Pulsed Field Ablation:

REAL REVOLUTION IN ELECTROPHYSIOLOGY

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Disclosures

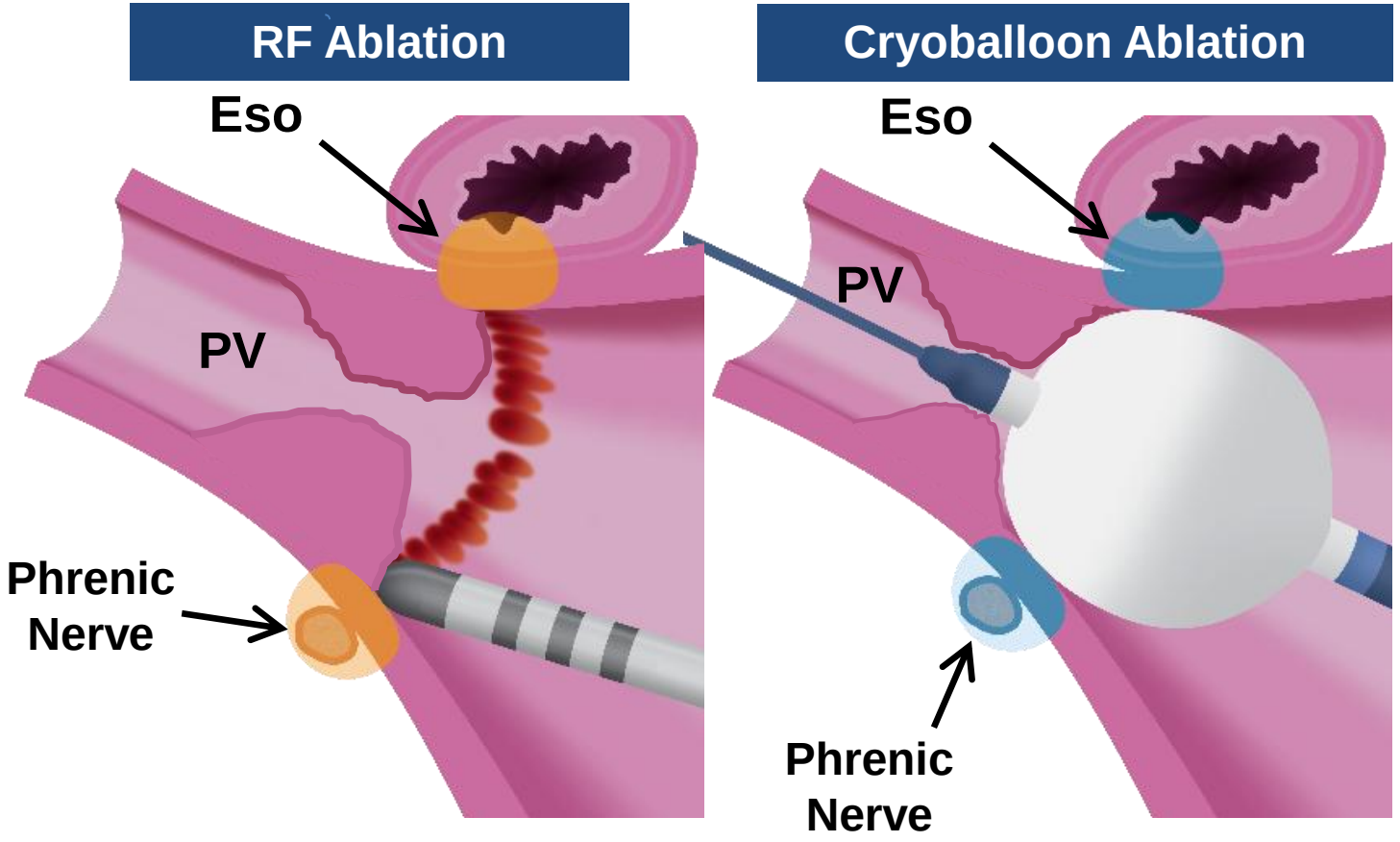
Scientific grant / Consultant : ***Farapulse/Boston Scientific, Affera / Medtronic, Biosence – Webster, Kardium, Acutus, BTL, Adagio, Abbott,***

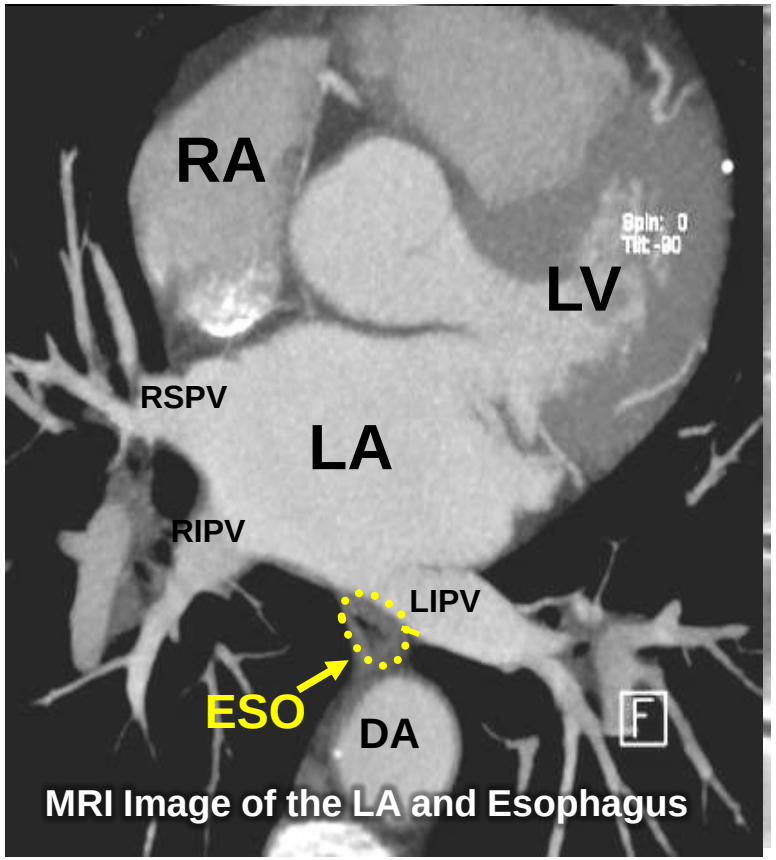
Thermal Ablation (Heat or Cold Energy)

Tissue-Indiscriminate Ablation

Thermal Ablation

Balance Between Safety & Efficacy



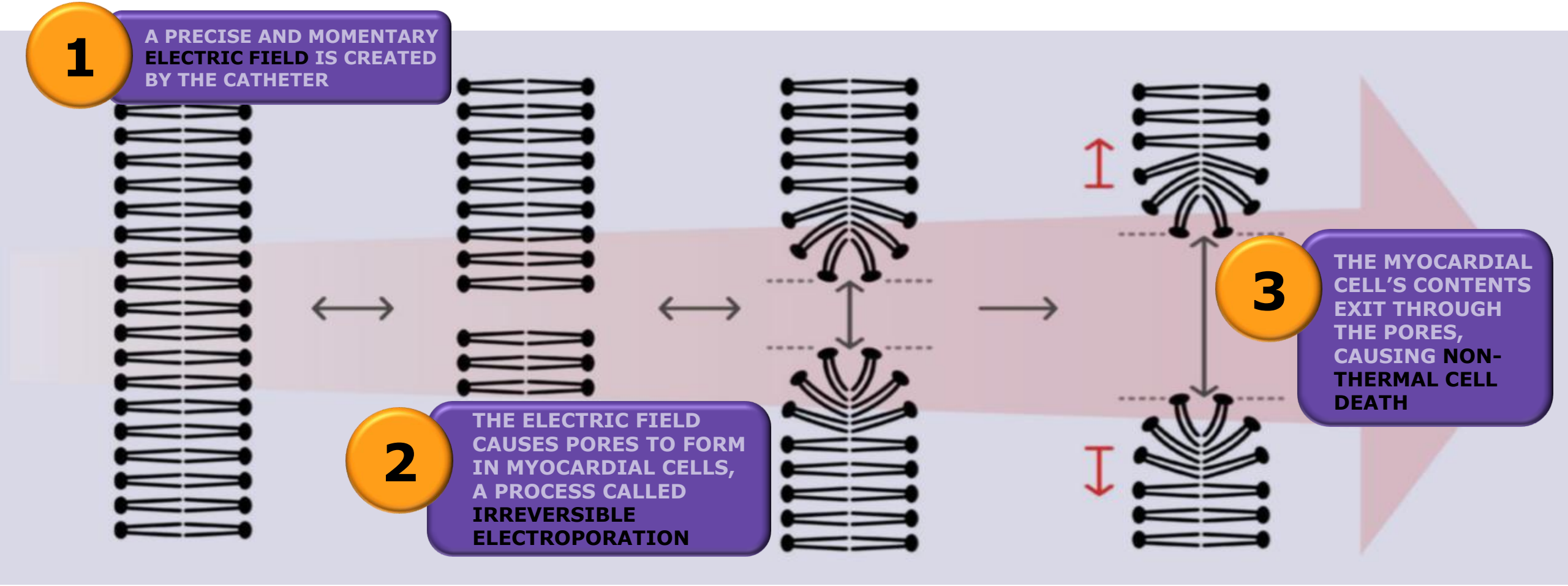


VY.Reddy, P.Neuzil, J.Koruth, et al, *JACC* 74:315–26 (2019)

Pulsed Field Ablation (PFA)

Mechanism

PFA is non-thermal, & induces necrosis through irreversible electroporation.

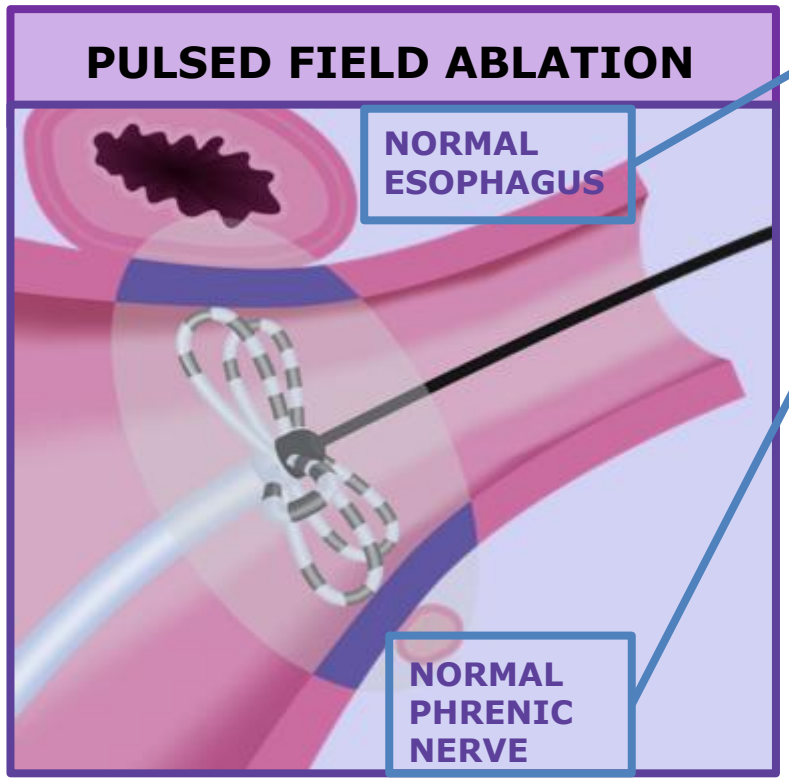


Pulsed Field Ablation (PFA)

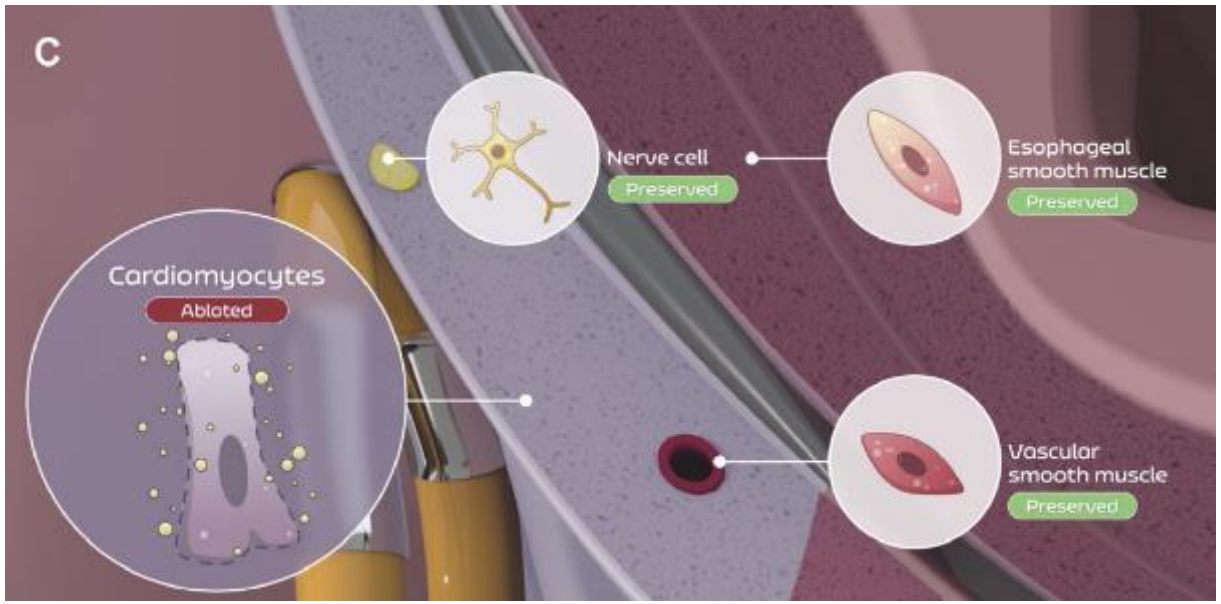
Tissue Selectivity

Optimized PFA has a significant degree of tissue-selectivity.

PFA can target myocardium while largely sparing surrounding tissues.



Other tissue types are more resistant to PFA and remain uninjured despite exposure to the field



[1] Reddy VY et al. J Am Coll Cardiol. 2019;74(3):315-26. [2] Reddy et al. *JACC: Clinical Electrophysiology* 7.5 (2021): 614-627.

Pulsed Field Ablation (PFA)

First-in-Human Acute Clinical Data (HRS-2018)

- 7 patients: epicardial system (surgical approach, box lesion)
- 15 patients: endocardial system (over-the-wire PVI catheter)
  - ➢ 100% acute isolation (endo), no acute SAEs

Epicardial Cohort (n = 7)		Endocardial Cohort (n = 15)
N/A	Procedure time	67.0 ± 10.5
N/A	Mapping time	41.4 ± 9.3
50.7 ± 19.5	Catheter time	26.0 ± 4.3
25.0 ± 17.5	Ablation time	19.0 ± 2.5
6.6 ± 3.8	Fluoroscopy time	12.3 ± 4.0
6/7 (86)	Isolation success	15/15 (100)

VY.Reddy, J.Koruth, P.Jais et al, *JACC EP* 4:987-995 (2018)

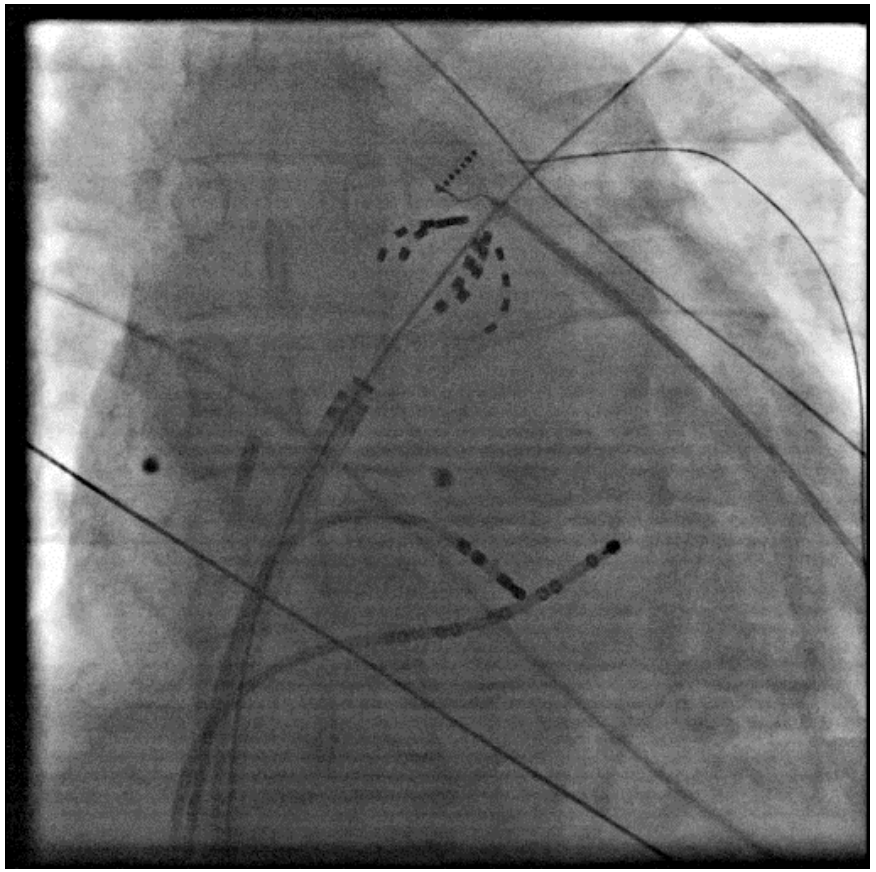
KARDIOCENTRUM

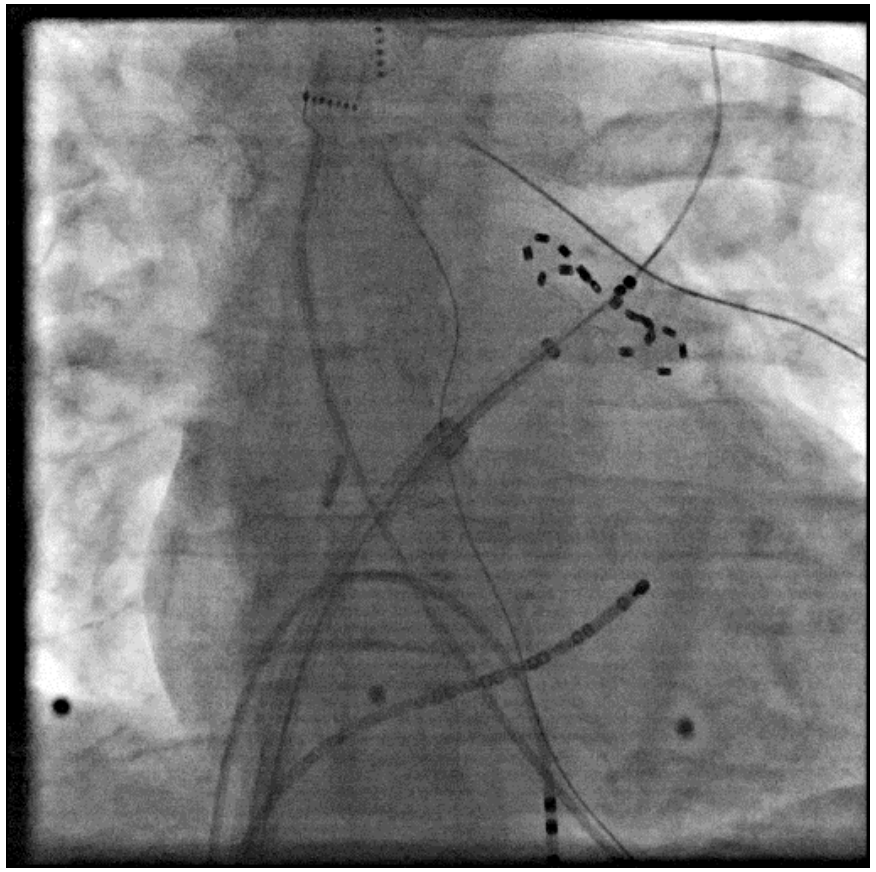
Biphasic PFA

FIH Clinical Experience

Improvements with biphasic delivery

- No general anesthesia or paralytic (except 1st patient)





Ablation Delivery Characteristics

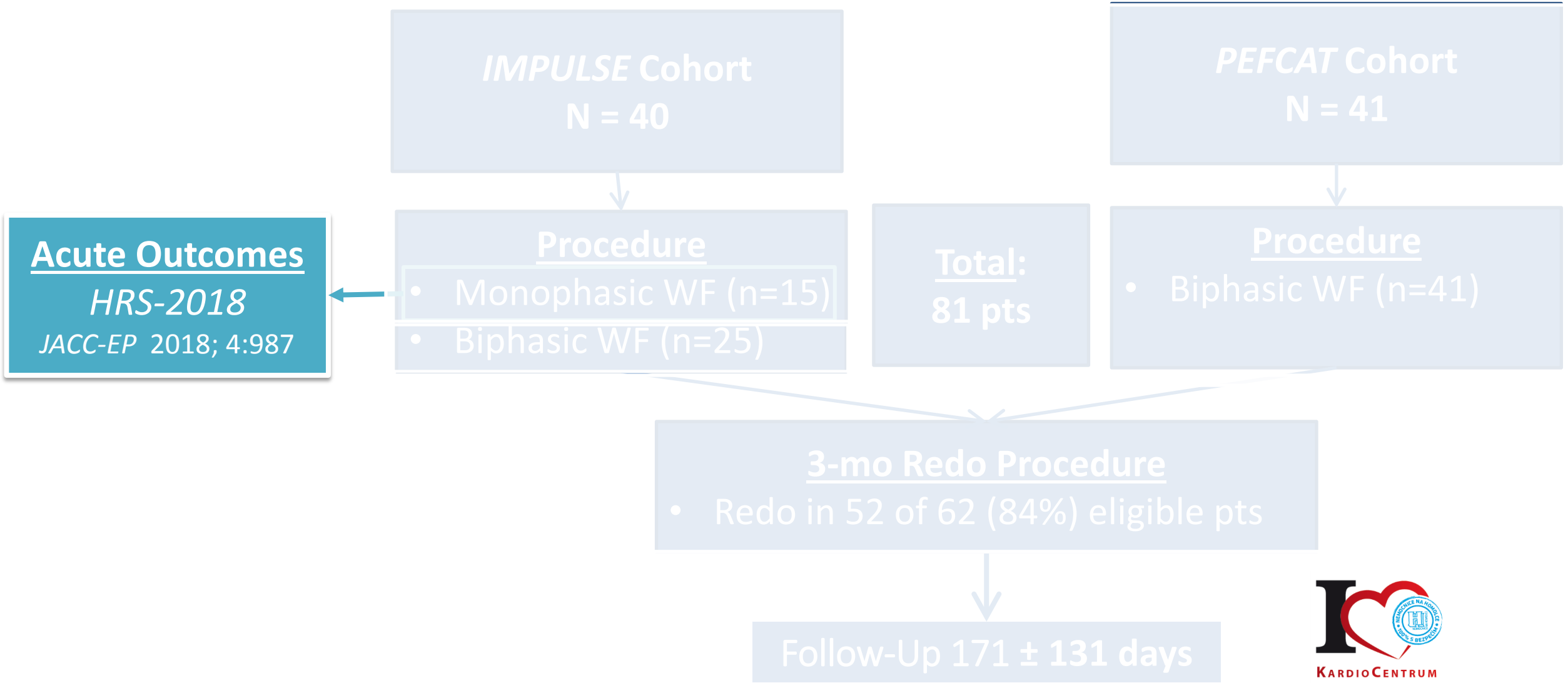
PFA Waveform Evolution

- Waveform is structured as a hierarchical set of msec bipolar pulses
- Pulse train is delivered across electrodes over 4 – 10 heartbeats
- No external patch is employed

	Monophasic	Biphasic-1	Biphasic-2	Biphasic-3	Biphasic-3x
Waveform polarity	Monophasic	Biphasic	Biphasic	Biphasic	Biphasic
Waveform composition	Protocol A	Protocol B	Protocol C	Protocol D	Protocol D
No. of heartbeats over which pulses delivered	4	10	8	5	5
Voltage amplitude	900 V	1800 V	1800 V	2000 V	1800 – 2000 V
Catheter pose	Flower	Flower	Flower and Basket	Flower and Basket	Flower and/or Basket

IMPULSE & PEFCAT

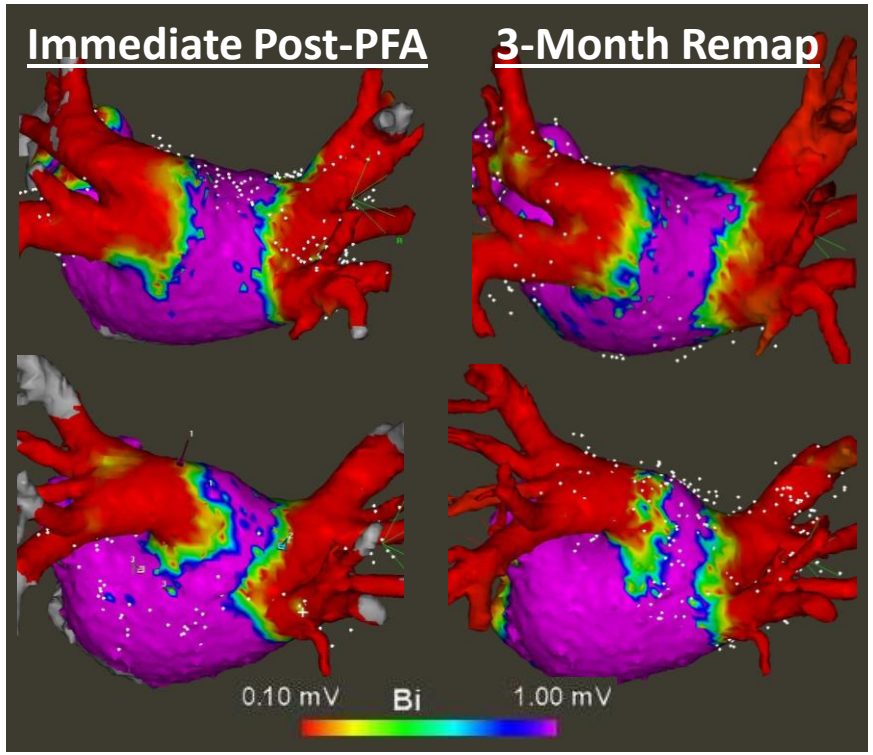
Patient Flow

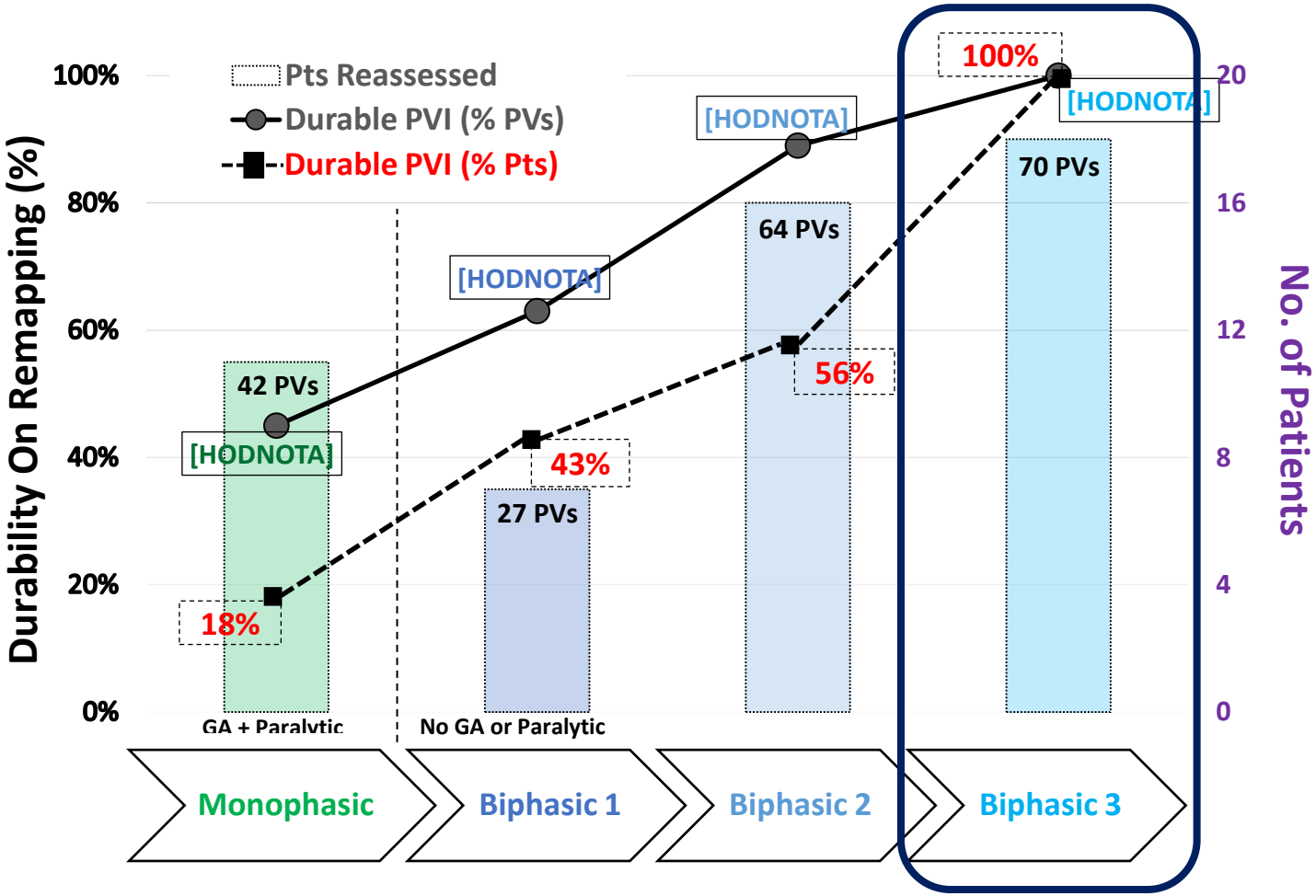


KardioCentrum

IMPULSE & PEFCAT

3-Month Remapping Outcomes

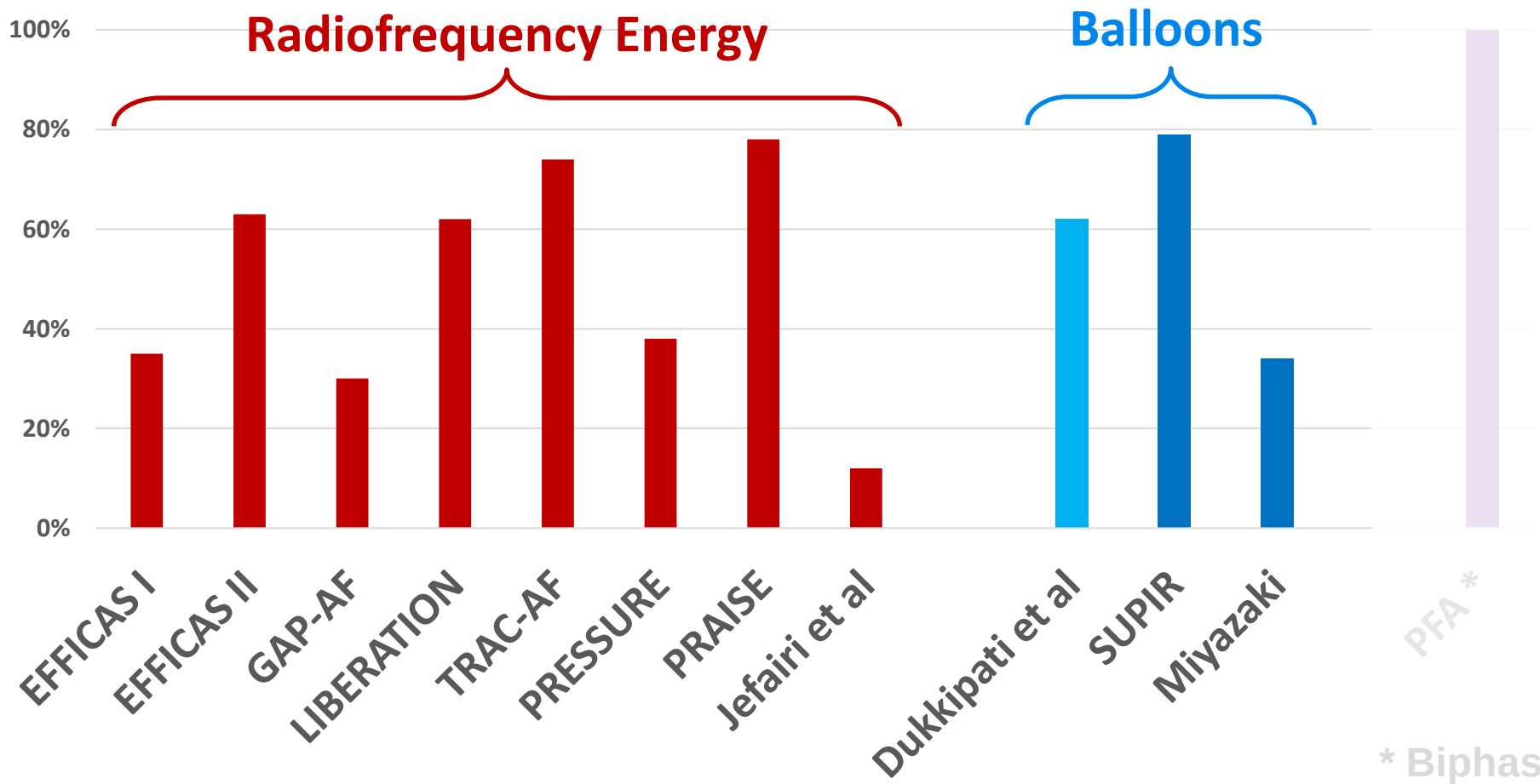




Durable PV Isolation

Data from Protocol-Driven Remap Studies

Patients with all PVs Durably Isolated



Pulsed Field Ablation

Catheter Technology for AF (In Clinical Trials)

FDA Trial (*ADVENT*) Ongoing

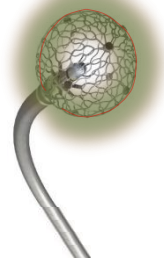
CE-Mark approved

FIH trial Ongoing (EU)

FIH trial Ongoing (China)

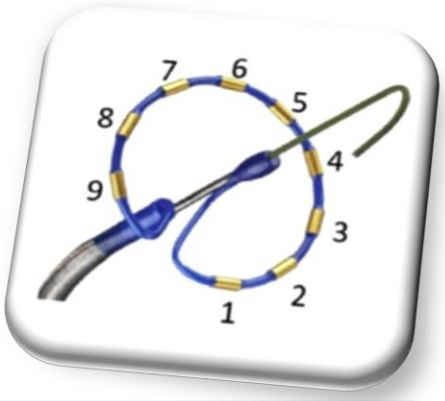
Focal PFA

Lattice-Tip: RF/PF



Gold-Tip: RF/PF

FIH trials Ongoing (EU)

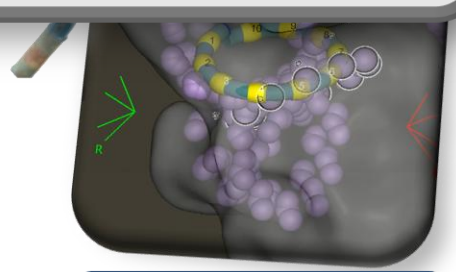


FDA Trial (*PULSED-AF*) Ongoing

FIH trial Ongoing (EU)

Remapping Studies

Clinical Effectiveness



FIH trial Ongoing (EU)

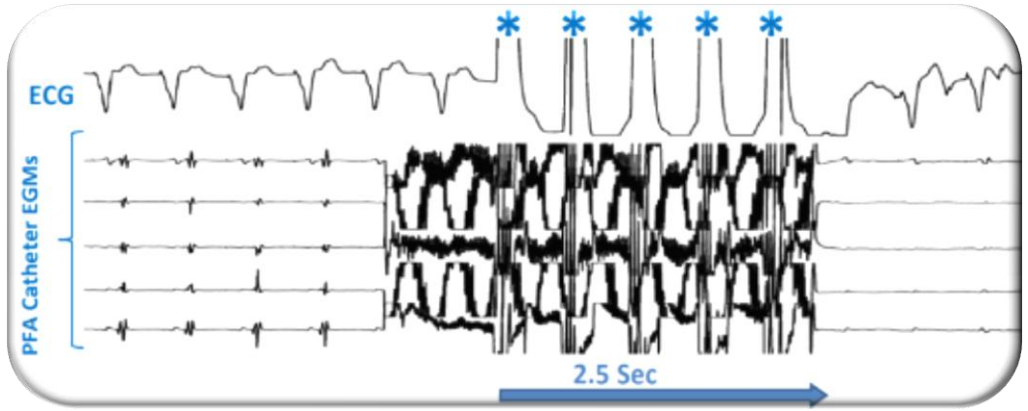
FIH trial Ongoing (EU)

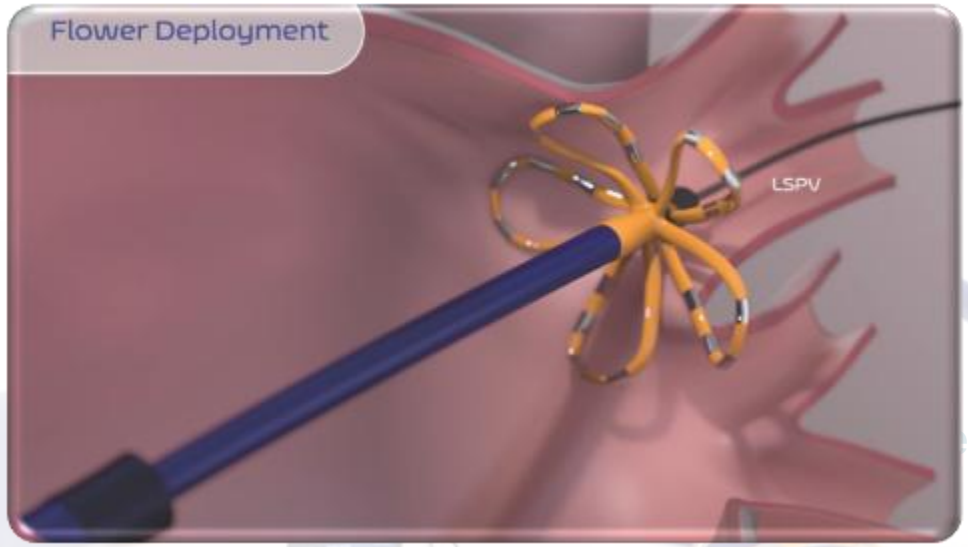
FIH trial Ongoing (EU)

Pentaspline PFA Catheter

Procedure Methodology

- Equipment (Farapulse-Boston Scientific, Inc)
  - PFA Catheter: Farawave
  - (0.035 Amplatz extra stiff straight guidewire)
  - 13-Fr Deflectable Sheath: Faradrive
  - Generator: Farastar
- Lesion sets (standard protocol per training):
  - PVI: 2 x basket → rotate → 2 x basket → : 2 x flower → rotate → 2 x flower
  - LAPW (all flower pose): 2 x at each location
- Esophageal “management”: nothing
  - No temp monitoring / eso deviation / eso cooling/etc





Pentaspline PFA Catheter

FIH Clinical Trial Data: Promising (*But <150 PFA pts*)

FOCUS ON NOVEL OBSERVATIONS IN AF ABLATION

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Pulsed Field Ablation of Paro… Atrial Fibrillation

1-Year Outcomes of IMPULSE, PEFCAT, an…

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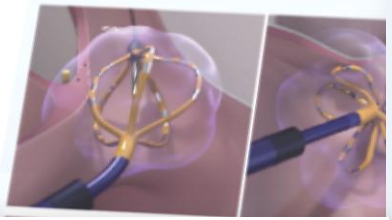
Pulsed Field Ablation in Patien… Persistent Atrial Fibrillation

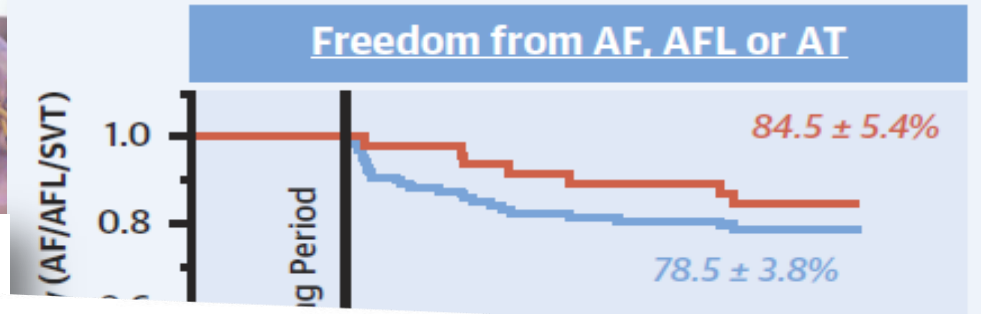
Vivek Y. Reddy, MD,[a,b] Ante Anic, MD,[c] Jacob Koruth, MD,[b] Jan Petru, MD,[a] Moritoshi Funasako, MD,[a] Kentaro Minami, MD,[a] Toni Breskovic, MD, PhD,[c] Ivan Sikiric, MD,[c] Srinivas R. Dukkipati, MD,[b] Iwanari Kawamura, MD,[b] Petr Neuzil, MD, PhD[a]

CENTRAL ILLUSTRATION PFA for Paroxysmal AF

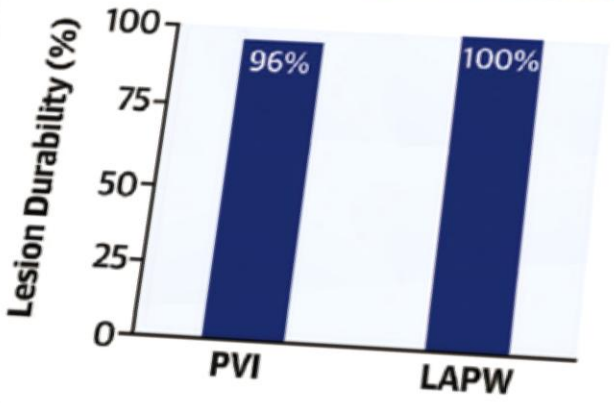
PFA Catheter & Mechanism of Ablation



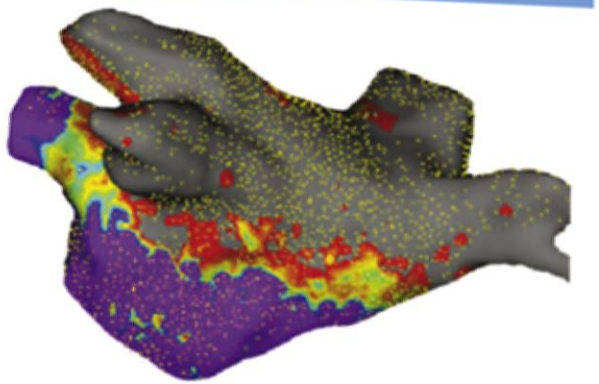
Freedom from AF, AFL or AT



Outcomes Upon Invasive Remapping



Electroanatomical Mapping



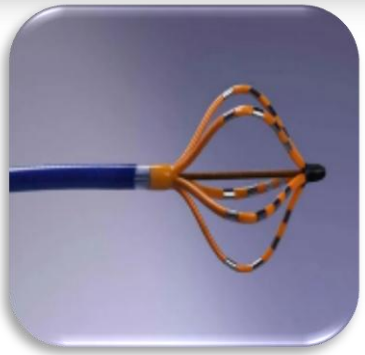
PFA Safety in the "Real World"

MANIFEST-PF Survey Outcomes

ESC European Society of Cardiology
Europace (2022) 00, 1–11
https://doi.org/10.1093/europace/euac050
CLINICAL RESEARCH

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

Emmanuel Ekanem[1], Vivek Y. Reddy[1,2], Boris Schmidt[3], Tobias Reichlin[4], Kars Neven[5,6], Andreas Metzner[7], Jim Hansen[8], Yuri Blaauw[9], Philippe Maury[10,11], Thomas Arentz[12], Philipp Sommer[13], Ante Anic[14], Frederic Anselme[15], Serge Boveda[16,17], Tom Deneke[18], Stephan Willems[19], Pepijn van der Voort[20], Roland Tilz[21,22,23], Moritoshi Funasako[2,24], Daniel Scherr[25], Reza Wakili[26], Daniel Steven[27], Josef Kautzner[28], Johan Vijgen[29], Pierre Jais[6], Jan Petru[2], Julian Chun[3], Laurent Roten[4], Anna Füting[5,30], Andreas Rillig[7], Bart A. Mulder[9], Arne Johannessen[8], Anne Rollin[10], Heiko Lehrmann[12], Christian Sohns[13], Zrinka Jurisic[14], Arnaud Savoure[15], Stephanes Combes[16,17], Karin Nentwich[18], Melanie Gunawardene[19], Alexandre Ouss[20], Bettina Kirstein[21,22,23], Martin Manninger[25], Jan-Eric Bohnen[26], Arian Sultan[27], Petr Peichl[28], Pieter Koopman[29], Nicolas Derval[6], Mohit K. Turagam[1], and Petr Neuzil[2]* (for the MANIFEST-PF Cooperative)

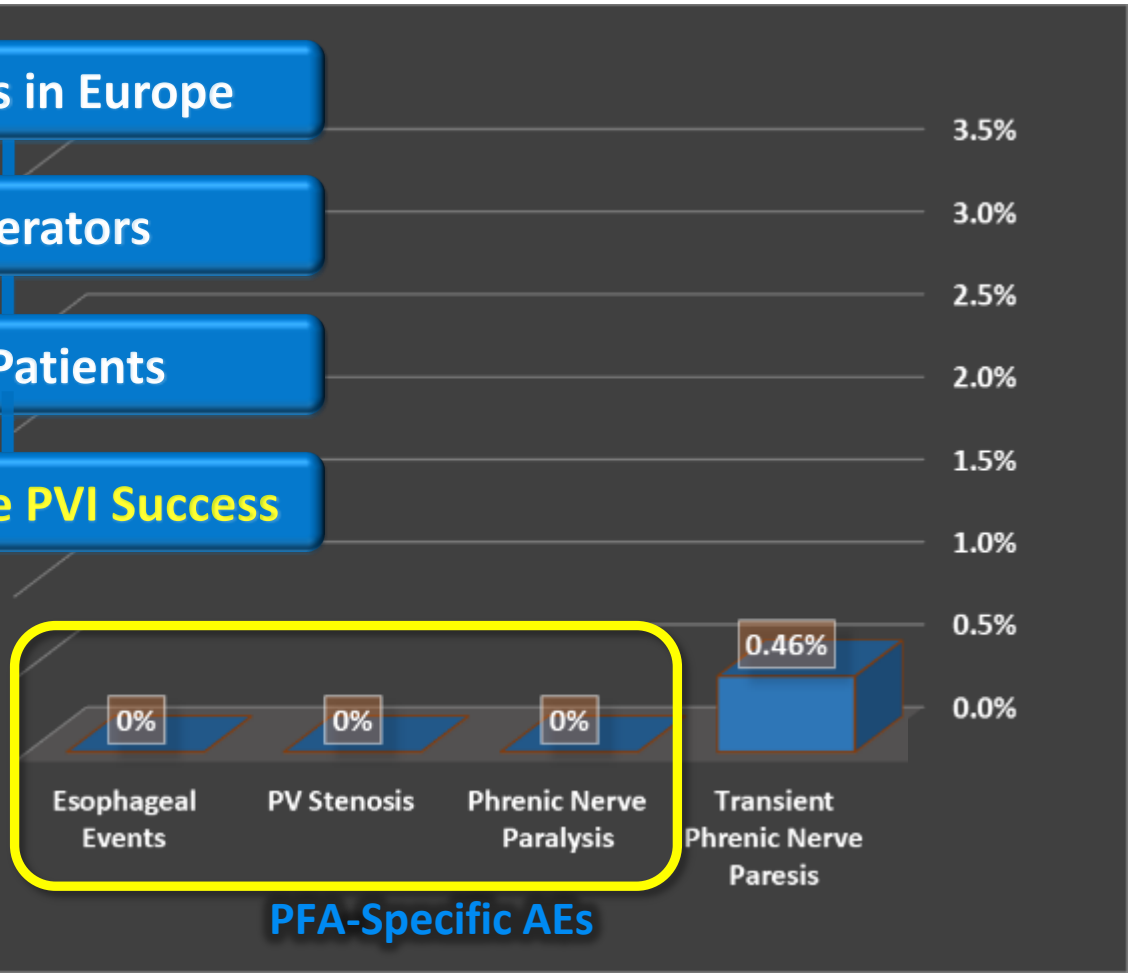


24 centers in Europe

90 Operators

1,758 Patients

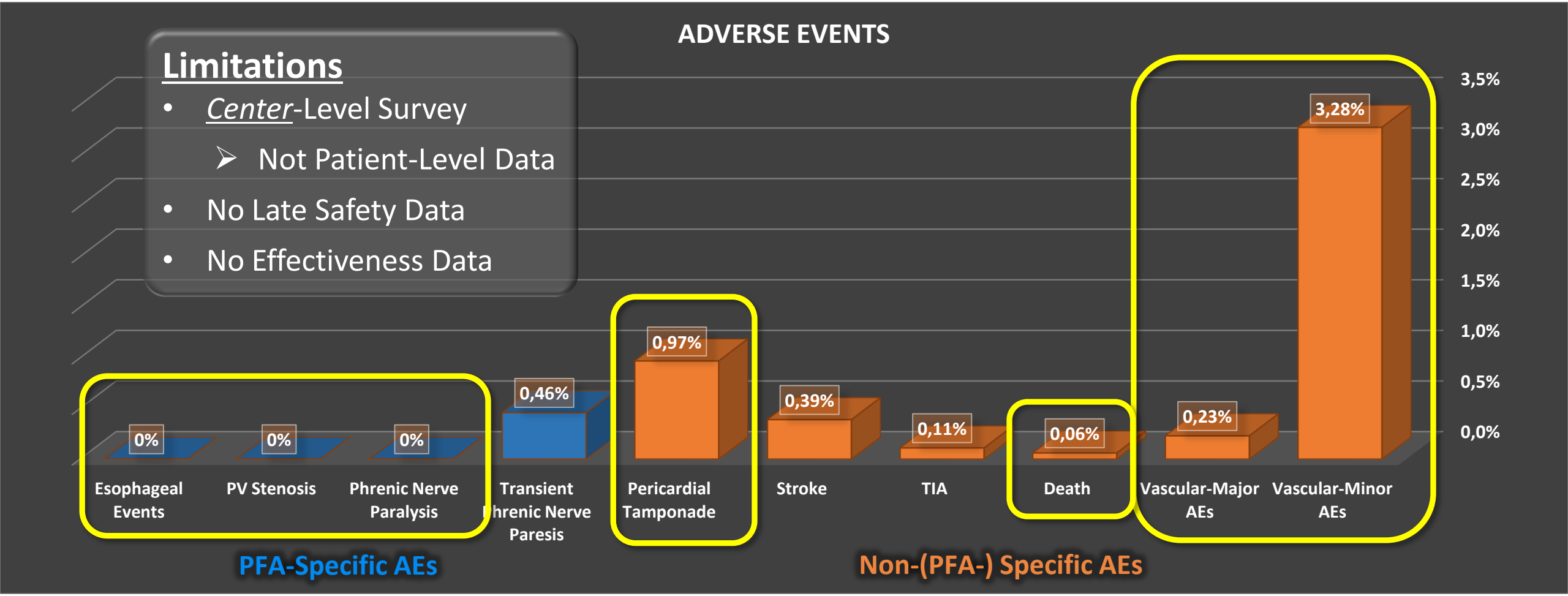
99.9% Acute PVI Success



E.Ekanem, VY.Reddy, B.Schmidt, et al, *Europace. 2022 Sep 1;24(8):1256-1266*

PFA Safety in the "Real World"

MANIFEST-PF Survey Outcomes

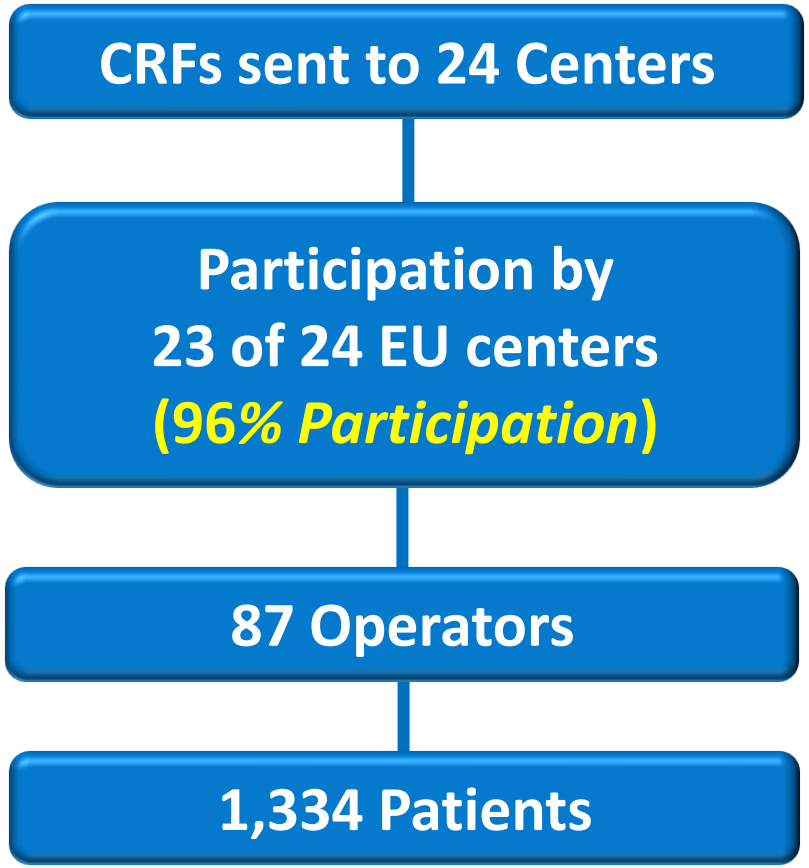


E.Ekanem, VY.Reddy, B.Schmidt, et al, *Europace. 2022 Sep 1;24(8):1256-1266*

MANIFEST-PF Registry

Design

- Retrospective study that included all commercial PFA cases prior to Dec 2021
- Deidentified *patient-level* data was analyzed
- Primary Efficacy Endpoint:
  - Freedom from atrial arrhythmia (AF/AFL/AT) recurrence ≥30 seconds (post 3-mo blanking period)
  - Follow-up per usual center practice
- Safety Data
  - Patient-Level Data
  - Also collected any potential Late adverse events
- Included Patient Population
  - All consecutive patients undergoing PFA (Post-CE Mark)
  - Only First-time AF ablation procedures
- Approved by the EC at Homolka Hospital, Prague



MANIFEST-PF: Results

Baseline Patient Characteristics-1

	Pts w/ Available Data	Value (%)
Age, years (mean±SD)	1,334 (100%)	**63.4±11.5**
Female (%)	1,334 (100%)	**435 (33%)**
Body mass index (kg/m2) (mean±SD)	1,334 (100%)	**28.1±4.9**
AF duration, (months) (median, IQR)	1,170 (88%)	**24 (8.5 – 51.8)**
AF Type		
Paroxysmal	1,334 (100%)	**864 (65%)**
Persistent		**419 (31%)**
Long standing persistent		**51 (4%)**
Past Medical History		
CHA_2DS_2-VaSc	1,334 (100%)	**2.1±1.5**
Atrial flutter (%)	1,334 (100%)	**175 (13%)**
Coronary artery disease	1,334 (100%)	**185 (14%)**
Diabetes	1,334 (100%)	**172 (13%)**
Hypertension	1,334 (100%)	**796 (60%)**
Heart failure	1,334 (100%)	**188 (14%)**
Alcohol abuse	1,334 (100%)	**15 (1%)**
Sleep apnea	1,334 (100%)	**105 (8%)**
Stroke/TIA	1,334 (100%)	**87 (7%)**
COPD	1,334 (100%)	**54 (4%)**

MANIFEST-PF: Results

Baseline Patient Characteristics-2

	Pts. w/ Available Data	Value (%)
Echocardiographic parameters		
LVEF (%)	1,259 (94%)	**57±10**
LA diameter, mm (mean±SD)	1,057 (79%)	**42±8**
Antiarrhythmic Medications		
Class I AADs (%)	1,334 (100%)	**343 (26%)**
Class II AADs (%)	1,334 (100%)	**696 (52%)**
Class III AADs (%)	1,334 (100%)	**279 (21%)**
Class IV AADs (%)	1,334 (100%)	**68 (5%)**
Oral Anticoagulants		
Vitamin K antagonist (%)	1,334 (100%)	**82 (6%)**
NOAC (%)	1,334 (100%)	**1,173 (88%)**
Other (%)	1,334 (100%)	**5 (0.4%)**
None (%)	1,334 (100%)	**74 (6%)**

MANIFEST-PF: Results

Procedural Characteristics -1

	Pts. w/ Available Data	Value (%)
Patient Management		
Deep Sedation (%)	1,334 (100%)	**990 (74%)**
Endotracheal intubation (%)	1,334 (100%)	**344 (26%)**
Electroanatomical mapping (%)	1,334 (100%)	**478 (36%)**
Intracardiac echo (%)	1,334 (100%)	**429 (32%)**
Ablation Lesion Sets		
Pulmonary vein isolation (%)	1,334 (100%)	**1334 (100%)**
Acute success (%)	1,334 (100%)	**1321 (99%)**
Additional non-PV ablation (%)	1,334 (100%)	**364 (27%)**
LA posterior wall isolation (%)	1,334 (100%)	**191 (14%)**
CTI ablation (%)	1,334 (100%)	**83 (6%)**
Mitral line (%)	1,334 (100%)	**30 (2%)**
Roof line (%)	1,334 (100%)	**13 (1%)**
Other ablation (%)	1,334 (100%)	**47 (4%)**

MANIFEST-PF: Results

Procedural Characteristics-2

	Pts. w/ Available Data	Value (%)
Type of Energy used to perform additional ablation		
Pulse-field energy	364 (100%)	**306 (84%)**
Radiofrequency energy	364 (100%)	**58 (16%)**
Fluoroscopy time (min) (mean±SD)	1,291 (97%)	**16.6±10.6**
Total procedure time (min) (mean±SD)	1,324 (99%)	**79.0±44.2**
Same day discharge (%)	1,334 (100%)	**109 (8%)**
AADs on discharge	1,184 (89%)	**408 (34%)**
Class I		**225 (19%)**
Class III		**183 (15%)**
Class I/III AADs at 3 months	1,241 (93%)	**271 (22%)**
No. of patients without 3-months of follow up	1,334 (100%)	**165 (12%)**

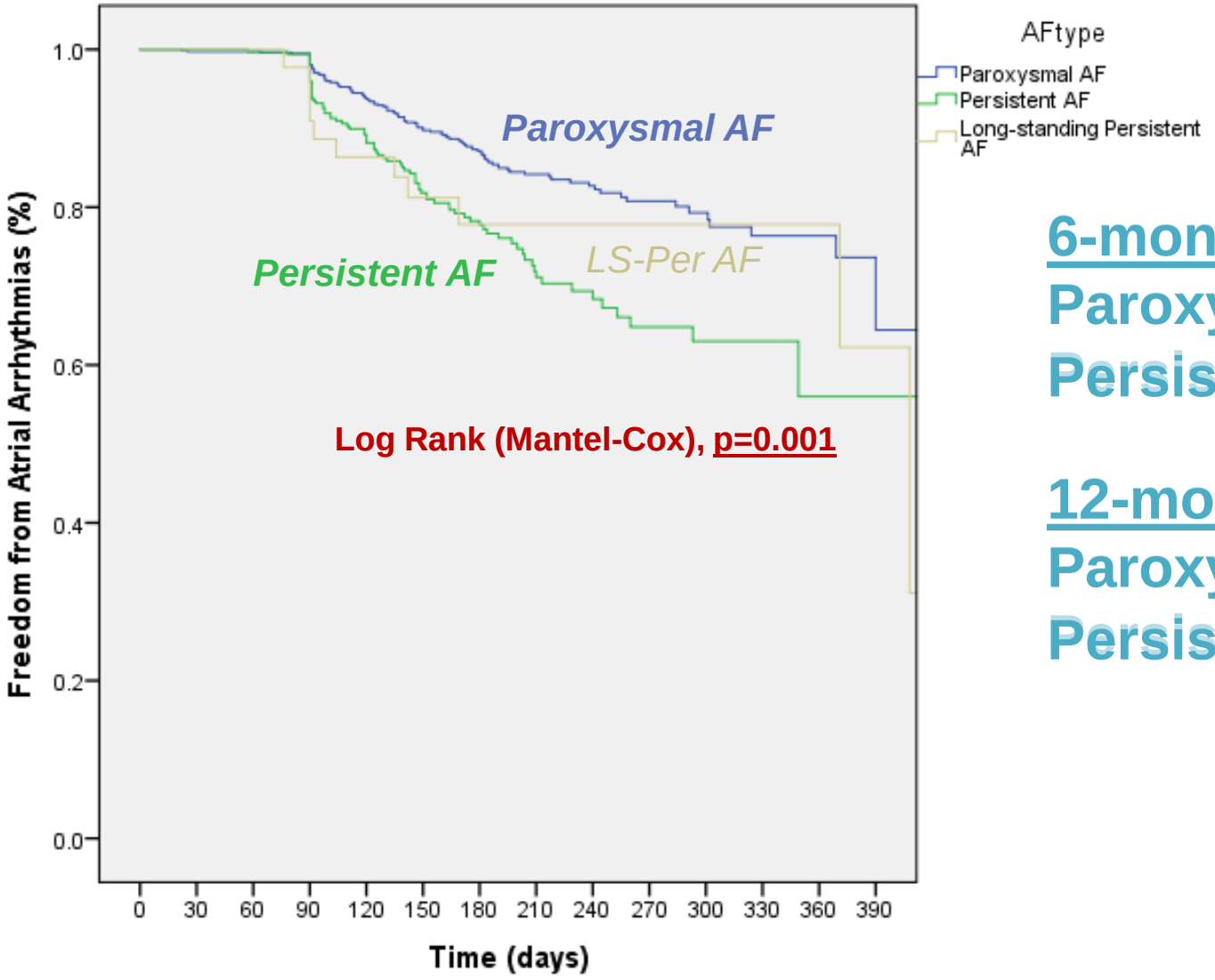
MANIFEST-PF: Results

Efficacy Outcomes

	N=1,334
Follow up duration, days (median, IQR)	188 (129 – 242)
No. of follow-up Holter's (median, IQR)	2 (1 – 3)
No. of follow-up visits (median, IQR)	1 (1 – 2)
Time to AF/AFL recurrence, days (median, IQR)	182 (121-230)
Redo-ablation procedure	91 (7.7)

MANIFEST-PF: Efficacy

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



6-month Estimate

Paroxysmal AF: 86.6%

Persistent AF: 79.6%

12-month Estimate

Paroxysmal AF: 73.4%

Persistent AF: 58.2%

MANIFEST-PF Registry: Safety

Major *vs* Minor AEs

	N=1,334 (%)
Major Complications	**22 (1.6%)**
Esophageal Fistula	0
Esophageal Dysmotility	0
Pulmonary Vein Stenosis	0
Pericardial Tamponade	**16 (1.1%)**
Percutaneous Treatment	12 (0.9%)
Surgical Treatment	2 (0.1%)
Stroke	**3 (0.2%)***
Phrenic Nerve Injury (persistent) †	0
Vascular AEs requiring surgery	2 (0.1%)
Coronary artery spasm	1 (0.07%)
Death	1 (0.07%)*

	N=1,334 (%)
Minor Complications	**55 (4.1%)**
Pericardial effusion (w/o intervention)	4 (0.3%)
Pericarditis	1 (0.07%)
TIA	2 (0.1%)
Phrenic Nerve Injury	
Transient Effect §	4 (0.3%)
Vascular	**35 (2.5%)**
Hematoma	26 (1.9%)
Pseudoaneurysm	2 (0.1%)
AV Fistula	5 (0.4%)
Other	2 (0.1%)
Respiratory-related	4 (0.3%)
Deep venous thrombosis	1 (0.07%)
Air embolism	2 (0.1%)
Other	2 (0.1%)

**** One patient who sustained a stroke subsequently died.***

† Defined as persisting beyond hospital discharge.

§ Defined as recovering before hospital discharge

There were no patients with late complications

MANIFEST-PF Registry: Safety

PFA-Specific *vs* Non-(PFA-) Specific AEs

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Esophageal Fistula	0
Esophageal Dysmotility	0
Pulmonary Vein Stenosis	0
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Vascular	
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† Defined as persisting beyond hospital discharge.

§ Defined as recovering before hospital discharge

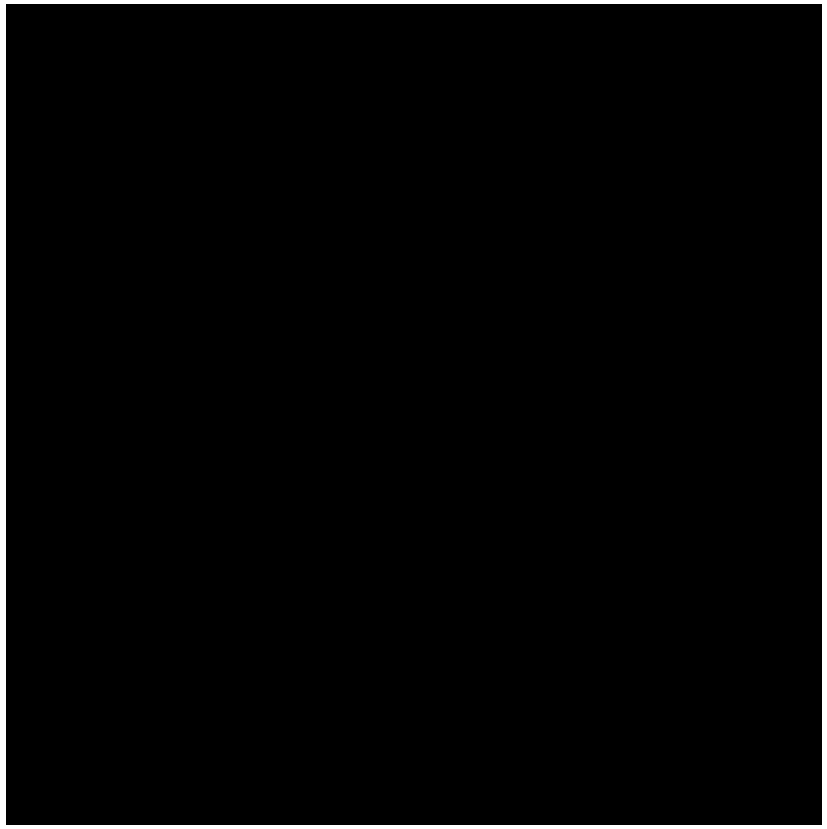
MANIFEST-PF Registry: Safety

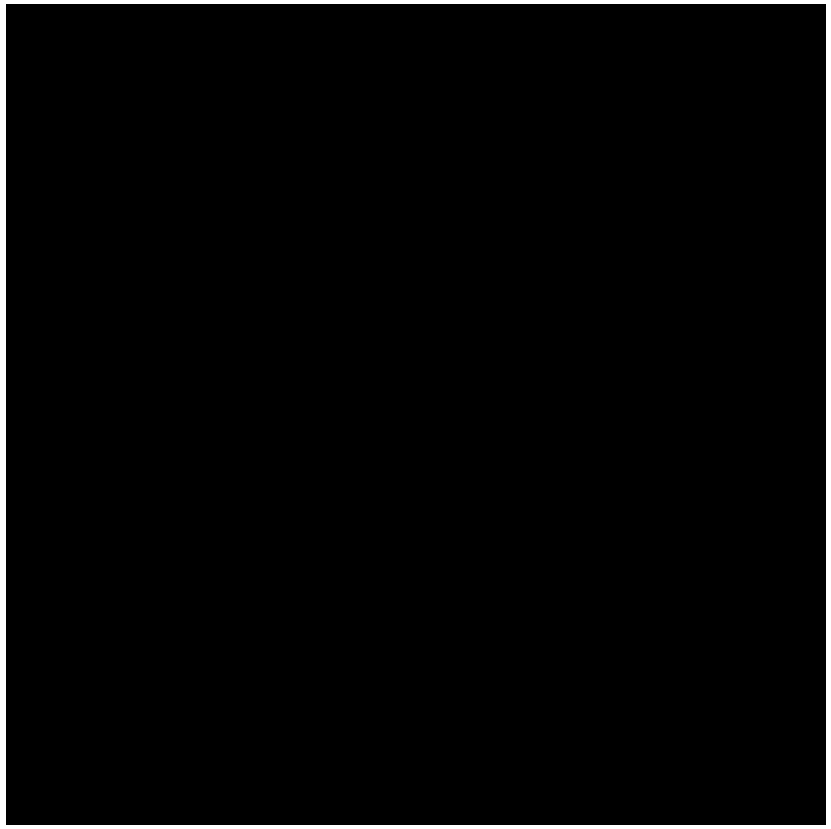
Coronary Spasms

ORIGINAL RESEARCH ARTICLE

Coronary Arterial Spasm During Pulsed Field Ablation to Treat Atrial Fibrillation

Vivek Y. Reddy, MD; Jan Petru, MD; Moritoshi Funasako, MD; Karel Kopriva, MD; Pavel Hala, MD; Milan Chovanec, MD; Marek Janotka, MD; Stepan Kralovec; Petr Neuzil, MD, PhD





MANIFEST-PF Registry
Conclusions

- In an unselected population undergoing first-ever AF ablation in routine practice, using the pentaspline PFA catheter:
  - Is being employed in both paroxysmal and persistent AF patients
  - Beyond PVI, ablation in ~1/4 of pts (most often LAPW ablation)
    - Achieves PVI in 99%, with good procedural times
  - Despite first use of a novel PFA catheter, Good safety profile:
    1. C/w preferential tissue ablation (particularly no evidence of esophageal damage, PV stenosis or phrenic nerve injury persisting beyond hospitalization)
    2. Significant rate of "generic" catheter complications (particularly pericardial tamponade & vascular complications)
    3. Was not associated with any Late Complications
  - Efficacy profile: Freedom from Recurrent AF/AT/AFL was quite good (better for paroxysmal than persistent AF)

MANIFEST-PF Registry
Limitations

- Retrospective study
  - Follow-up was not pre-specified
  - Though many centers had prospective center-level registries
- Efficacy results
  - Minority of patients reached 1-year duration of follow-up
  - Variability in frequency and/or intensity (eg, ±Holters) of f/u
  - Durability of PVI is unknown (as well as other lesions sets)
- Safety results:
  - Little data on safety of lesion sets beyond PVI
  - What happens when >10,000 pts are treated?

Ongoing Clinical Trials

ADVENT IDE & BEAT AF

ADVENT IDE

350+ Patients
Paroxysmal AF |
30+ US Centers

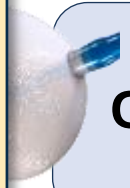
1:1

FARAPULSE PFA
FARAWAVE OTW
Catheter

Standard-of-Care

1:1

Cryo



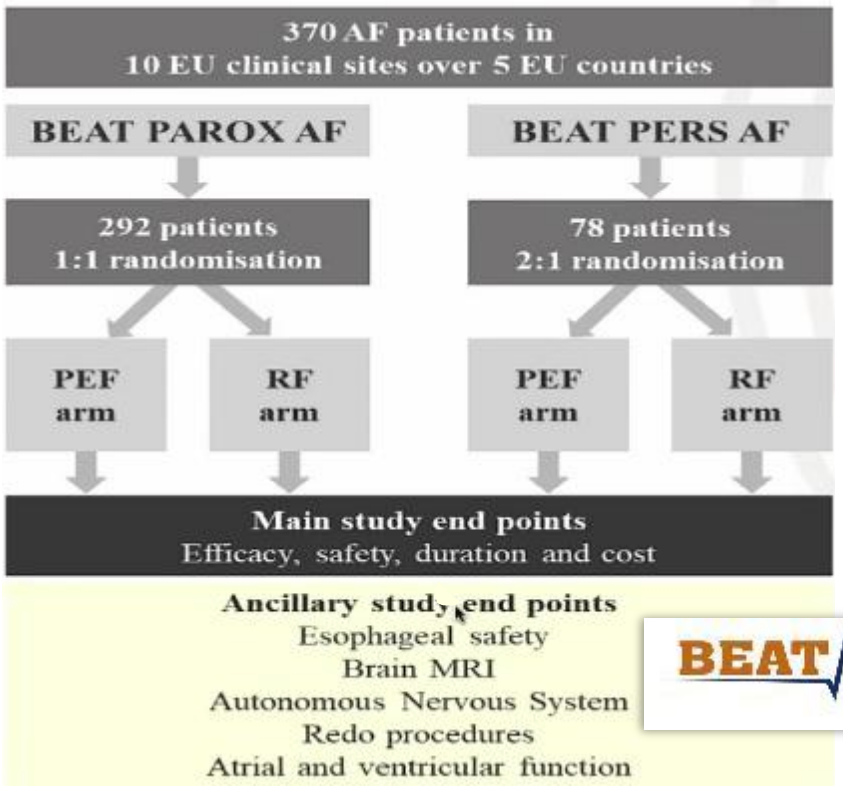
CF RF

Key design elements:

- Single-procedure endpt
- 1-year follow-up
- Brain MRI sub-study
- PV stenosis sub-study

BEAT AF

Aim: Assess whether PFA is faster, more effective and safer (tissue selectivity) than RF or cryo ablation.



PRAGUE RHYTHM

25th

PRAGUE RHYTHM

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NEMOCNICE
NA HOMOLCE

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Tobias Reichlin, Lauren Roten	Inselspital – Bern University Hospital, Switzerland
Kars Neven, Anna Füting	Alfried Krupp Hospital, Essen, Germany
Andreas Metzner, Andreas Rillig	University Heart and Vascular Center, UKE-Hamburg
Jim Hansen, Arne Johannessen	Copenhagen University Hospital, Denmark
Yuri Blaauw, Bart Mulder	Universitair Medish Groningen, Netherlands
Philippe Maury, Anne Rollin	University Hospital Rangueil, Toulouse, France
Thomas Arentz, Heiko Lehmann	Universitätsklinikum Freiburg, Germany
Philipp Sommer, Christian Sohns	Heart & Diabetes Center NRW, Ruhr-Univ Bochum, Germany
Ante Anic, Zrinka Jurisic	University Hospital Center Split, Split, Croatia
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Serge Boveda, Stephanes Combes	Clinique Pasteur, Toulouse, France

The *MANIFEST-PF* Cooperative

Physicians & Centers-2

Thomas Deneke, Karin Nentwich	Heart Center Bad Neustadt, Germany
Stephan Willems, Melanie Gunawande	Asklepios Hospital St.Georg, Hamburg, Germany
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Roland Tilz, Bettina Kirstein	University Heart Center, Lubeck, Germany
Moritoshi Funasako, Petr Neuzil	Neuron Medical, Brno, Czech Republic
Daniel Scherr, Martin Manninger	Medical University of Graz, Austria
Reza Wakili, Jan-Eric Bohnen	University Duisburg-Essen, Germany
Daniel Steven, Arian Sultan	Universitätsklinikum Köln AöR, Germany
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Pierre Jais, Nicolas Derval	IHU LIRYC, CHU Bordeaux, University of Bordeaux, France
Mohit Turagam, Vivek Reddy	Mount Sinai Hospital, New York, US

MANIFEST-PF Registry: Safety

Adverse Events

	N=1,334 (%)
Major Complications	**22 (1.6%)**
Esophageal Fistula	0
Esophageal Dysmotility	0
Pulmonary Vein Stenosis	0
Pericardial Tamponade	16 (1.1%)
Percutaneous Treatment	12 (0.9%)
Surgical Treatment	2 (0.1%)
Stroke	3 (0.2%)*
Phrenic Nerve Injury (persistent) †	0
Vascular AEs requiring surgery	2 (0.1%)
Coronary artery spasm	1 (0.07%)
Death	1 (0.07%)*

	N=1,334 (%)
Minor Complications	**55 (4.1%)**
Pericardial effusion (w/o intervention)	4 (0.3%)
Pericarditis	1 (0.07%)
TIA	2 (0.1%)
Phrenic Nerve Injury	
Transient Effect §	4 (0.3%)
Vascular	
Hematoma	26 (1.9%)
Pseudoaneurysm	2 (0.1%)
AV Fistula	5 (0.4%)
Other	2 (0.1%)
Respiratory-related	4 (0.3%)
Deep venous thrombosis	1 (0.07%)
Air embolism	2 (0.1%)
Other	2 (0.1%)

** One patient who sustained a stroke subsequently died.*

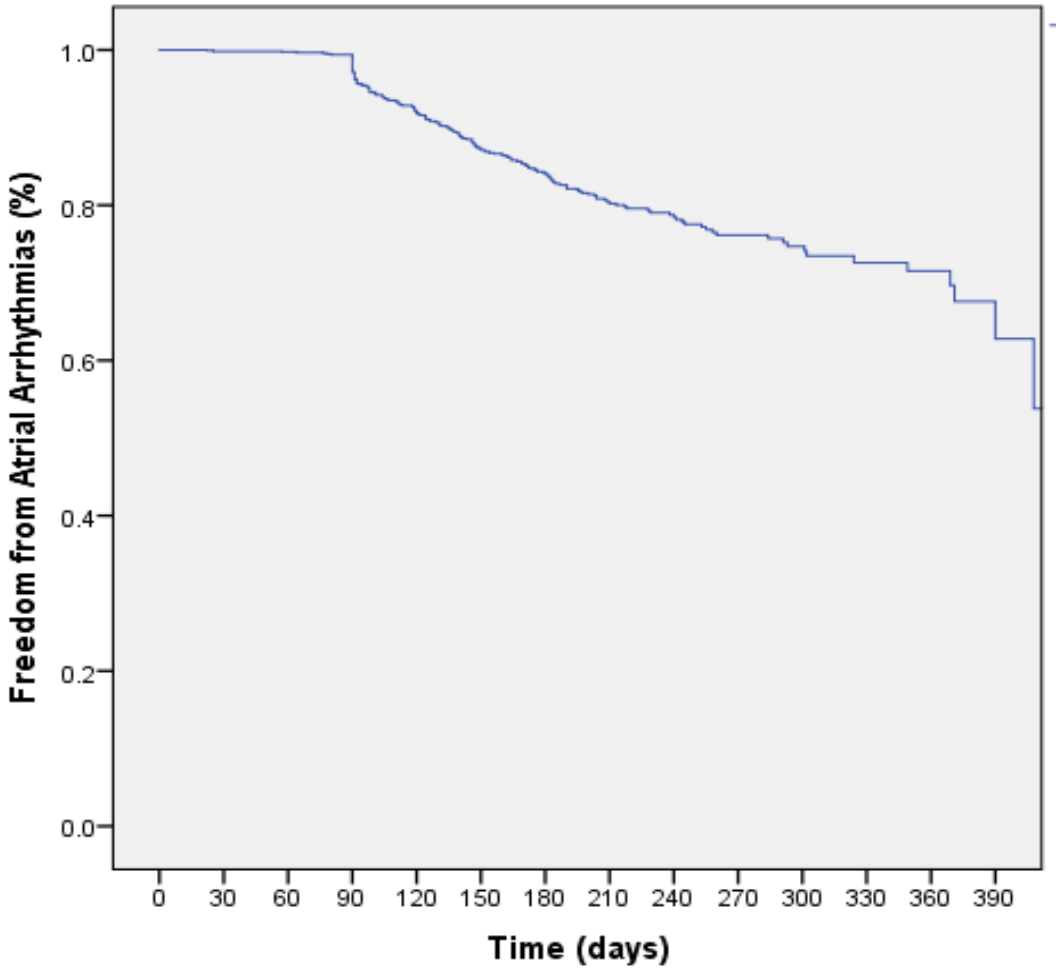
† Defined as persisting beyond hospital discharge.

§ Defined as recovering before hospital discharge

There were no patients with late complications

MANIFEST-PF: Efficacy

Kaplan-Meier Analysis of Freedom from AF/AFL



No. of Patients							
	1,160	1,157	887	**611**	266	133	**48**

6-mo Estimate: 81.5%

12-mo Estimate: 68.9%

MANIFEST-PF Registry: Safety

PFA-Specific *vs* Non-(PFA-) Specific AEs

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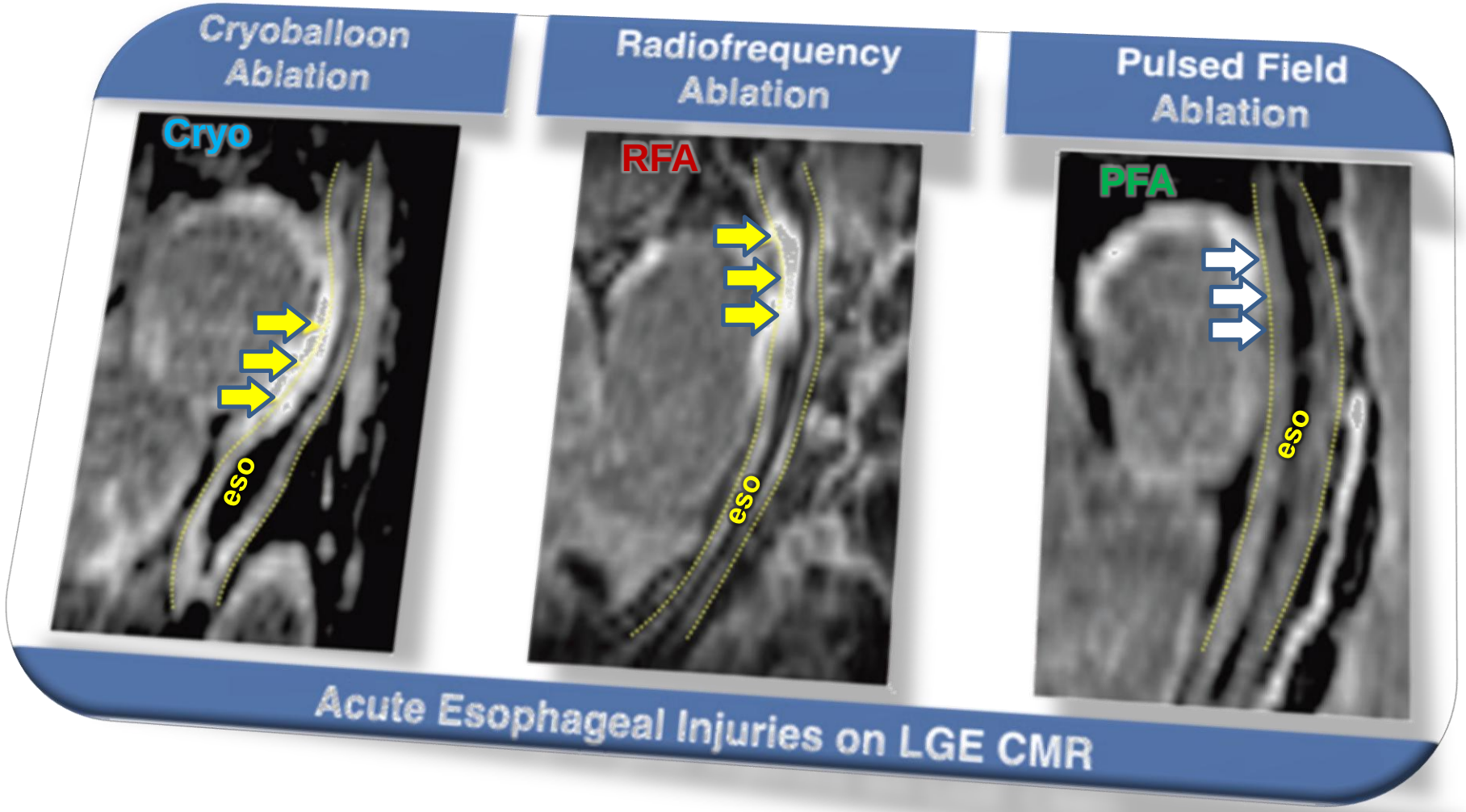
PFA: ”Preferential” Tissue Ablation

PFA vs RFA vs Cryo



H.Cohet, Y.Nakatani, S.Sridi-Cheniti, et al, *Europace* (2021)

Pentaspline PFA Catheter

Procedure Methodology

- Equipment (Farapulse-Boston Scientific, Inc)
  - PFA Catheter: Farawave
  - (0.035 Amplatz extra stiff straight guidewire)
  - 13-Fr Deflectable Sheath: Faradrive
  - Generator: Farastar
- Lesion sets (standard protocol per training):
  - PVI: 2 x basket → rotate → 2 x basket → : 2 x flower → rotate → 2 x flower
  - LAPW (all flower pose): 2 x at each location
- Esophageal “management”: nothing
  - No temp monitoring / eso deviation / eso cooling/etc