibrosis, back box denotes area detailed in **B**. **B**, Double arrow denotes mature endothelialized fibromuscular neoendocardium (healed endocardium), arrows denote intact autonomic nerves, arrowhead denotes intact arteriole within the healed ablated area. **C**, Posterior wall. Green dotted line denotes healed ablated area showing no adverse changes, arrow denotes thin neoendocardium, arrowheads denote healed ablation with mild fibrosis.



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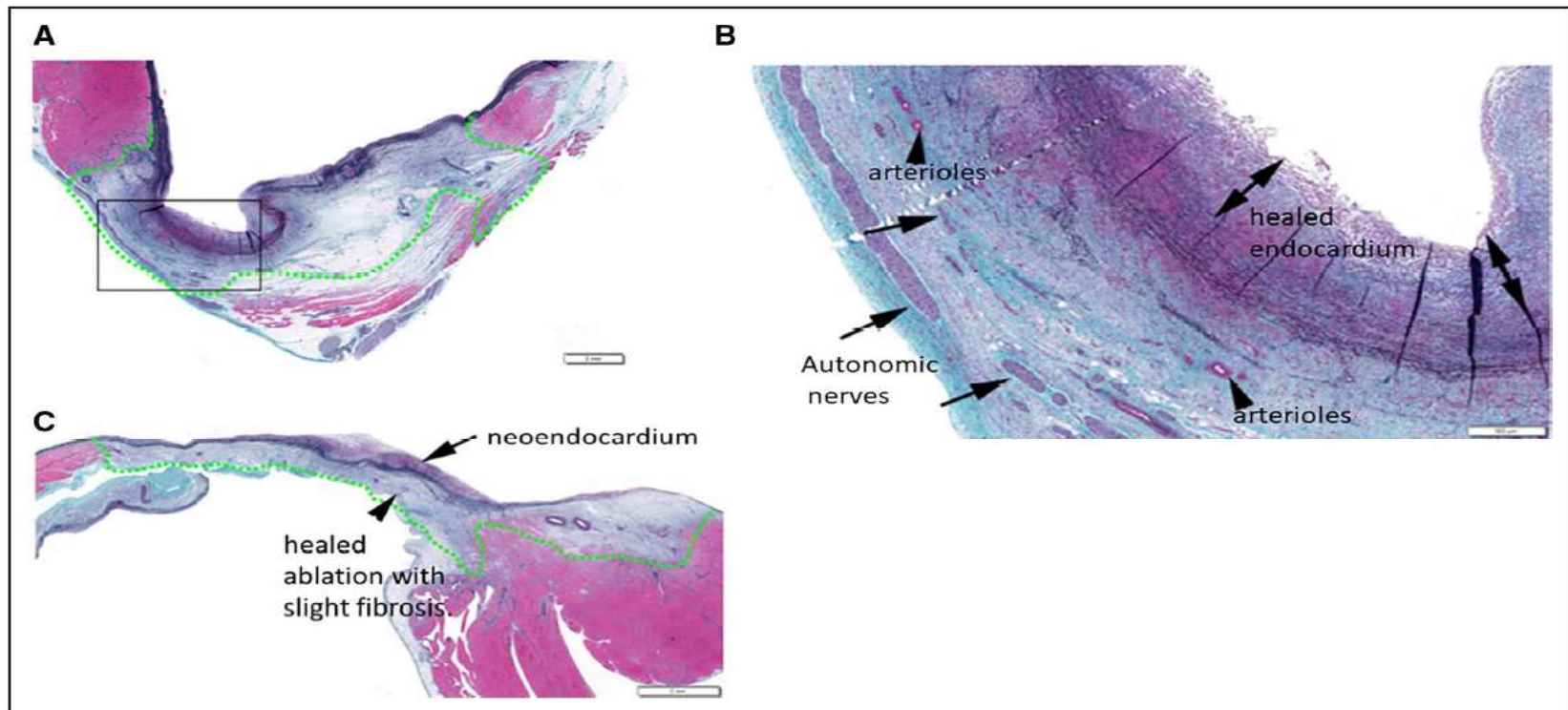


Figure 5. Histological analysis after 28 days from pulsed-field ablation.

A, Right superior pulmonary vein. Green dotted line= healed ablated area showing no adverse changes. back box= area detailed in **B**. **B**, Double arrows denote mature endothelialized fibromuscular neoendocardium (healed endocardium), arrows denote intact autonomic nerves, arrowheads= intact arterioles within the healed ablated area. **C**, Superior vena cava. Green dotted line denotes healed ablated area showing no adverse changes, arrow= thin neoendocardium, arrowhead denote healed ablation with slight fibrosis.



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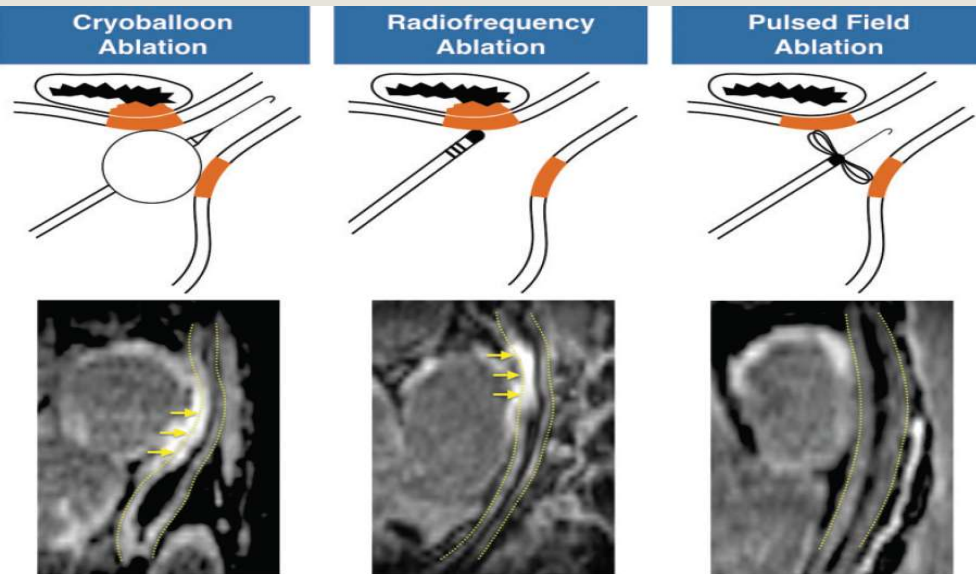
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Pulsed field ablation selectively spares the oesophagus during pulmonary vein isolation for atrial fibrillation

Cochet et al. EP Europace (2021)..

Hubert Cochet^{1,2*}, Yosuke Nakatani³, Soumaya Sridi-Cheniti²,



Acute Esophageal Injuries on LGE CMR

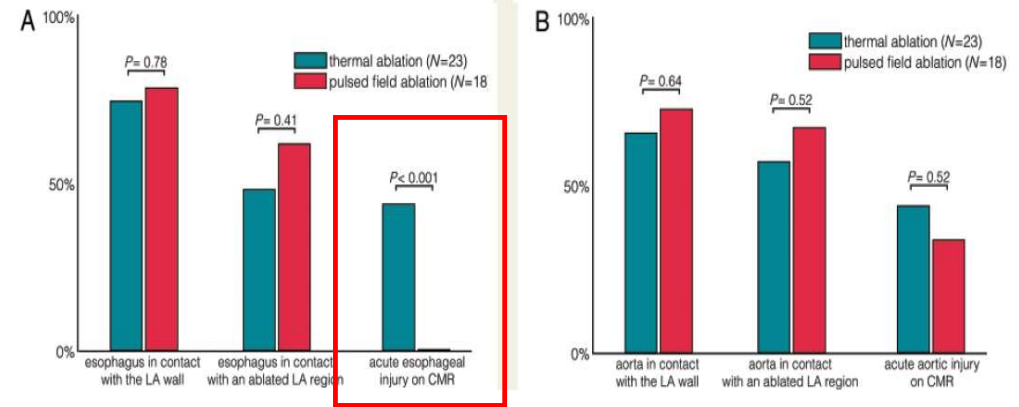
Danno Esofageo

Oesophagus

CMR imaging was performed before, acutely (<3h) and 3mo post-ablation (18 PFA; 23 thermal ablation)

No esophageal lesions were observed in PFA patients

Thermal methods induced high rates of esophageal lesions (43%)



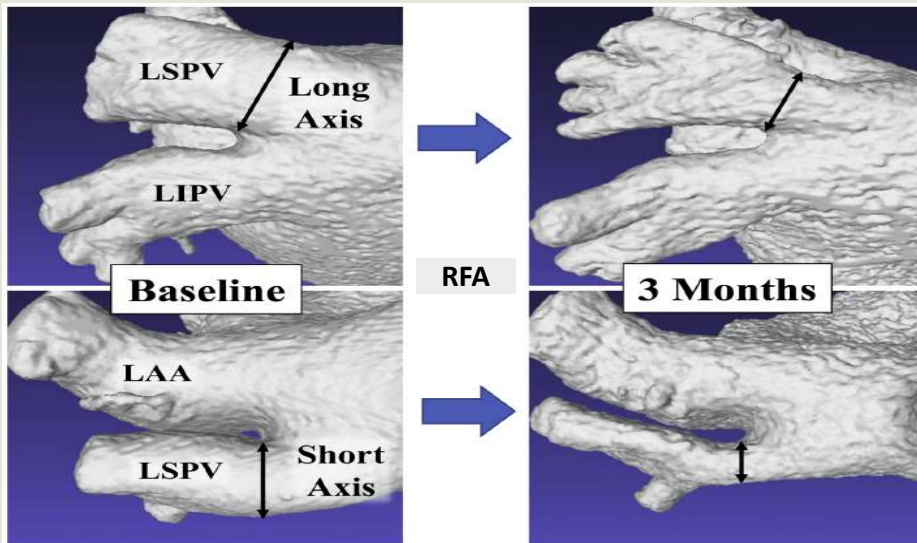


Stenosi delle vene polmonari

Ostial dimensional changes after pulmonary vein isolation: Pulsed field ablation vs radiofrequency ablation [©] Kuroki et al. Heart rhythm 17.9 (2020): 1528-1535.

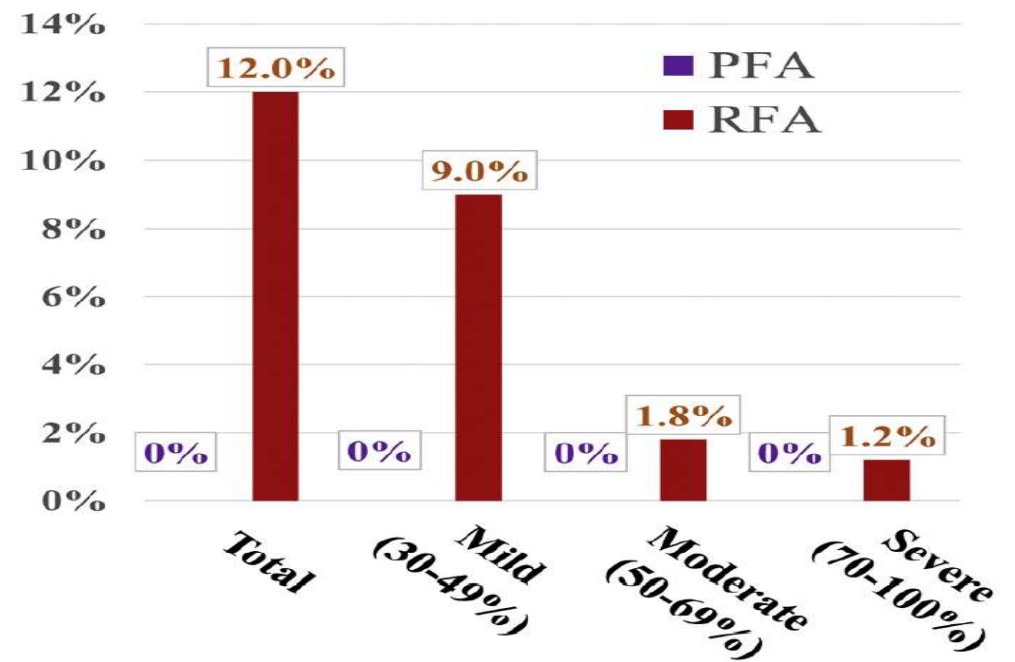
PV Stenosis: EAM and CT at 3-months post-PVI

- No instances PV stenosis or narrowing



PV Stenosis

PV Narrowing / Stenosis
 Quantitative + Qualitative Analysis





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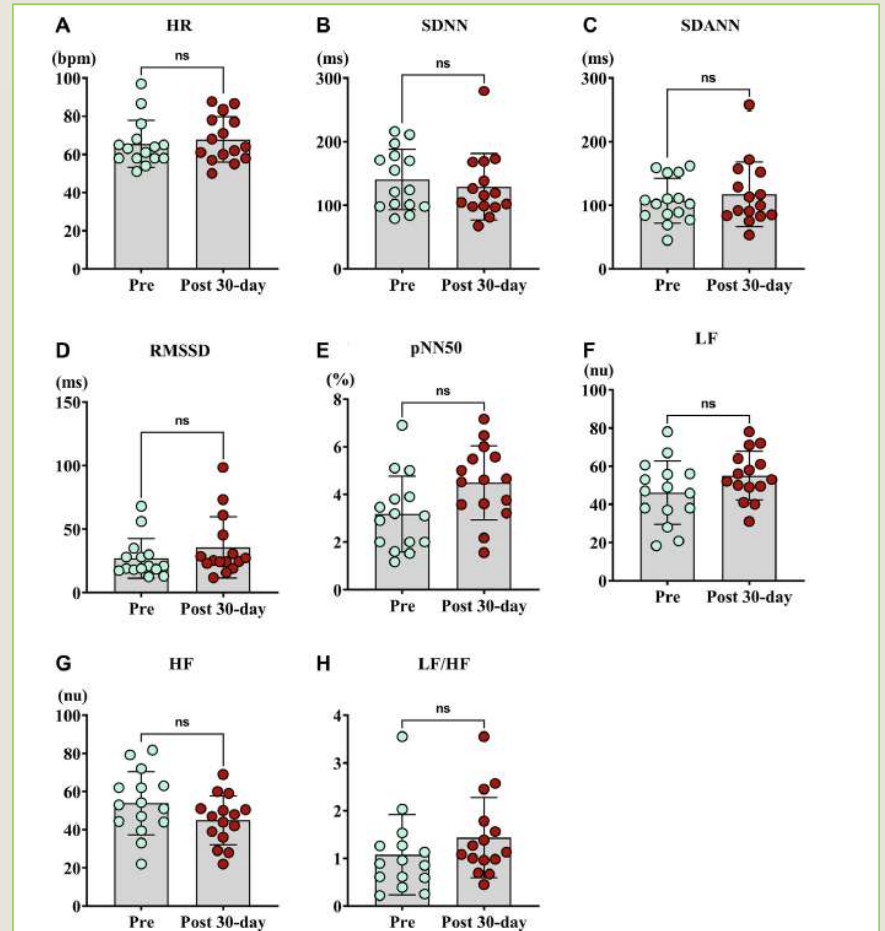
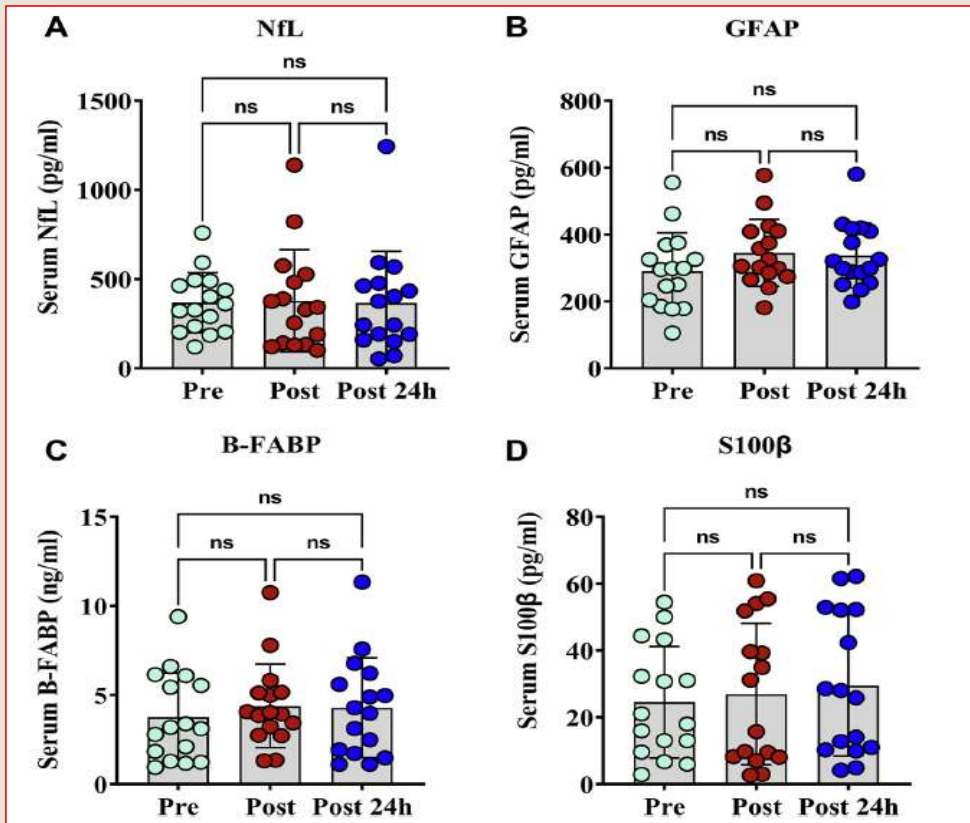
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Sistema nervosa autonomo





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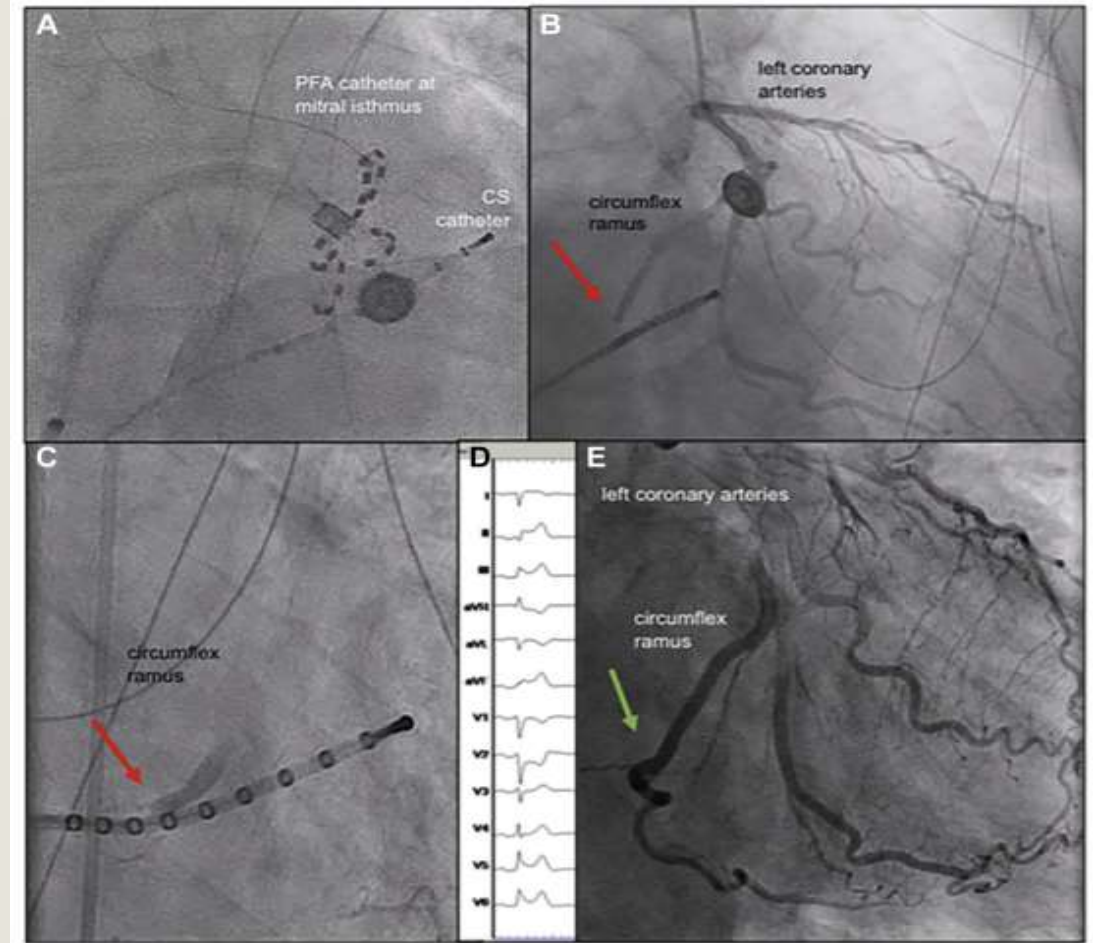
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Coronary Spasm During Pulsed Field Ablation of the Mitral Isthmus Line



JACC CE 2021;12:1618-27



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Circulation: Arrhythmia and Electrophysiology

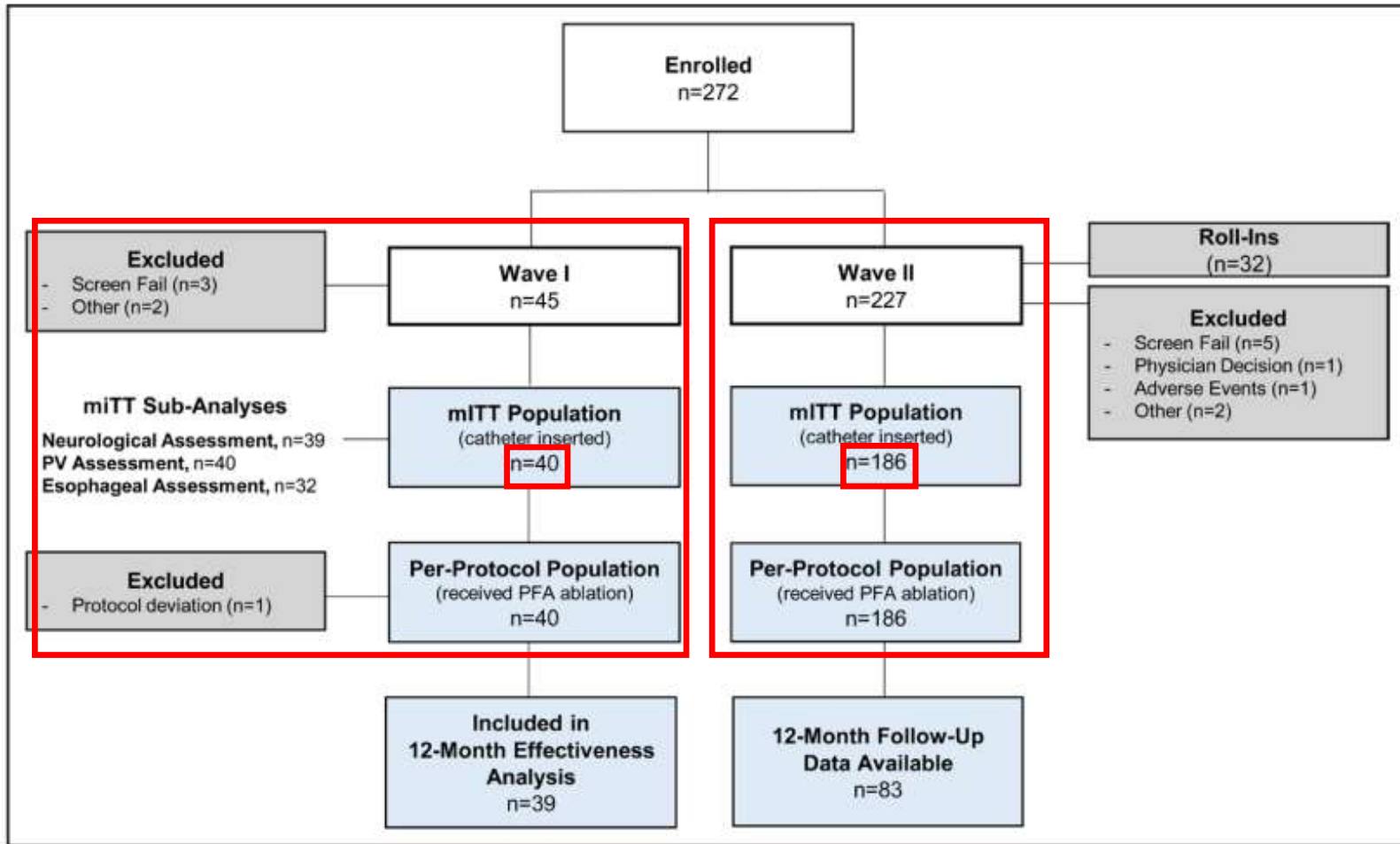
ORIGINAL ARTICLE



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

Mattias Duytschaever¹, MD, PhD; Tom De Potter², MD; Massimo Grimaldi³, MD, PhD; Ante Anic⁴, MD; Johan Vijgen⁵, MD; Petr Neuzil⁶, MD, PhD; Hugo Van Herendael, MD; Atul Verma⁷, MD; Allan Skanes⁸, MD; Daniel Scherr, MD; Helmut Pürerfellner⁹, MD; Gediminas Rackauskas¹⁰, MD; Pierre Jaïs¹¹, MD; Vivek Y. Reddy¹², MD; on behalf of the insPIRE Trial Investigators*







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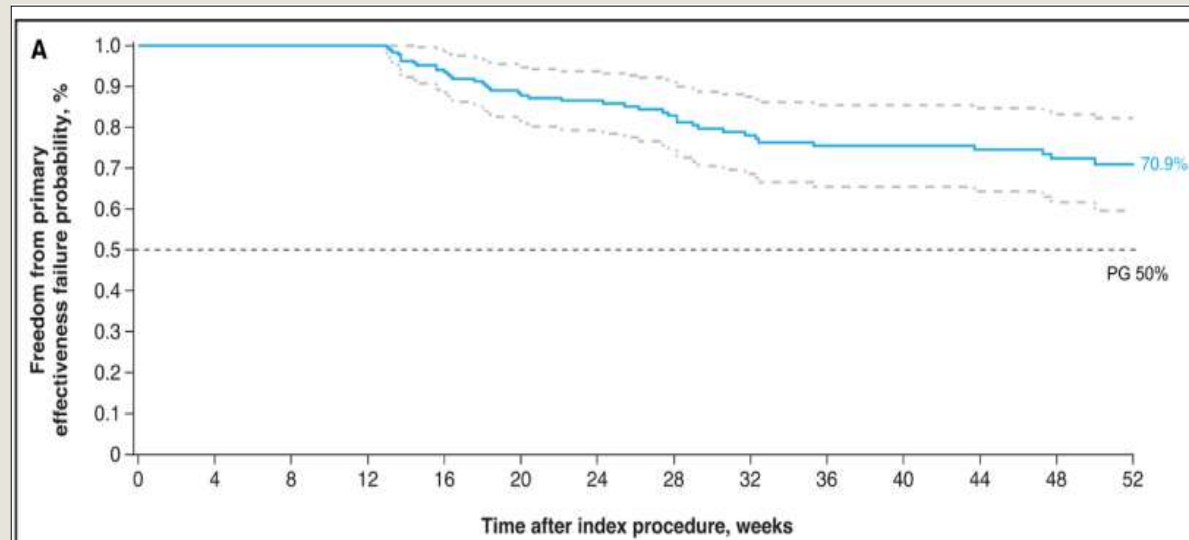
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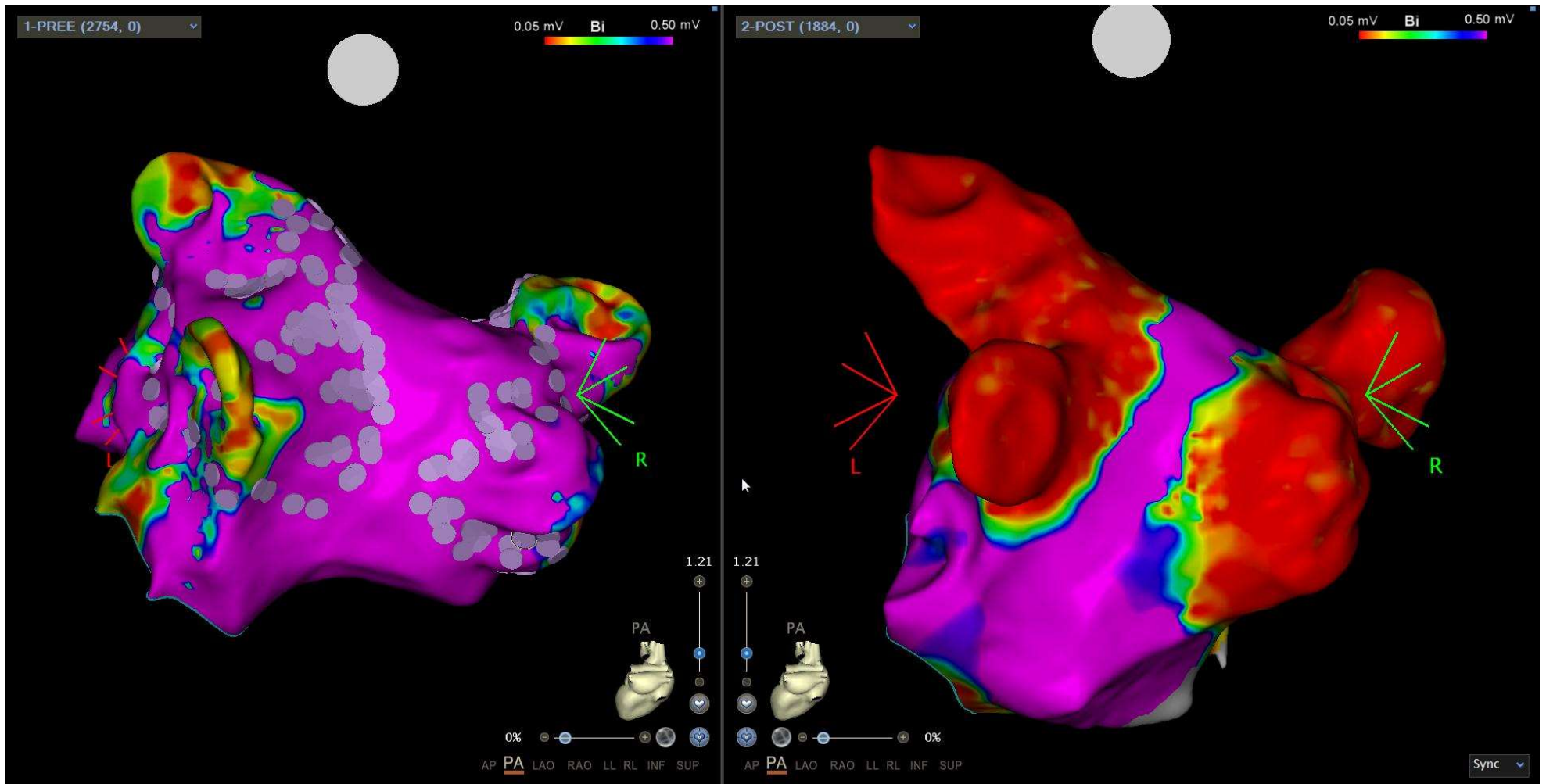
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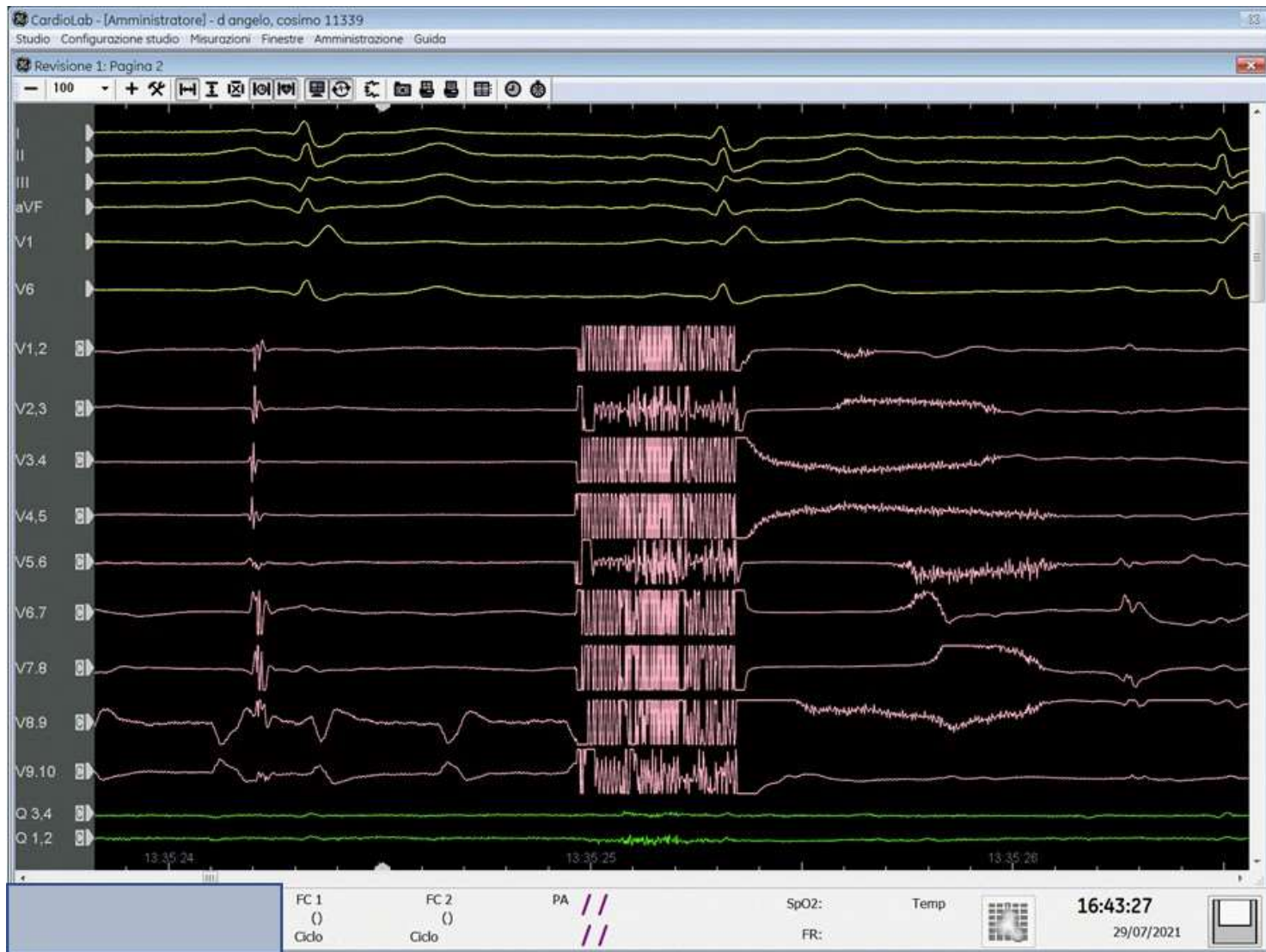
Adverse events*	Wave I (n=40)	Wave II (n=186)
PAEst	0 (0)	0 (0)
Atrioesophageal fistula	0 (0)	0 (0)
Cardiac tamponade/perforation	0 (0)	0 (0)
Pulmonary vein stenosis	0 (0)	0 (0)
Device- or procedure-related death	0 (0)	0 (0)
Major vascular access complication/bleeding	0 (0)	0 (0)
Myocardial infarction	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



Circ Arrhythm Electrophysiol. 2023;16:e011780









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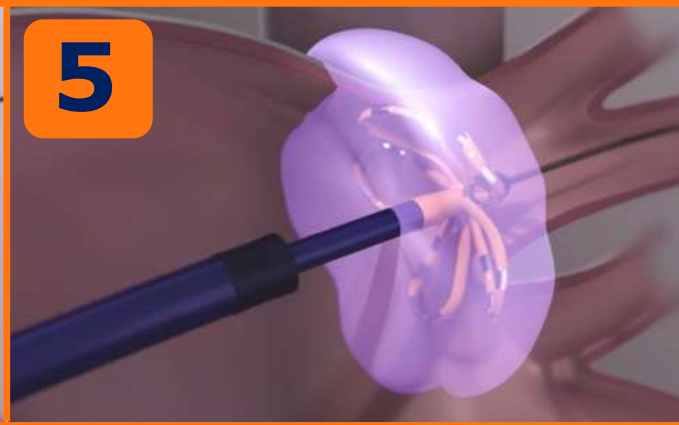
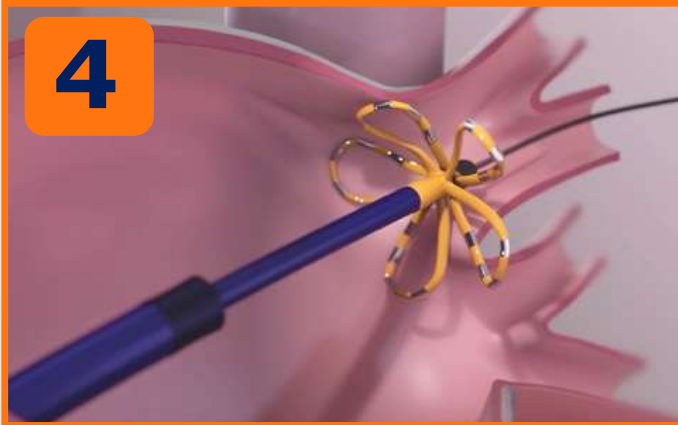
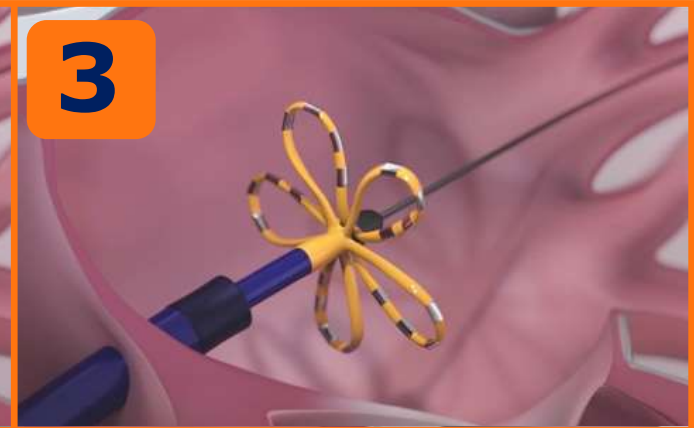
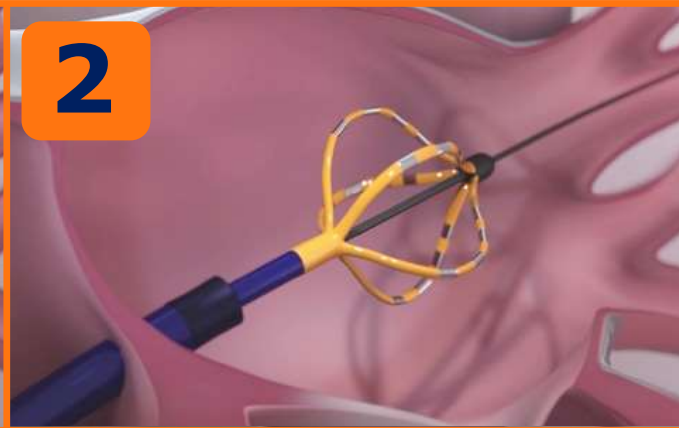
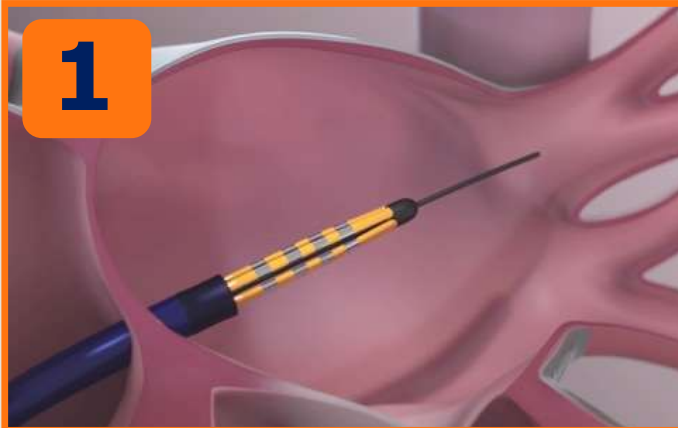
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IMPULSE, PEFCAT, PEFCAT II

Pulsed Field Ablation of Paroxysmal Atrial Fibrillation

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

121 patients with **paroxysmal AF** were treated with PFA (3 centers, 5 operators)

- IMPULSE (40 pts; NCT03700385)
- PEFCAT (71 pts; NCT03714178)
- PEFCATII (10 pts; NCT04170608)

Waveform

- Monophasic PFA: 15 patients
- Early biphasic PFA: 57 patients
- Optimized biphasic PFA: 49 patients

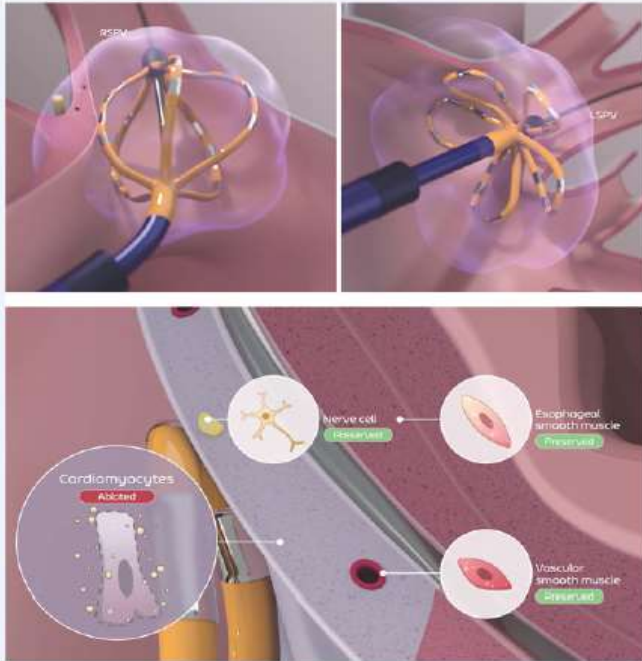
TABLE 1 Patient Characteristics

	Total Cohort (N = 121)	Optimized Waveform Cohort (n = 49)
Age, yrs	57.4 ± 10.3	56.9 ± 10.4
Male	89 (73.6)	32 (65.3)
LA diameter, mm	40.5 ± 4.5	40.0 ± 5.0
LVEF, %	62.5 ± 5.7	61.2 ± 7.2
Sleep apnea	4 (3.3)	2 (4.1)
COPD	4 (3.3)	0 (0.0)
Hypertension	68 (56.2)	29 (59.2)
Diabetes	11 (9.1)	3 (6.1)
Dyslipidemia	41 (33.9)	17 (34.7)
Stroke or TIA	6 (5.0)	3 (6.1)
CAD (MI/CABG)	4 (3.3)	2 (4.1)
Antiarrhythmics	118 (97.5)	49 (100.0)
Class I	83 (68.6)	38 (77.6)
Class III	23 (19.0)	8 (16.3)
Beta-blockers	44 (36.4)	18 (36.7)



IMPULSE, PEFCAT, PEFCAT II

PFA Catheter & Mechanism of Ablation



Safety

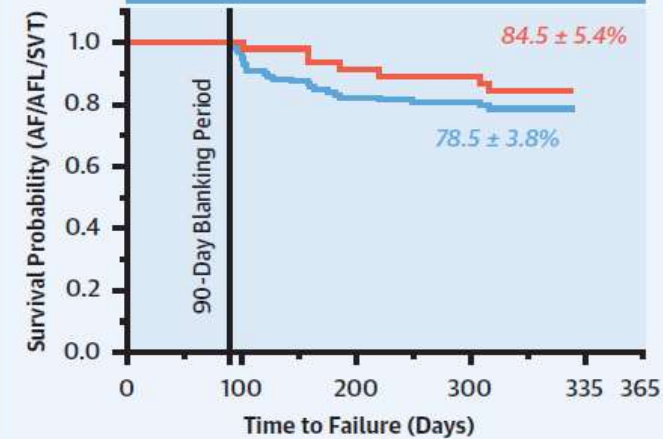
- *Esophageal Damage* 0%
 - *Esophageal Dysmotility* 0%
 - *Atrioesophageal Fistula* 0%
- *Pulmonary Vein Stenosis* 0%
- *Phrenic Nerve Injury* 0%
- *Stroke* 0%
 - *Transient Ischemic Attack* 0.9%
- *Pericardial Effusion* 0.8%
- *Vascular injury* 1.7%
- *Death* 0%

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%

Freedom from AF, AFL or AT



No. at Risk

	114	97	89	81
— Entire Cohort	114	97	89	81
— PFA-OW	46	43	40	36



PFA in persistent AF

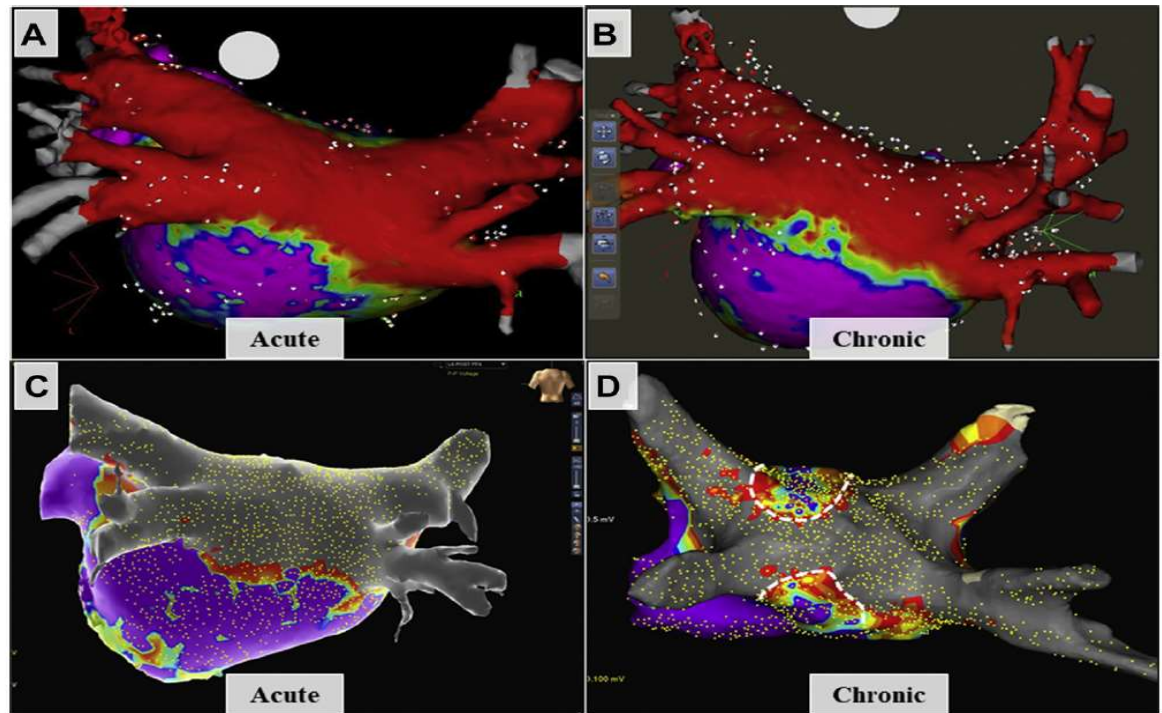
Pulsed Field Ablation in Patients With Persistent Atrial Fibrillation

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

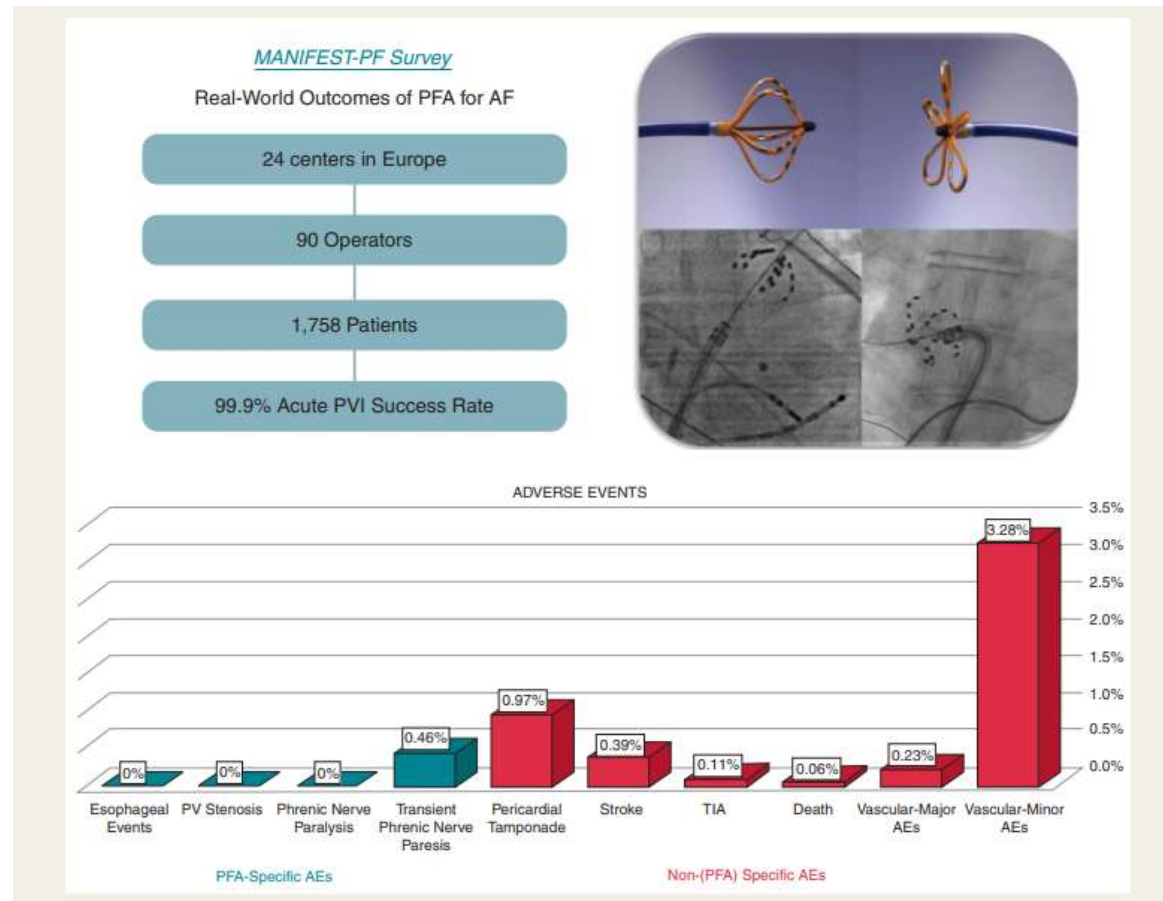


Posterior wall isolation

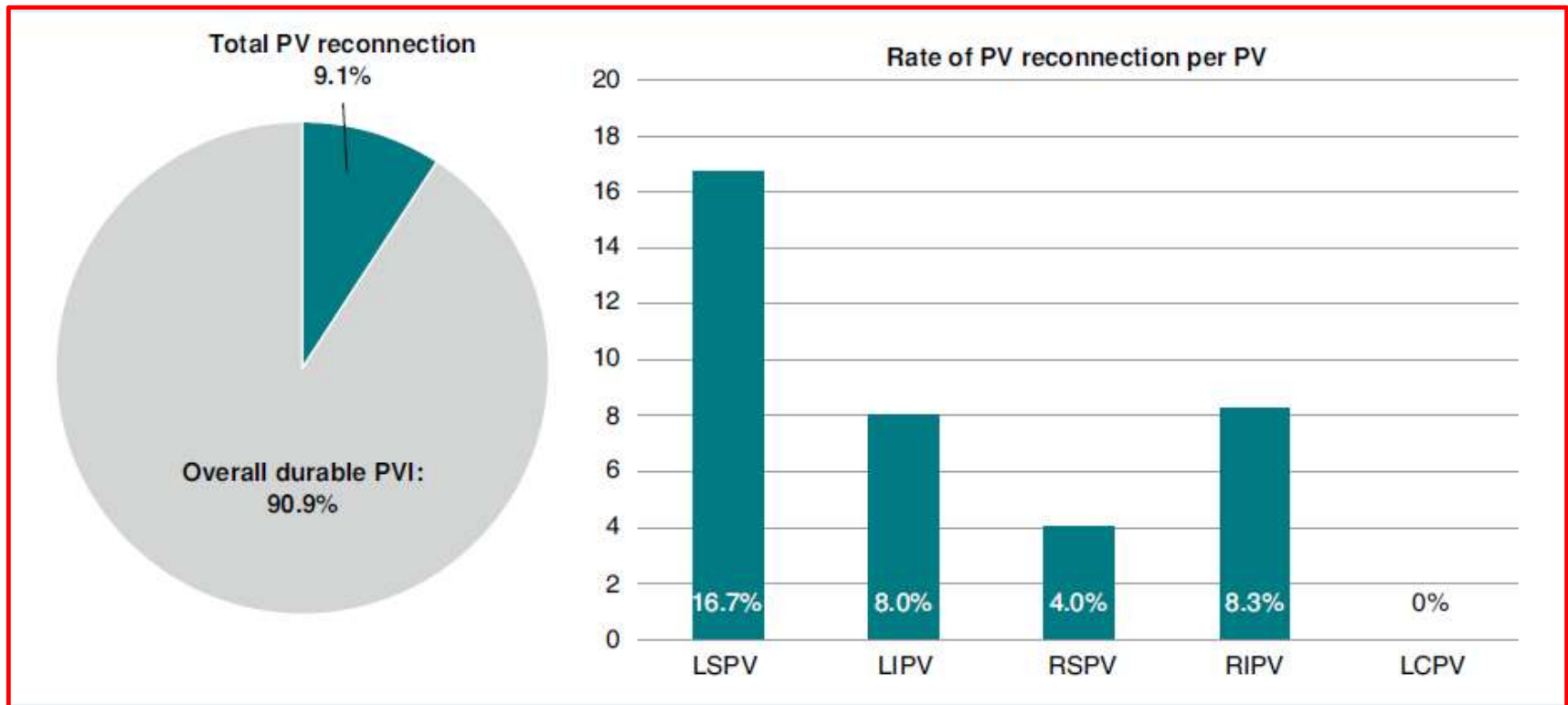
FIGURE 4 Durability of Posterior Wall PFA



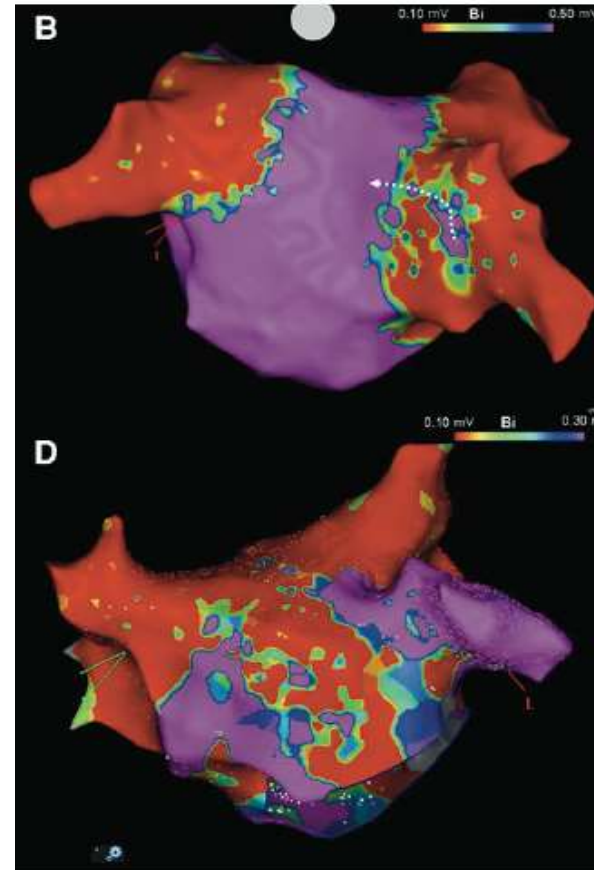
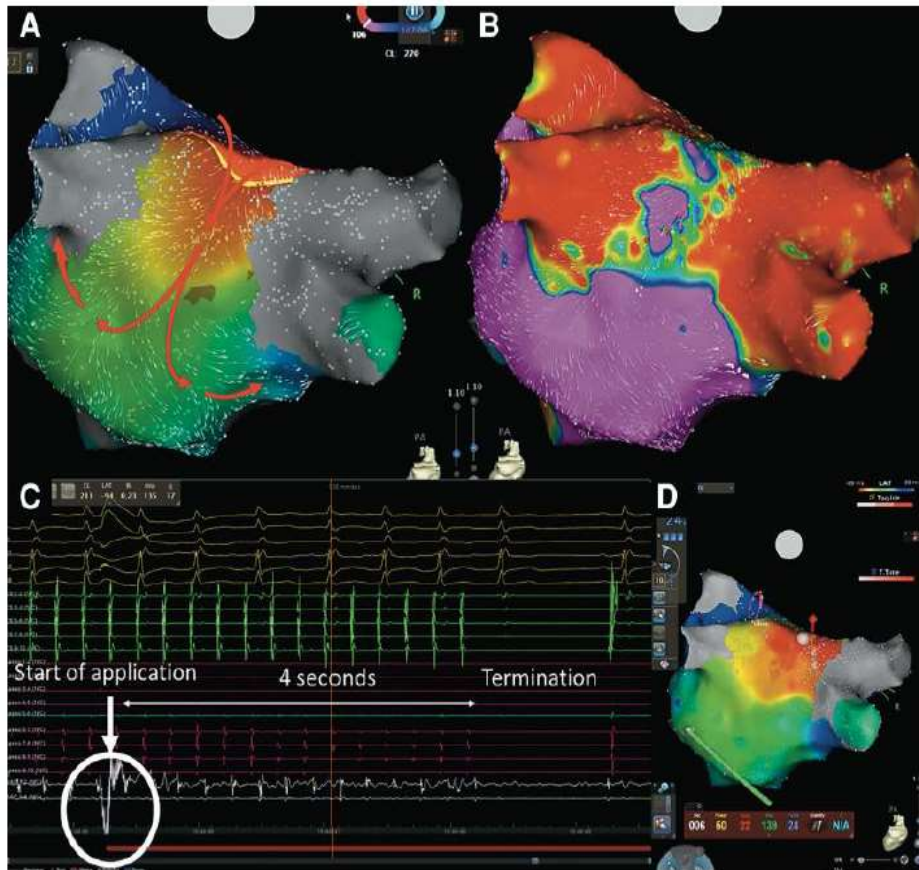
Multi-national survey on the methods, efficacy, and safety on the post-approval clinical use of pulsed field ablation (MANIFEST-PF)



Findings from repeat ablation using high-density mapping after pulmonary vein isolation with pulsed field ablation

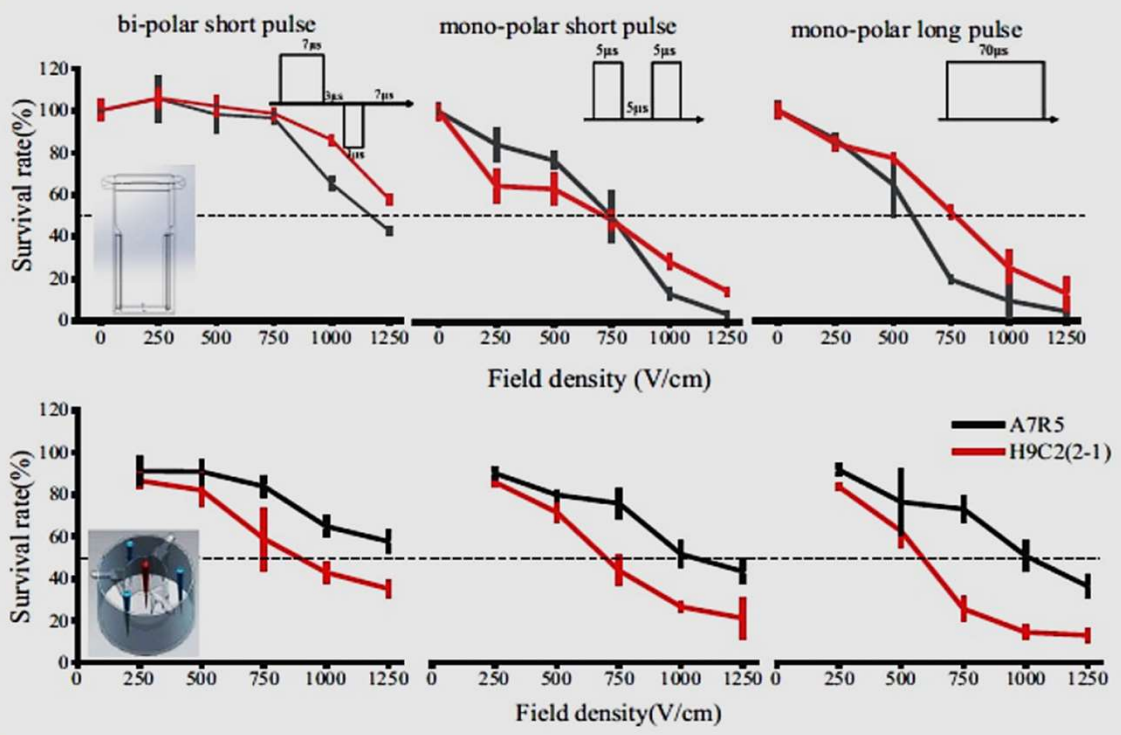


Findings from repeat ablation using high-density mapping after pulmonary vein isolation with pulsed field ablation

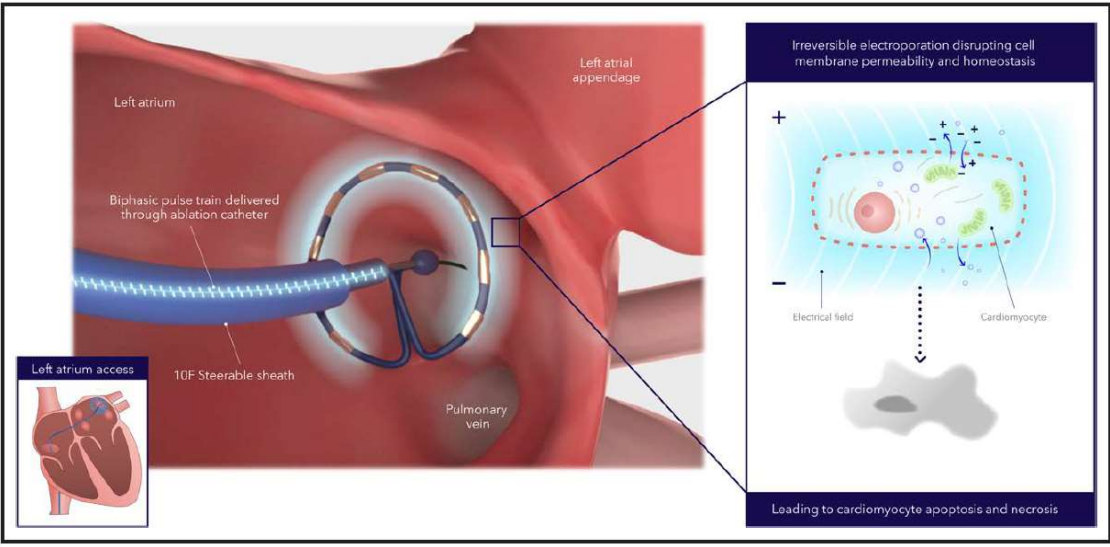
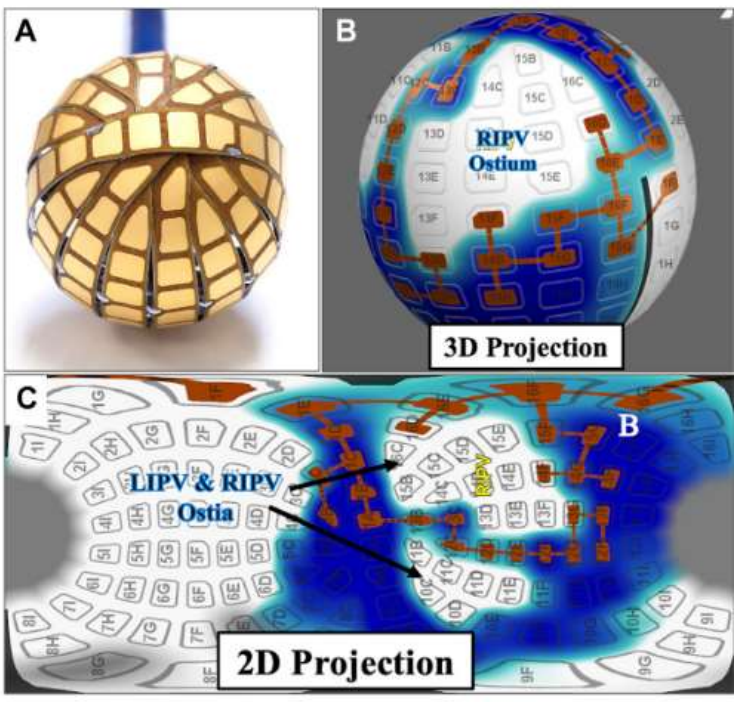
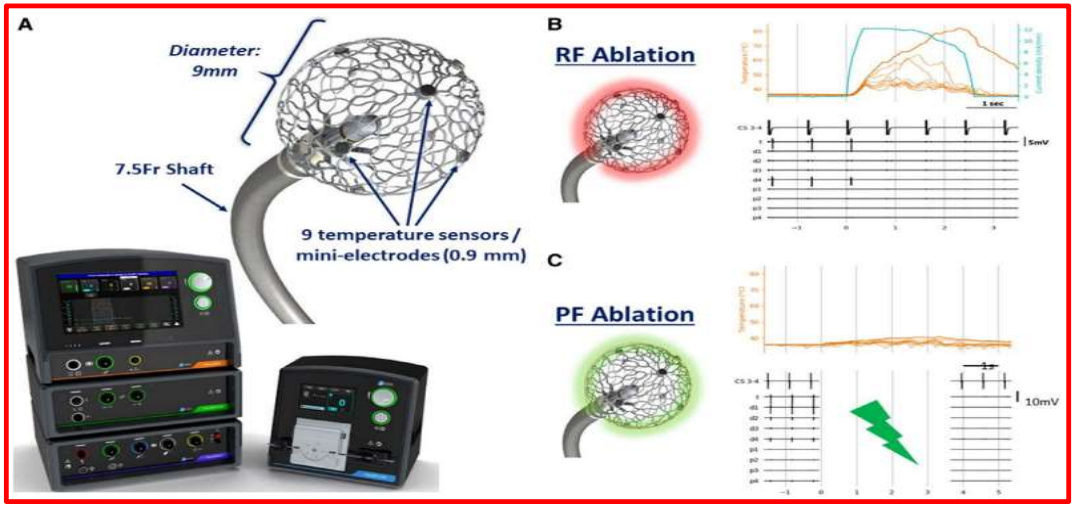


Study on Optimal Parameter and Target for Pulsed-Field Ablation of Atrial Fibrillation

Xuying Ye^{1,2}, Shangzhong Liu³, Huijuan Yin⁴, Qiang He², Zhixiao Xue^{3,5*}, Chengzhi Lu^{1,2*} and Siying Su⁵



- Energia
- Dimensioni elettrodi
- Distanza fra elettrodi
- Durata singolo impulso
- Numero impulsi
- Numero di treni di impulsi
- Intervallo fra treni di impulsi





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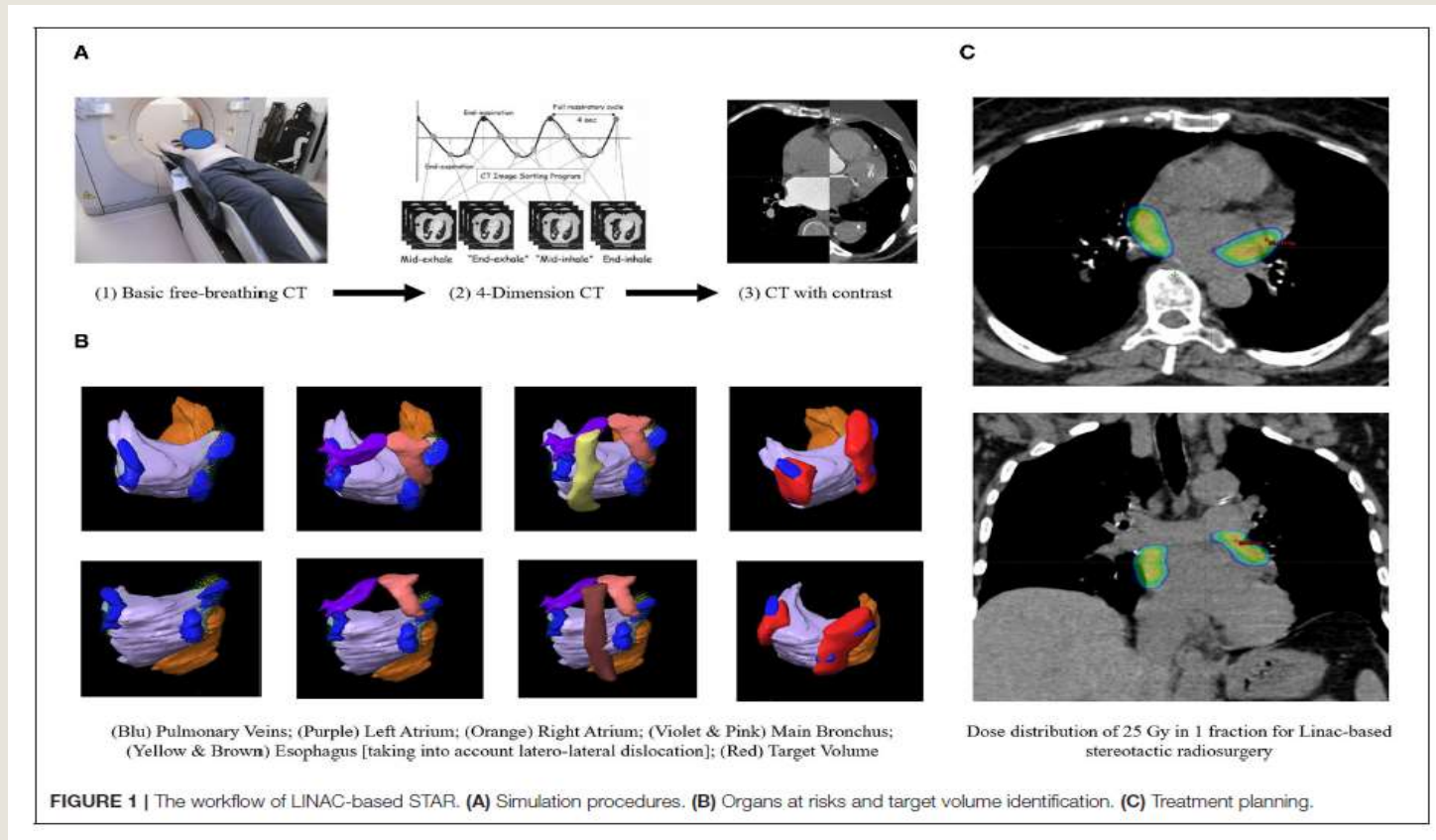
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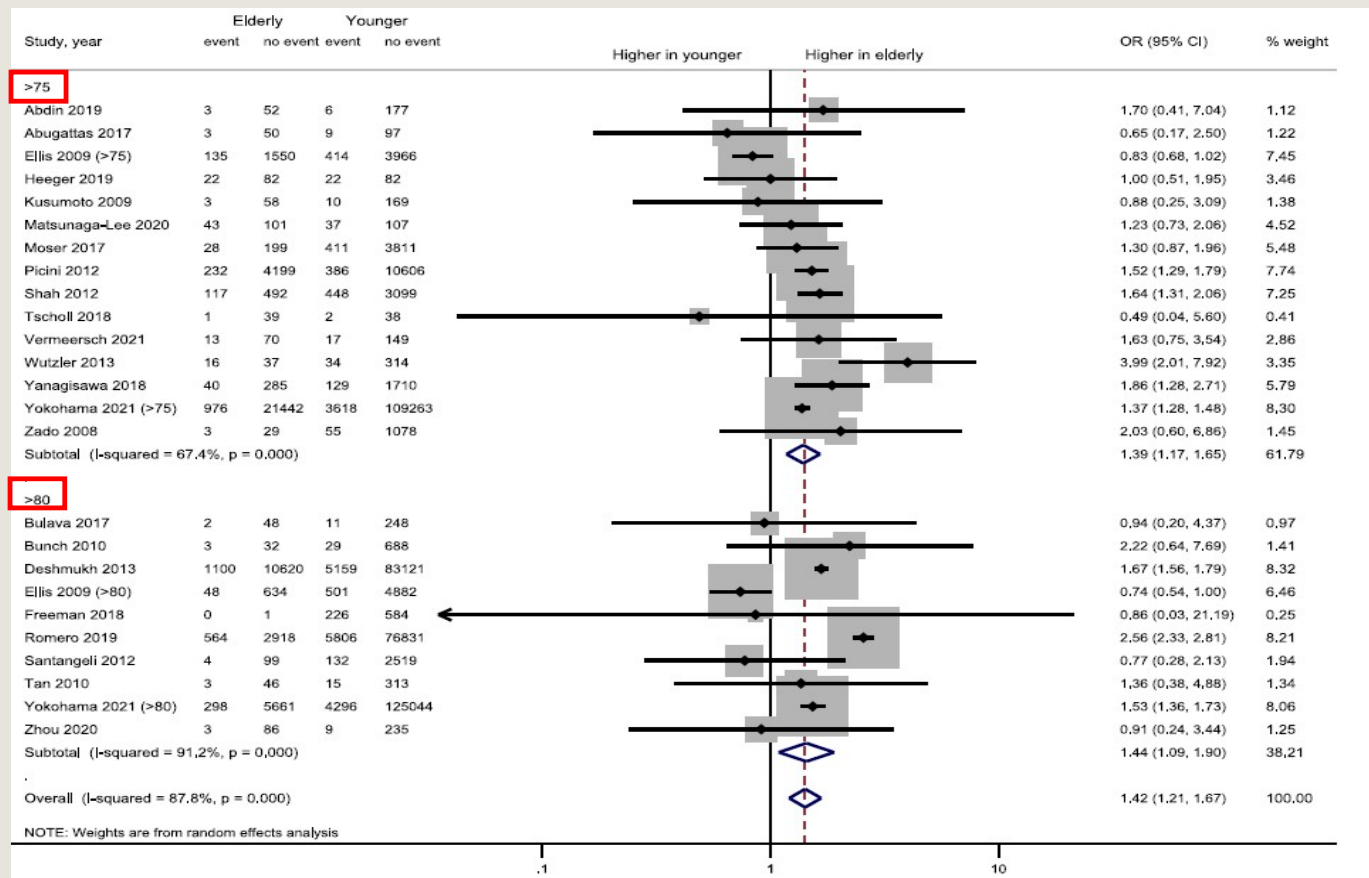
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STAR for PVI in elderly



Catheter ablation for atrial fibrillation in the elderly >75 years old: Systematic review and meta-analysis

Complication rates





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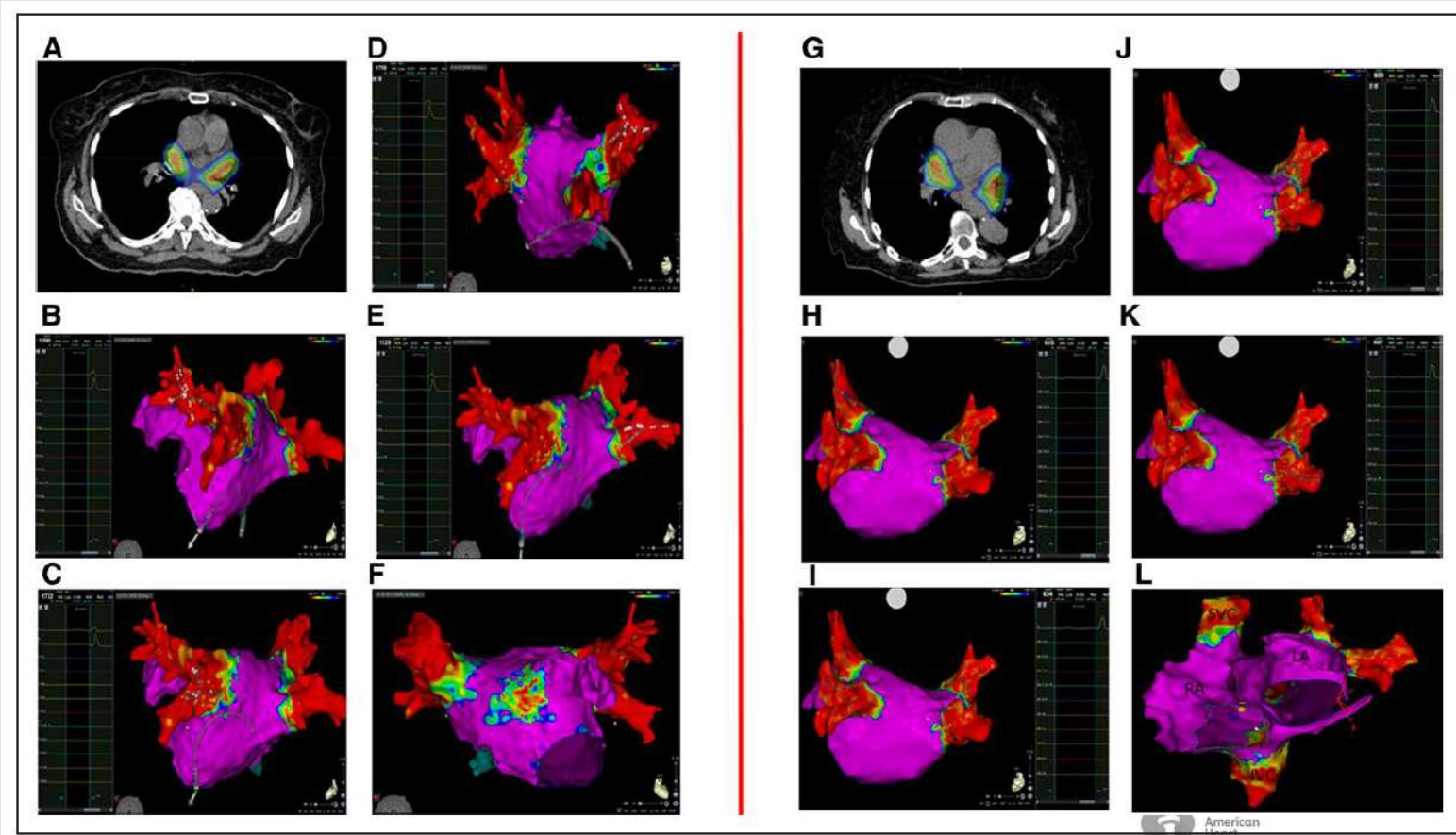
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STAR for PVI in elderly



Di Monaco A. Circ Arrhythm Electrophysiol. 2022;15:e010880



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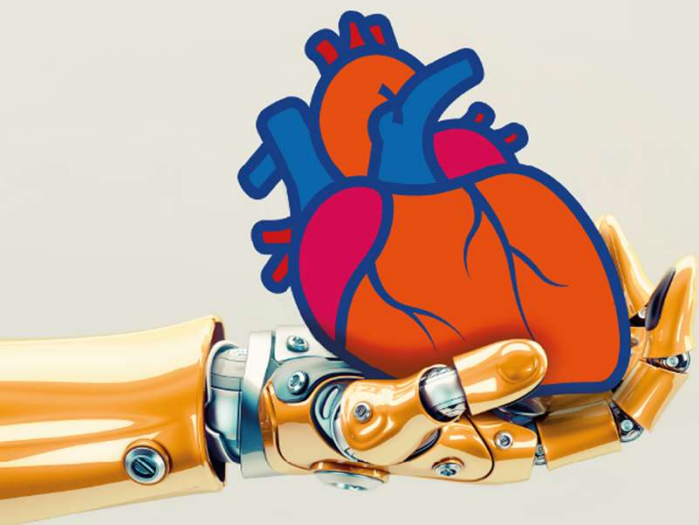


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European Heart Journal (2020) 00, 1–125



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Grazie per l'attenzione!