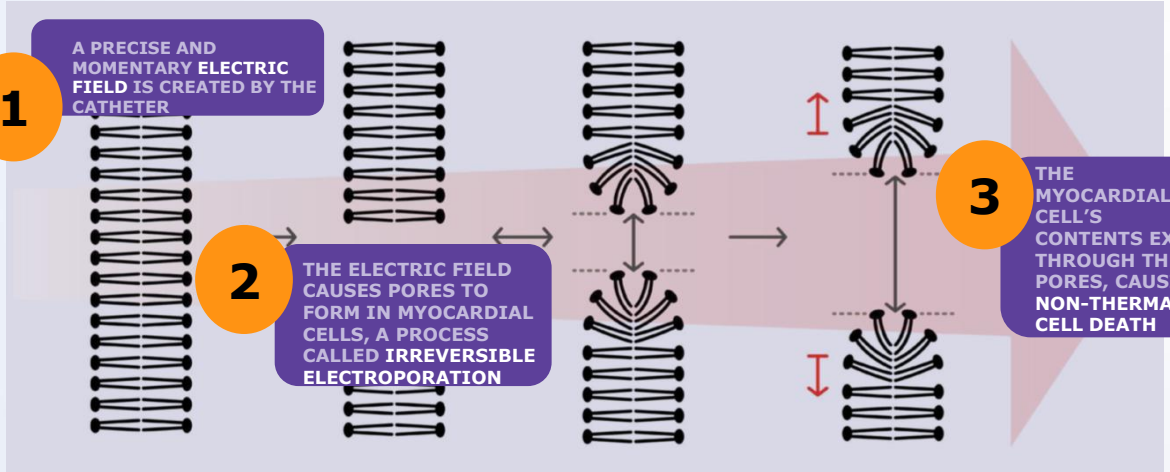
PulseSelect –
ne všechny PFA systémy jsou stejné

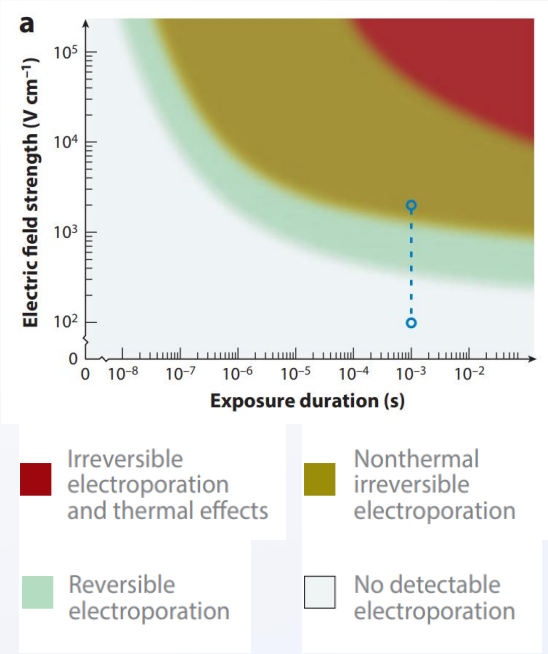
Prof MUDr Josef Kautzner, CSc, FESC
Kardiocentrum, Institut klinické a experimentální medicíny, Praha

joka@ikem.cz Twitter@JosefKautzner
www.ikem.cz

INSTITUT KLINICKÉ A EXPERIMENTÁLNÍ MEDICÍNY
KLINIKA KARDIOLOGIE

Ablace pulzním polem (PFA) – hlavní mechanismus

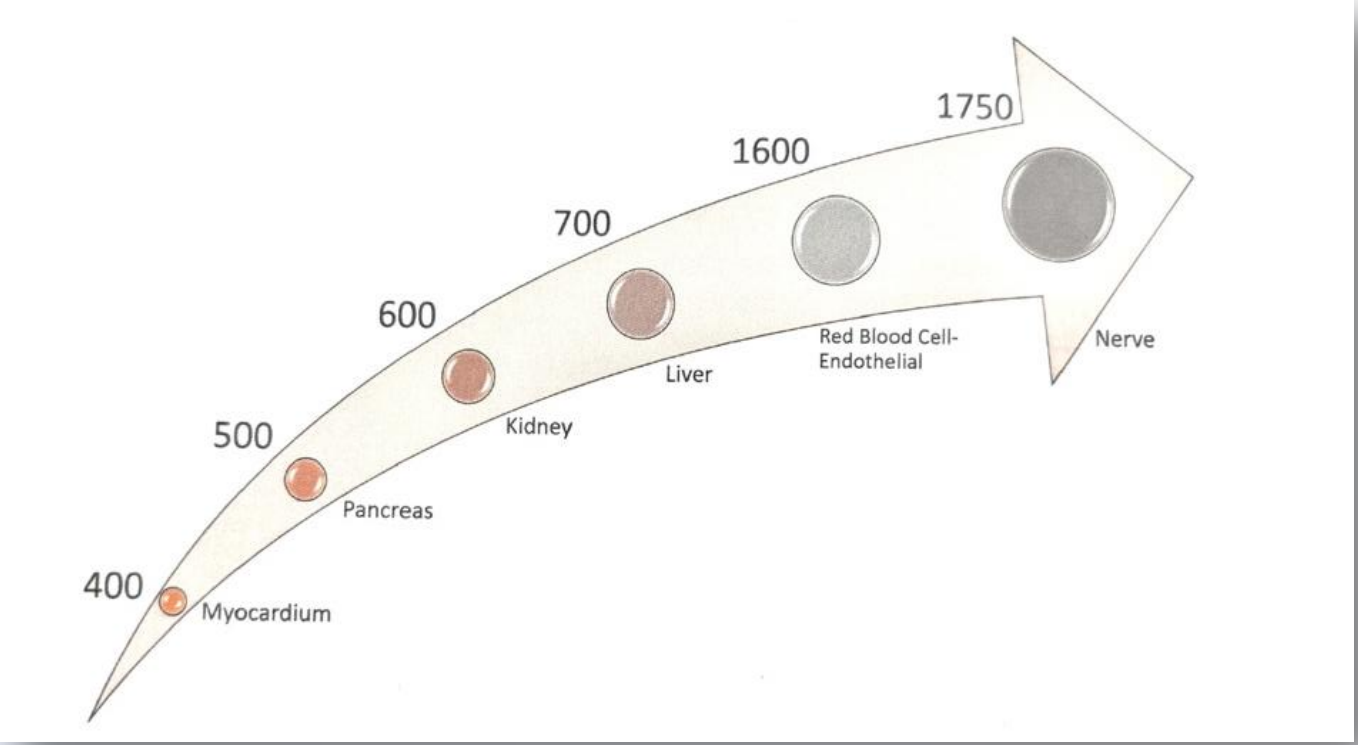




Kotnik et al. *IEEE Electrical Insulation Magazine* 28.5 (2012): 14-23.

Yarmush et al. Annual review of biomedical engineering 16 (2014): 295-320;

Různé tkáně mají různý práh pro poškození pFA

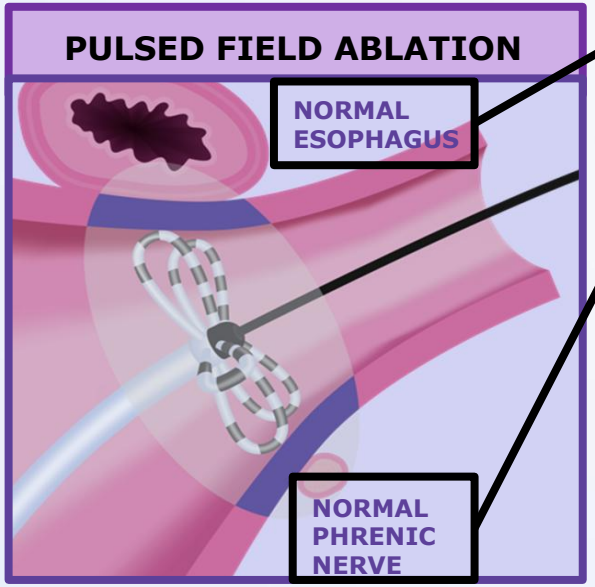


Kos B, et al. Front Cardiovasc Med 2023:10:1160231

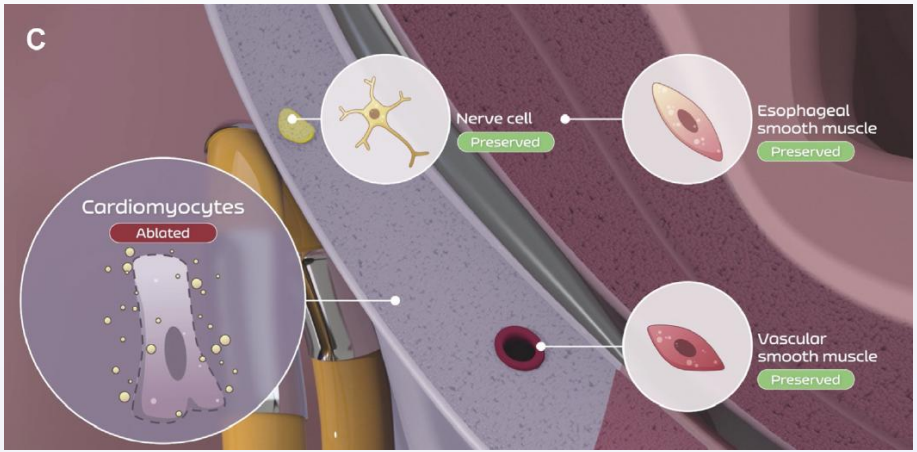
Ablace pulzním polem (PFA) – tkáňová selektivita

Optimalizovaná PFA = tkáňově selektivní

PFA ovlivňuje myokard a zachovává ostatní tkáně

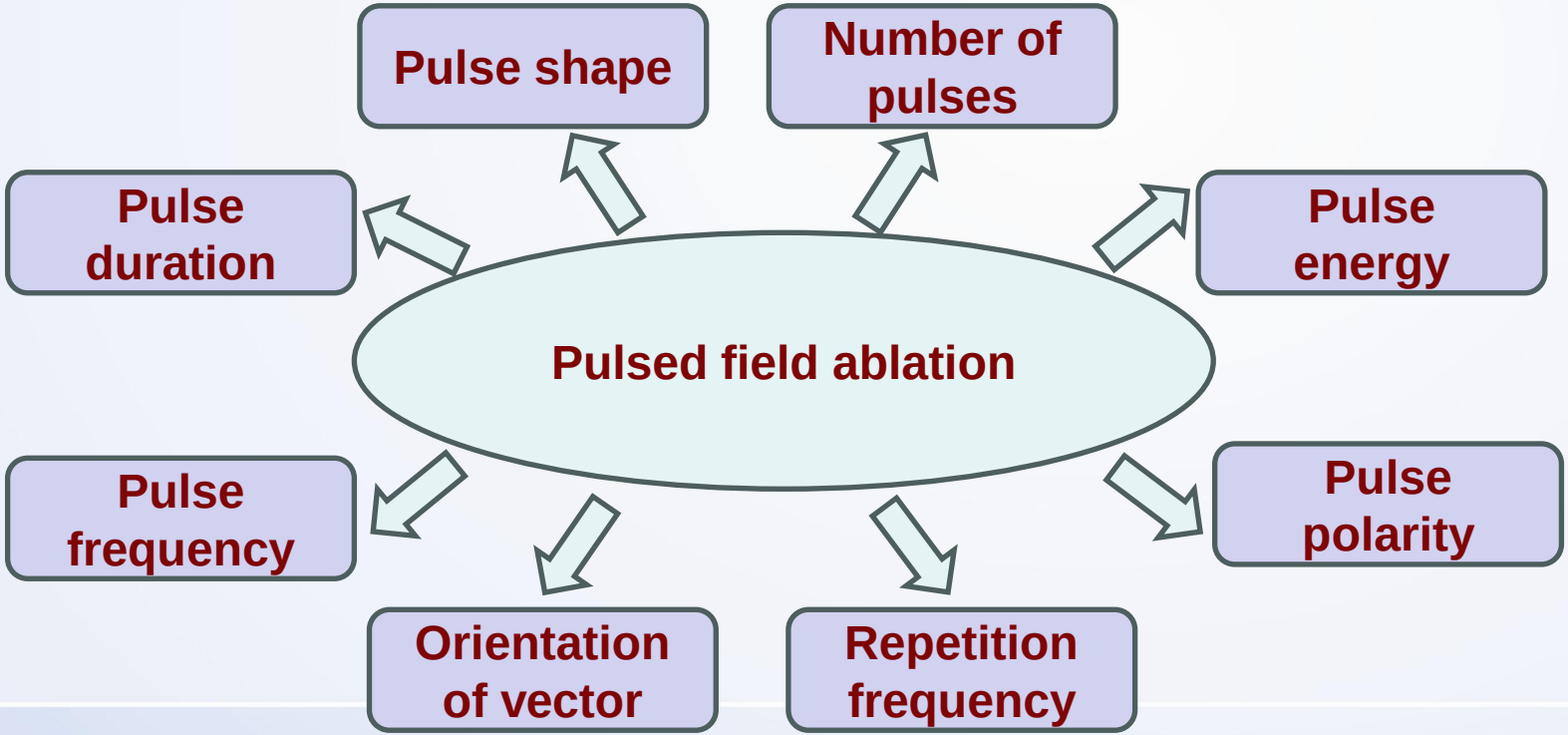


Ostatní tkáně jsou vice rezistentní k PFA a zůstávají nepoškozeny při aplikaci PFA



[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.

Ablace pulzním polem (PFA) – závislost na předem nastavených parametrech (žádný třídní efekt)



Určující prvky tvorby účinné léze

- Síla elektrického pole – čím silnější, tím větší efekt
- Počet pulzů a četnost opakování– čím více, tím větší efekt
- Trvání pulzu – delší = účinnější (ne však lineárně)
- Tvar pulzu – čtvercové vlny nejčastější,
- Velikost elektrod a vzdálenost– ovlivňuje distribuce pulzního pole
- Orientace elektrod– větší efekt při aplikaci paralelně k vláknům
- Unipolární vs bipolární – unipolární = hlubší léze s méně energií
- Joulový ohřev – minimální (může překročit 50 C)

Sugrue A, et al. Europace 2022;24:1213-1222

Regionální katetr: Koncept zjednodušené izolace plicních žil

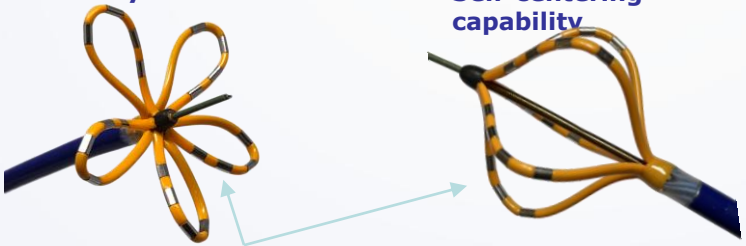
FARAPULSE PFA System – první pionýr

FARADRIVE
Steerable Sheath

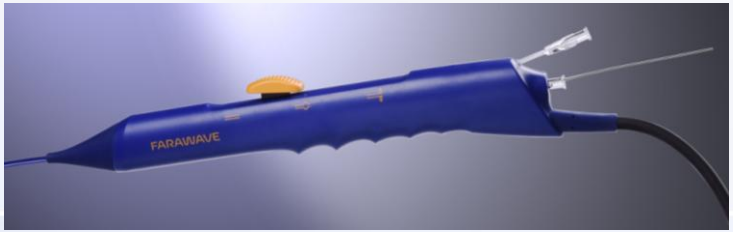
FARAWAVE
PFA Catheter

FLOWER
- Antral positioning
- Radially widest lesion

BASKET
- Ostial positioning
- Self-centering capability



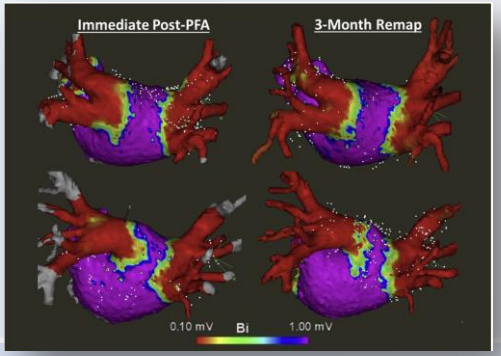
5 splines, each with 4 active electrodes
3rd electrode available for pacing and recording EGMs



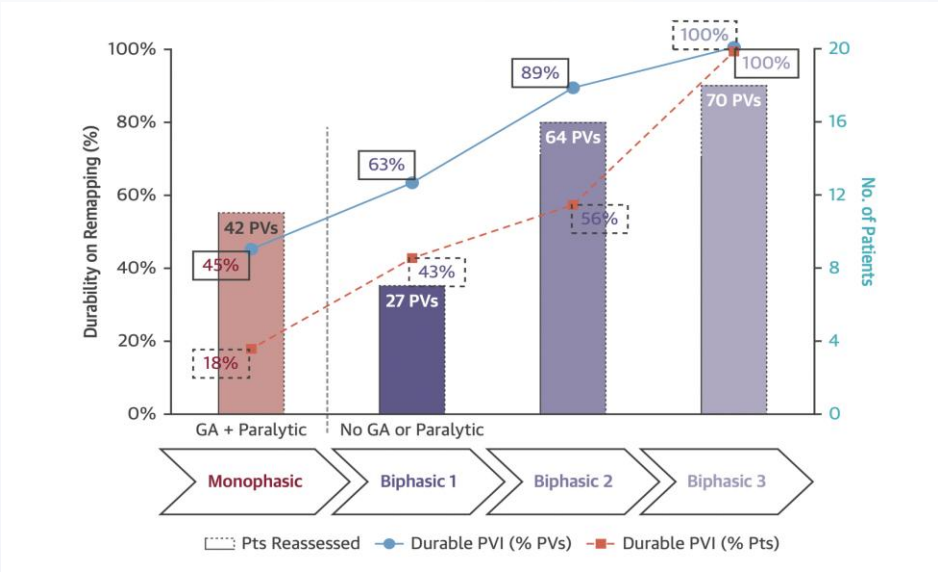
FARASTAR
PFA Generator

Klíčová studie s PFA pro izolaci plicních žil

- 81 pts, PVI monofazická (n=15) nebo bifazická (n=66) PFA
- skin-to-skin čas výkonu 92.2 " 27.4 min,
- Skia čas 13.1 ± 7.6 min
- 1 tamponáda

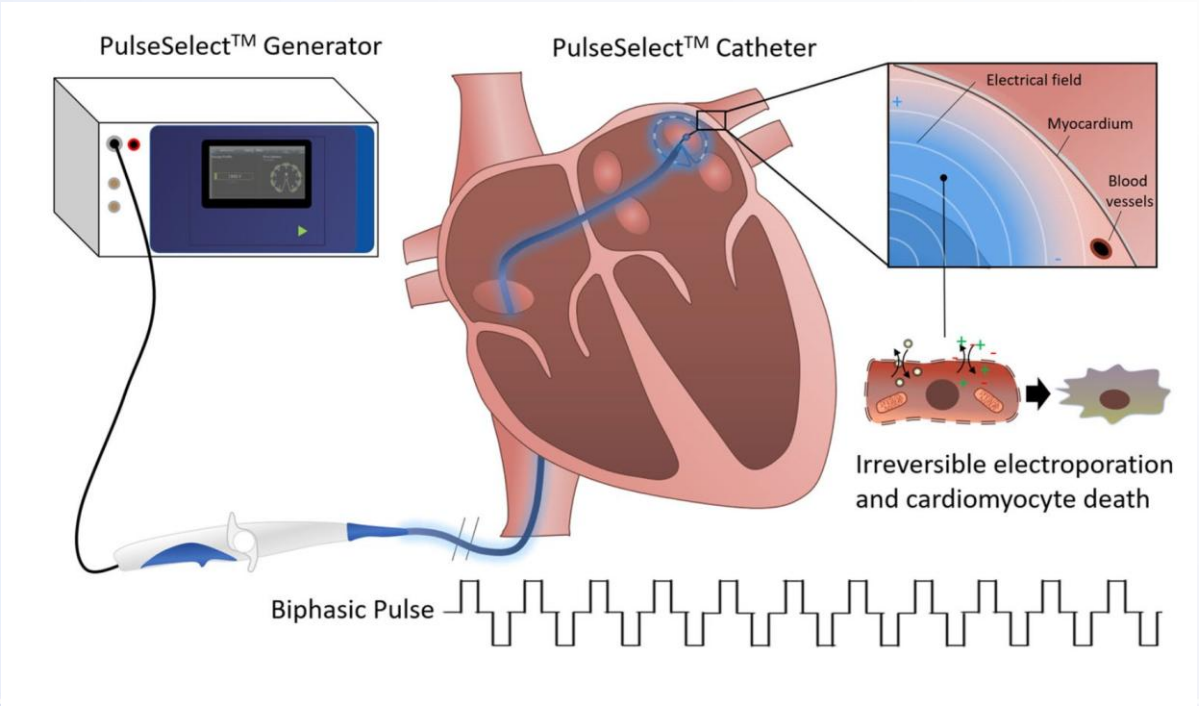


Data z remapování za 3 měs

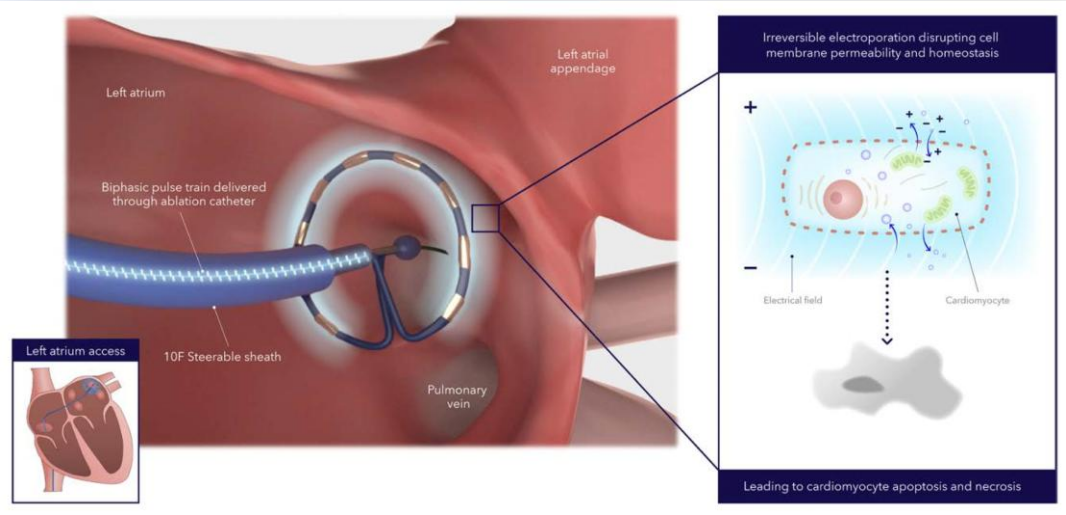


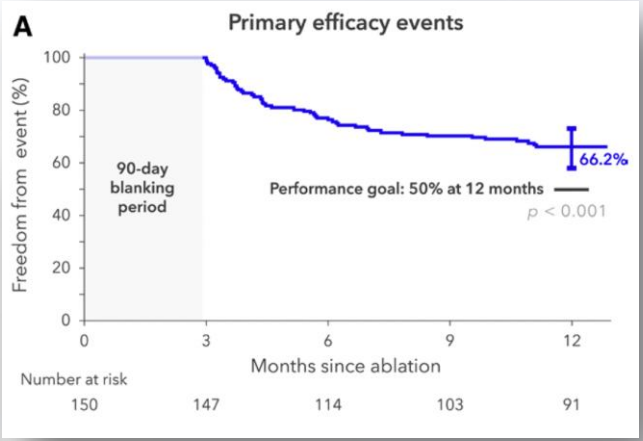
Reddy VY, et al. JACC 2019;74:315-326

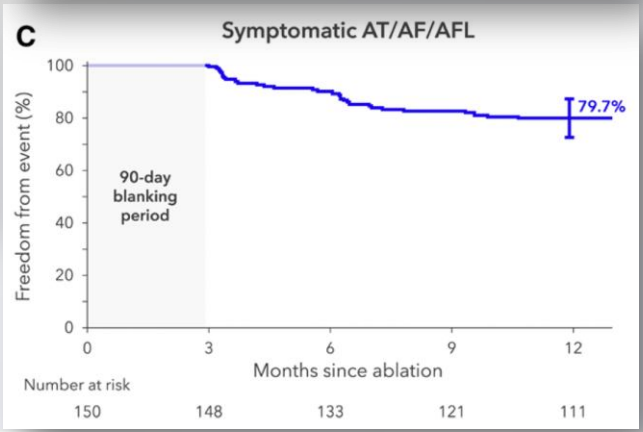
PulseSelect (Medtronic)



PULSED AF pivotal trial



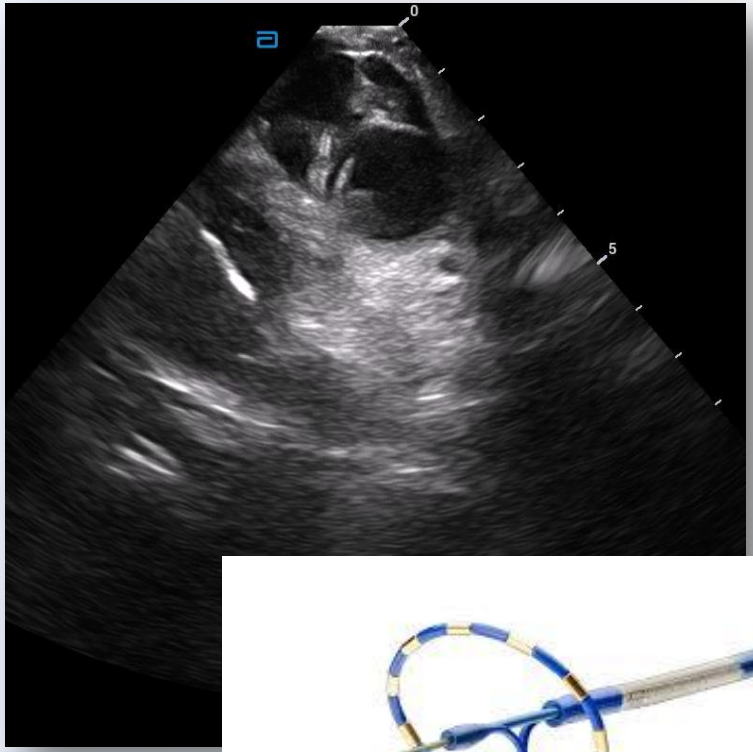


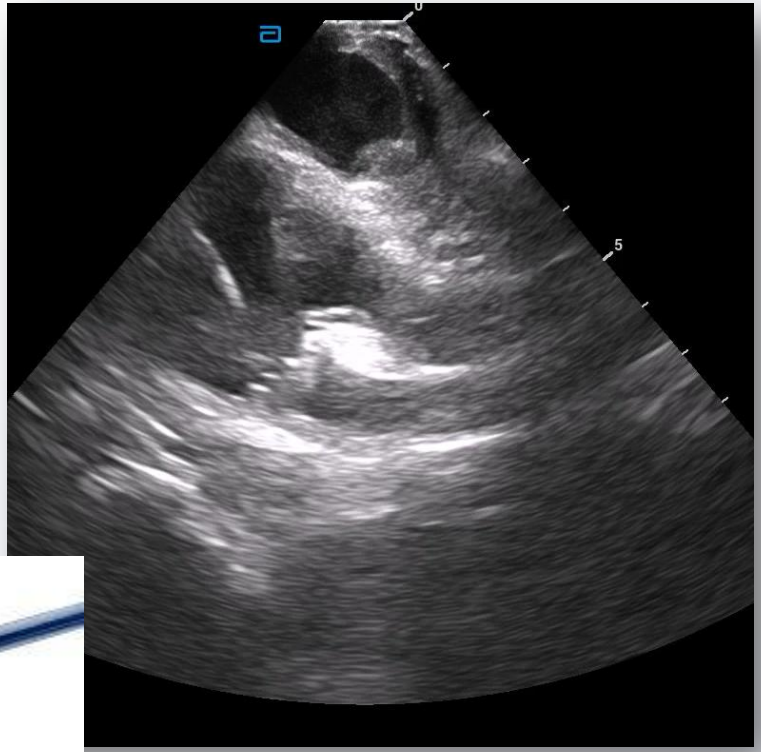


150 paroxysmální, 150 persistující FS pts
Bezpečnost: 1 CMP u parox, 1 tamponáda u persist
0.7% nežádoucí události

Verma A, et al. Circulation. 2023;147:1422–1432.

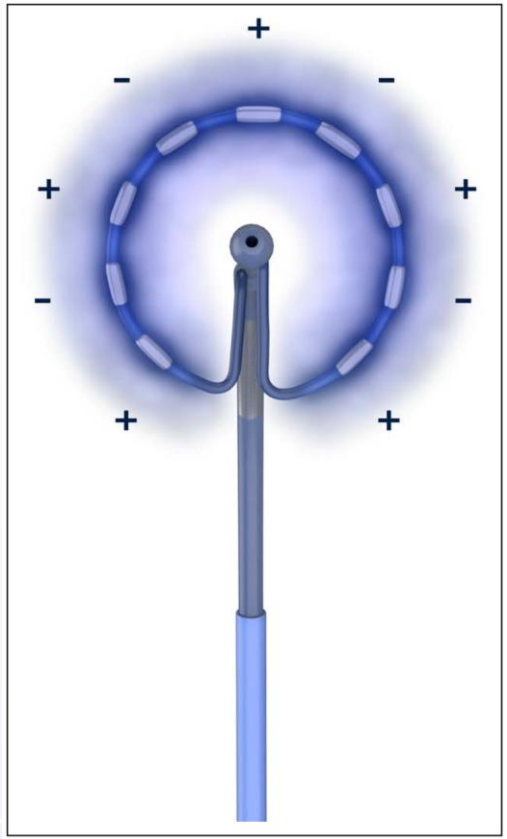
Technologie Pulse select (Medtronic)

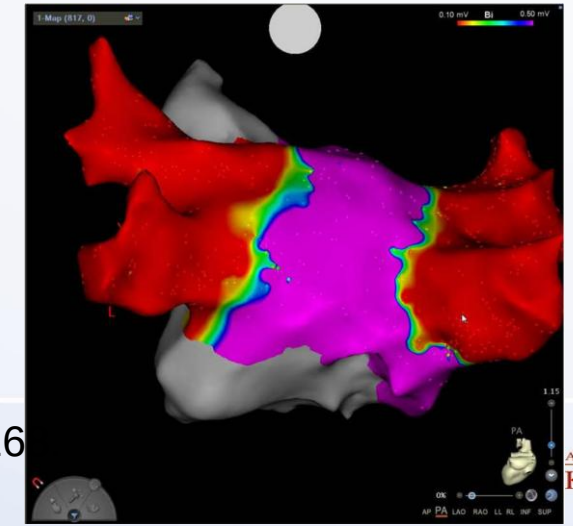




PULSED AF Pilot Trial

- Nerandomizovaná, multicentrická, prospektivní studie
- Proveditelnost a bezpečnost ablace pomocí Pulse Select (Medtronic)
- 38 FS pts, 9 center
- Akutní izolace PŽ 100%, skin-to-skin čas 160±91 min, skia 28±9 min
- Žádná nežádoucí událost

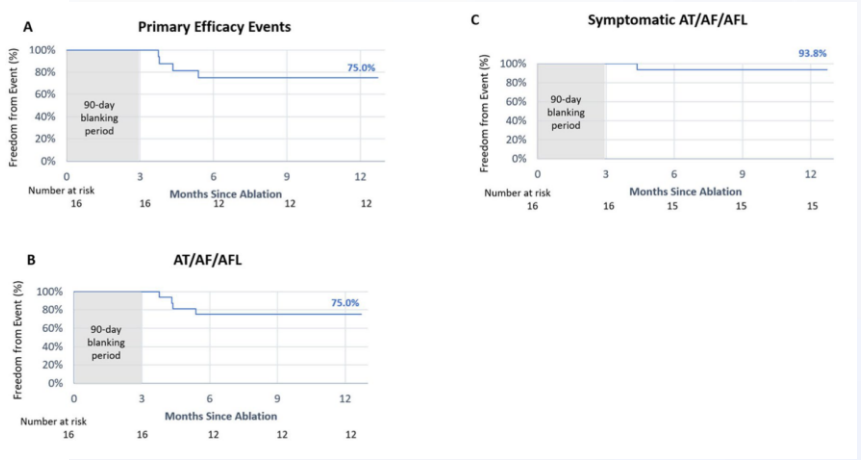




Verma A, et al. Circulation 2022;15: e010161

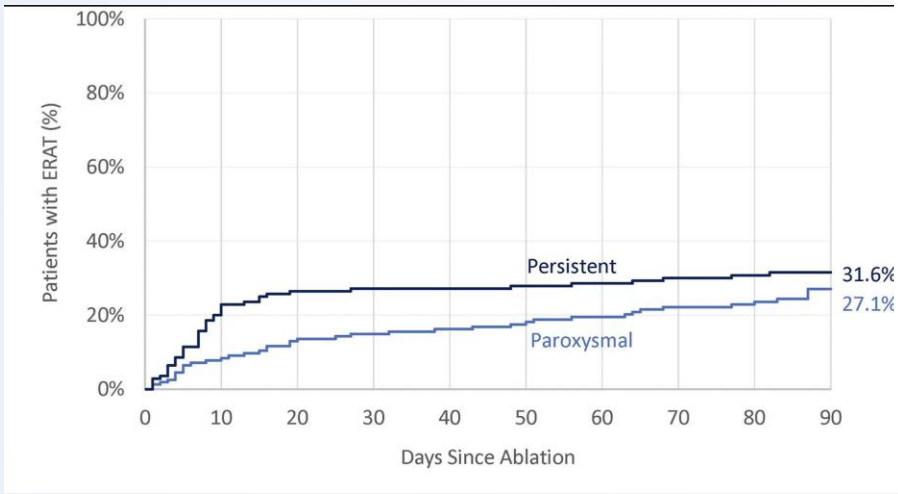
Pulsed AF Japonsko

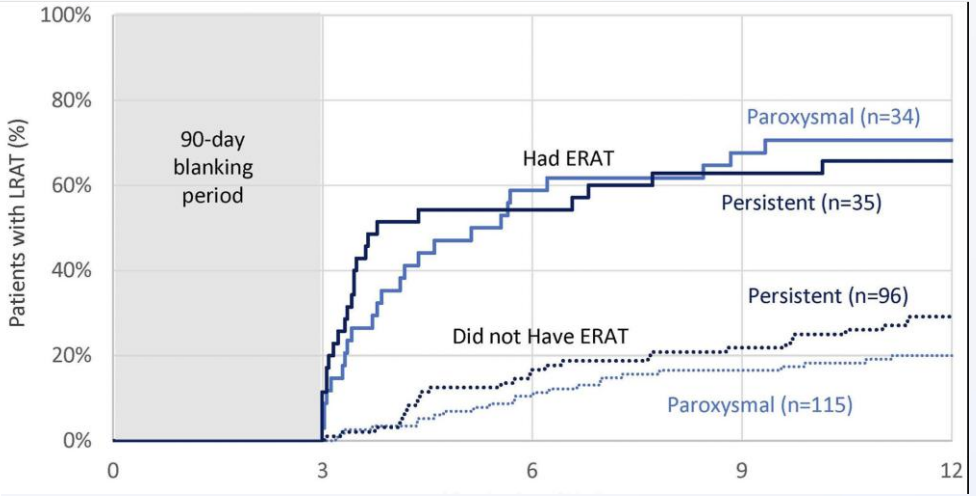
Parameter	Paroxysmal ($n = 16$)	Persistent ($n = 16$)
Skin-to-skin procedural time (min)[†]	146 ± 41 147.5 (111.5–175.5)	156 ± 63 133.5 (113.5–188.5)
Time between first and last application (min)[‡]	66 ± 27 65.5 (43–84)	64 ± 33 51.5 (47–78.5)
Fluoroscopy time during procedure (min)	45 ± 23 41 (24–65)	48 ± 28 47 (26–60)
Total pulsed field ablation energy delivered (sec)	21 ± 2 21 (19–22)	22 ± 3 23 (21–24)
Number of applications per procedure	40 ± 4 40 (37–43)	43 ± 5 43.5 (41–46.5)
Type of anesthesia used		
General anesthesia	0 (0)	0 (0)
Deep sedation	8 (50)	10 (63)
Conscious sedation	8 (50)	6 (38)
Neuromuscular blockade use	0 (0)	0 (0)
Isoproterenol and/or adenosine used to assess PVI	5 (31)	9 (56)
Intra-procedural cardioversions	4 (25)	12 (75)
Esophageal temperature change from baseline (°C)	0.3 ± 0.2[§] 0.4 (0.3–0.4)	0.3 ± 0.1[¶] 0.3 (0.2–0.4)
Intracardiac echocardiography	7 (44)	6 (38)
Mapping/navigation system used		
CARTO	2 (13)	2 (13)
EnSite	1 (6)	0 (0)
Rhythmia	12 (75)	11 (69)
None of the above	1 (6)	3 (19)
Acute Pulmonary Vein Isolation	62 (100)	64 (100)



Yamane T, et al. JICE (2025) 68:149–157

Prevalence časných rekurencí síňových arytmií časně po ablaci

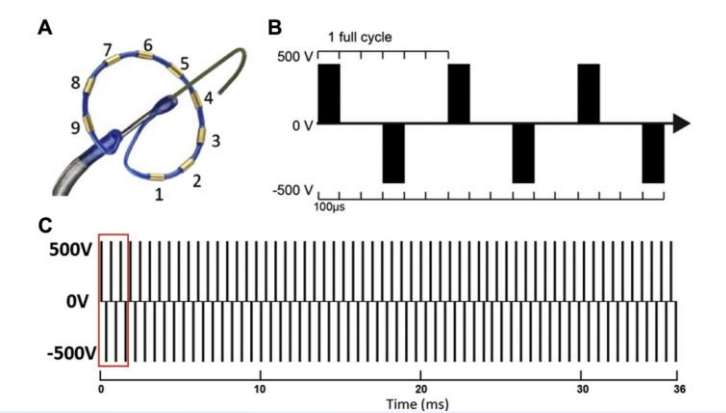




154 parox FS, 140 persist FS

Boersma L, et al. Heart Rhythm 2025 Apr;22(4):884-890.

PF vs RF



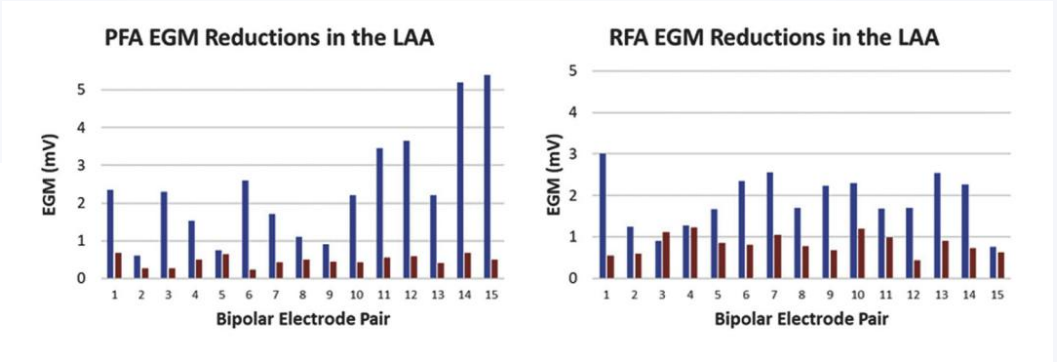
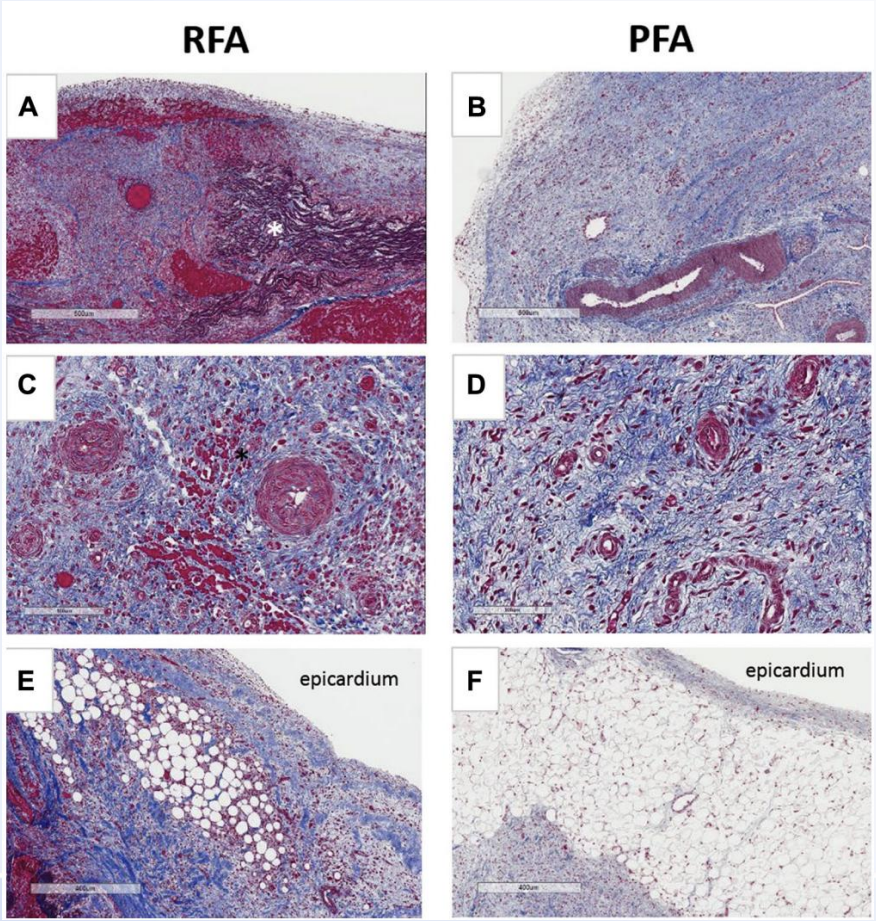


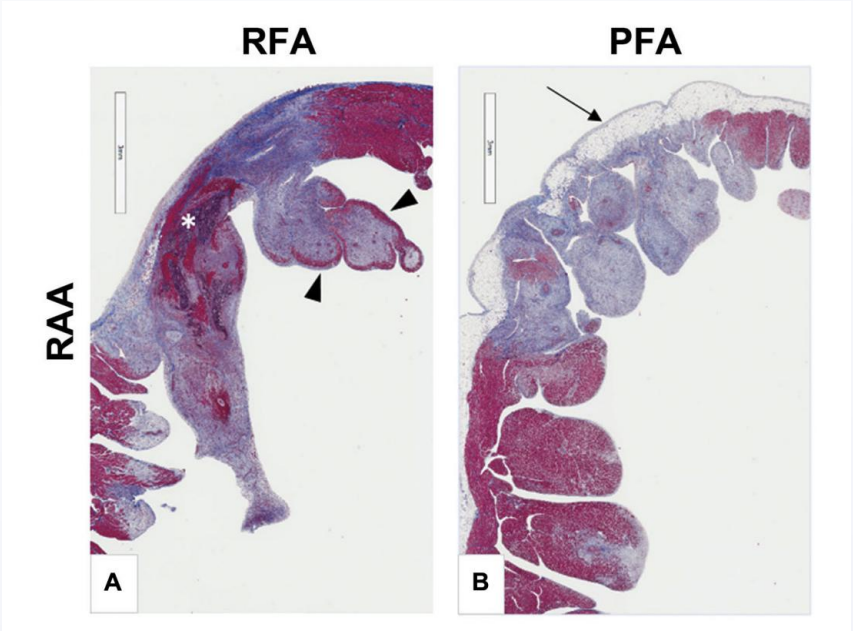
Table 1 Acute electrical results, histopathologic lesion measurements, and histopathologic cross-section focal transmurality assessments

	RFA			PFA			
	Avg	SD	n	Avg	SD	n	*P* value
EGM amplitude reduction* (%)	56.4	27.5	41	72.2	23.1	45	.005
>50% EGM amplitude loss* (%)	73.2	—	41	91.1	—	45	.027
EGM amplitude to <0.5 mV† (%)	27.0	—	111	67.5	—	114	.001
Loss of pace capture‡ (%)	92.2	—	78	100	—	69	.005
Lesion depth (mm)	2.47	1.01	21	2.25	0.85	20	.477
Lesion length (mm)	24.2	15.7	6	29.9	11.1	8	.479
Lesion width (mm)	6.5	4.6	7	12.0	3.9	8	.033

Energy	RPV transmural/total	LAA transmural/total	RAA transmural/total	Combined transmural/total
PFA	6/6 (100%)	4/8 (50%)	6/7 (86%)	16/21 (76%)
RFA	5/7 (71%)	1/5 (20%)	7/8 (88%)	13/20 (65%)

Stewart MT et al. Heart Rhythm 2019 ;16(5):754-764





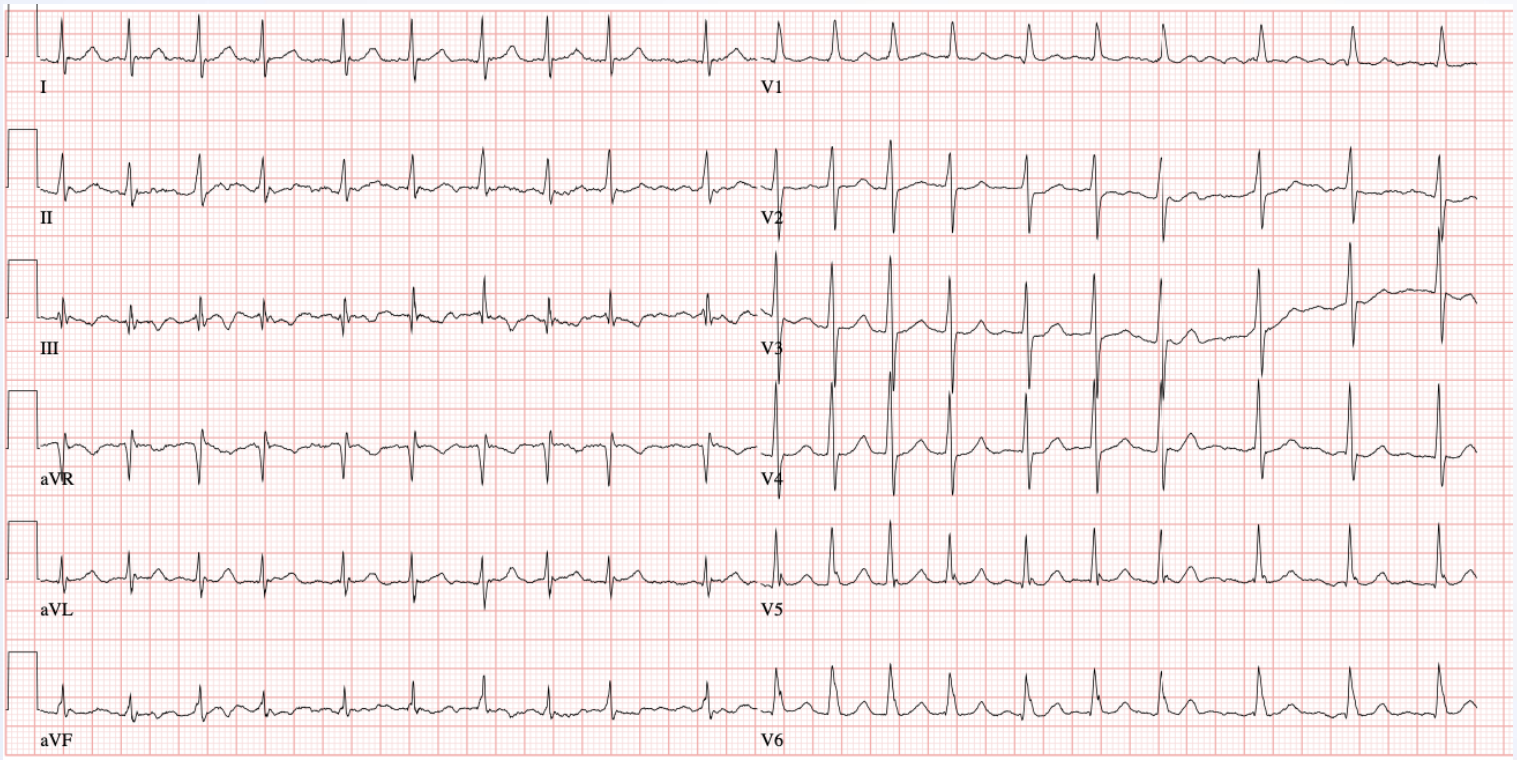
Prasečí model, 6 zvířat

Stewart MT et al. Heart Rhythm 2019 ;16(5):754-764

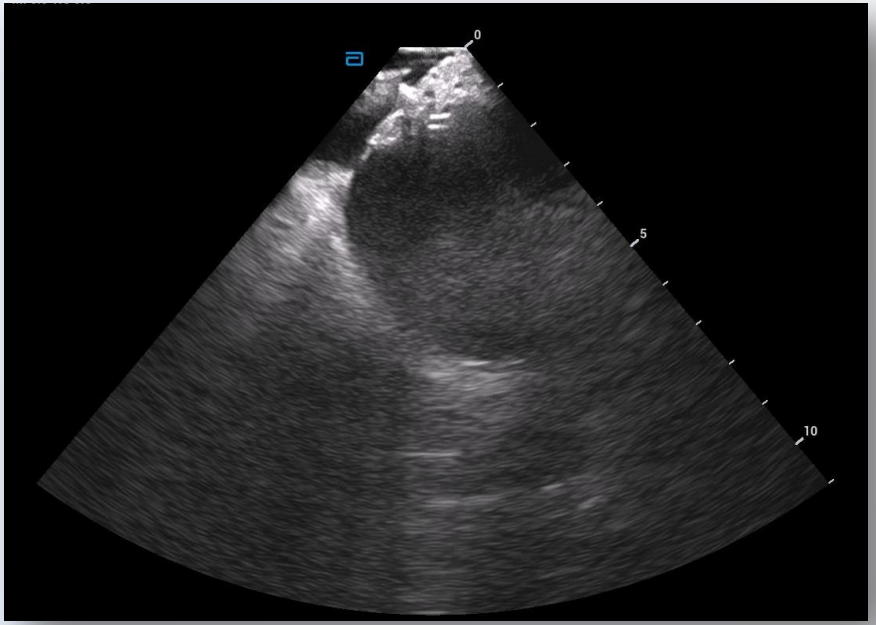
Ilustrativní případ

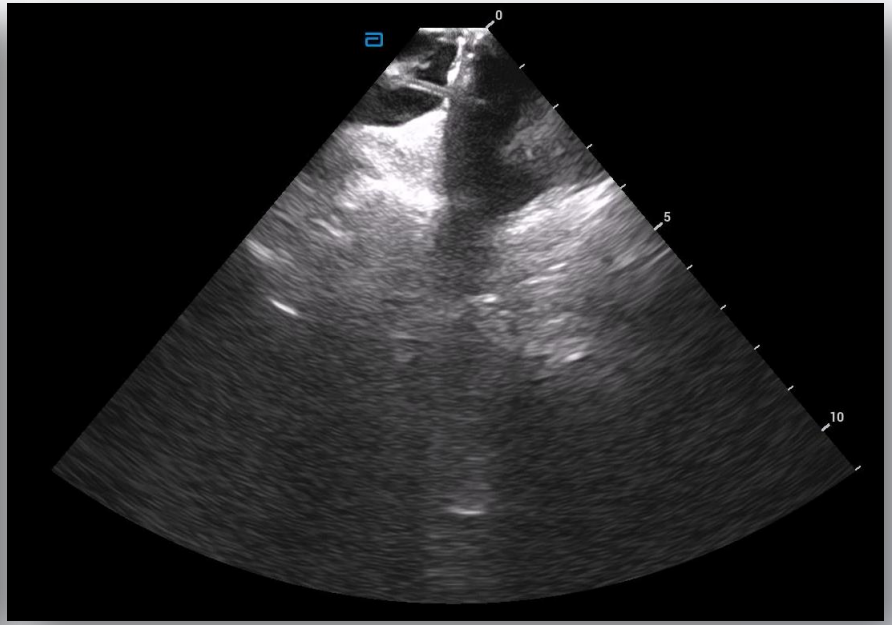
- 54-letý muž
- Arteriální hypertenze (2017)
- 2020 TIA, MRI (vícečetná ložiska v bílé hmotě)
- Normální echokardiogram, FOP s PL zkratem
- 2021-uzávěr FOP (při výkonu dokumentována poprvé FS)
- 2024 EKV, přechodně LVEF 45
- Recidivy FS i při léčbě propafenonem a BB

První dokumentace FS

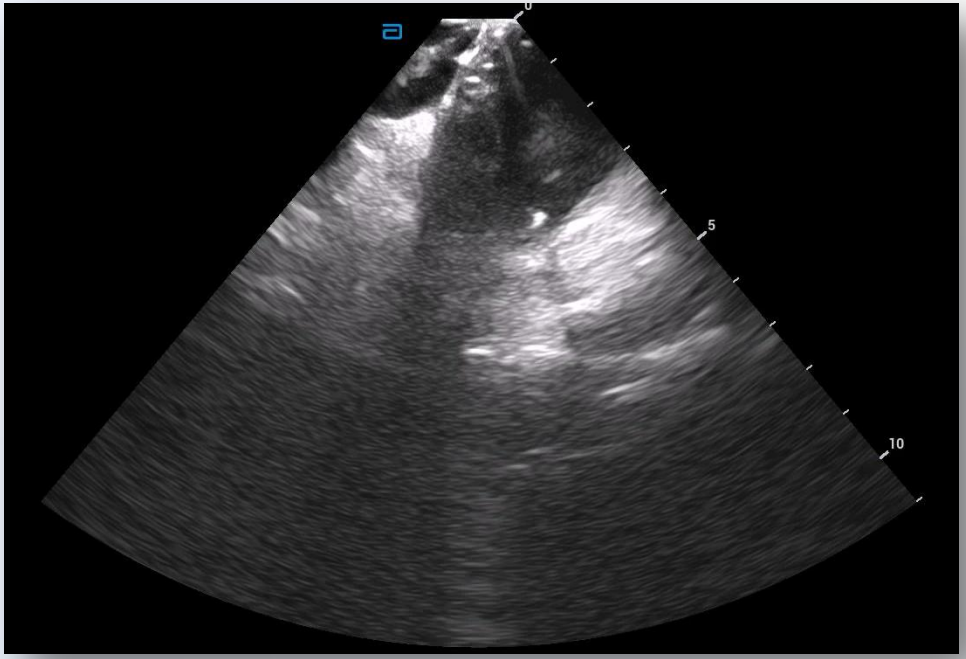


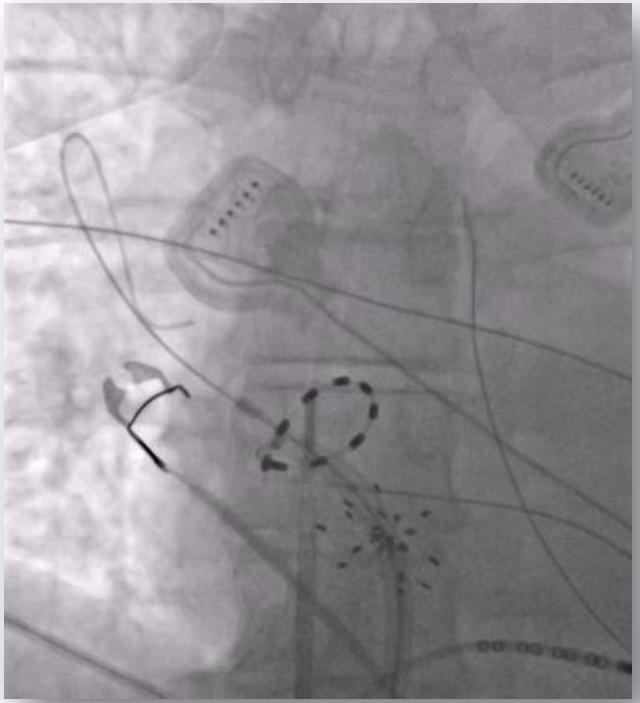
Okludér FOP a TS punkce



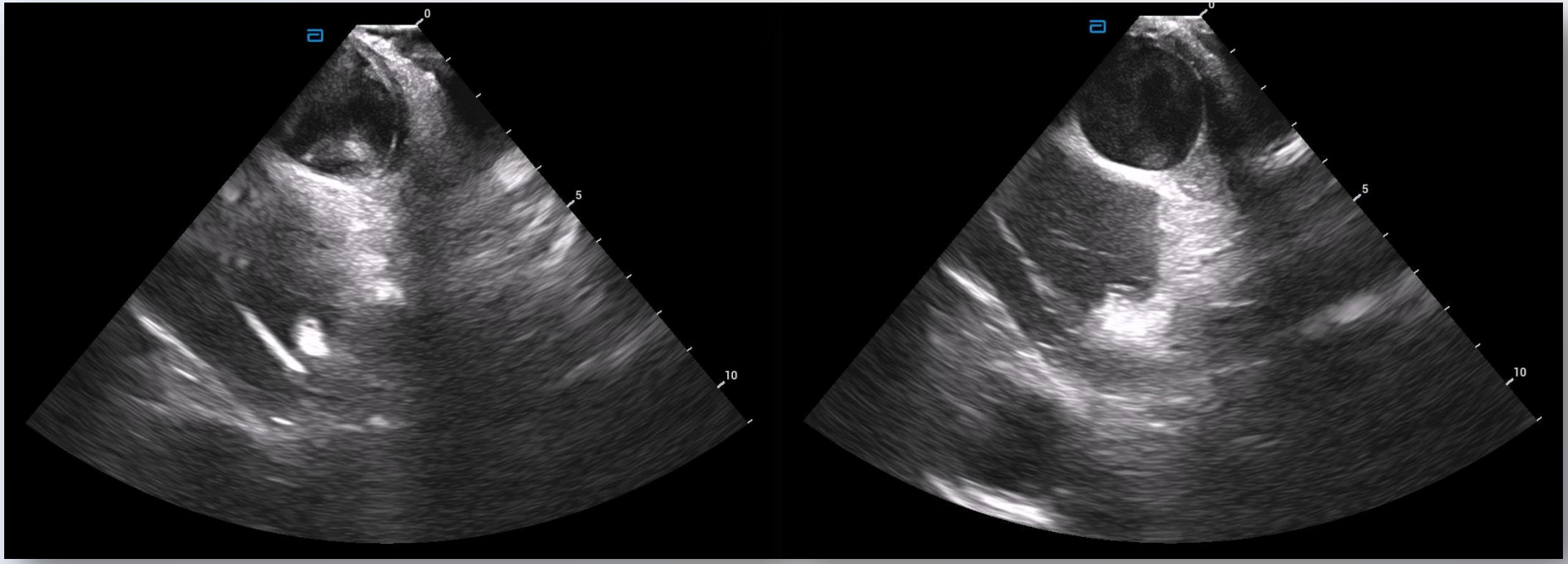


Ukázka ablace pravé dolní žíly



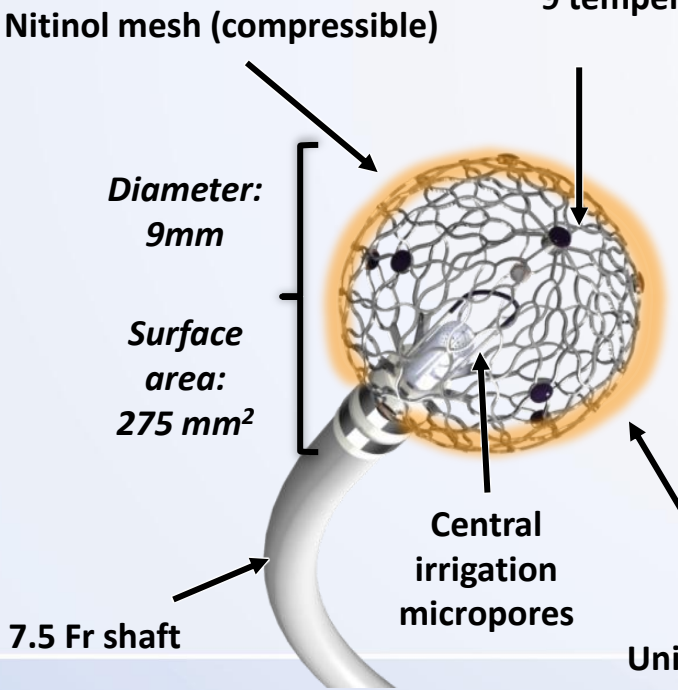


Oblast ouško-levá horní PŽ



AFFERA mapovací a ablační systém

Vyvinut Affera, Inc., Watertown, MA,
Získán Medtronic



Affera System:
- PFA
- RFA
- EAM

Sphere-9™ technology = lattice tip catheter

AFFERA 360 – přizpůsobitelný regionální katetr (nitinol)

Conformable lattice tip

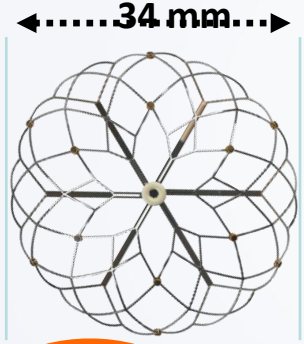
- Rotation free positioning
- 2-5 applications per PV

EM sensors

- Allow tracking, shape visualization, catheter orientation, tagging, & anatomical/activation/ voltage mapping.

Monopolar/Biphasic WF

- 5 sec per application



6 sections

Independently
and sequentially energized

Shape Adapting Design

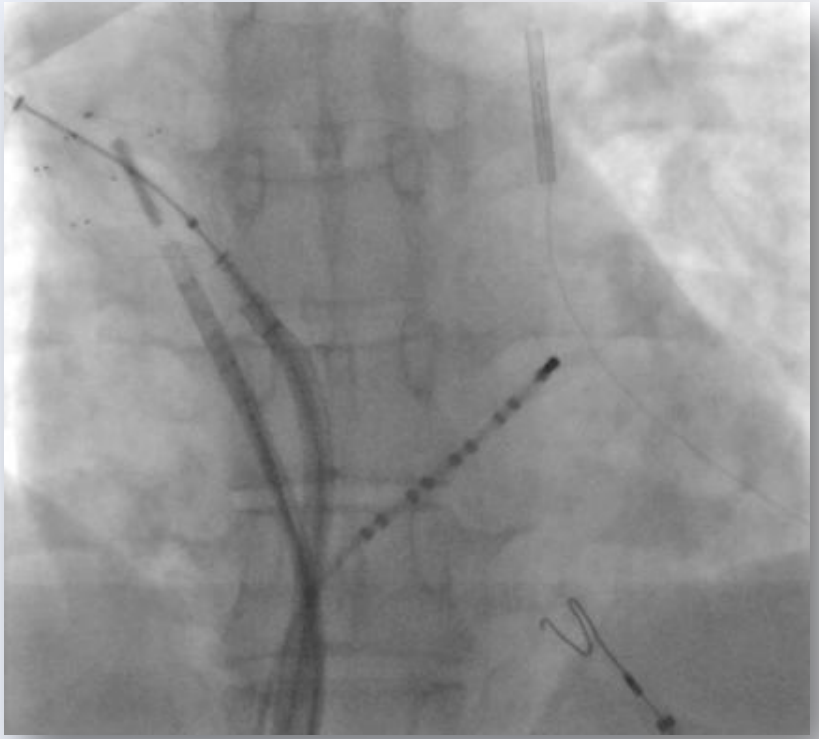
- Expandable to 34 mm with 3 shapes

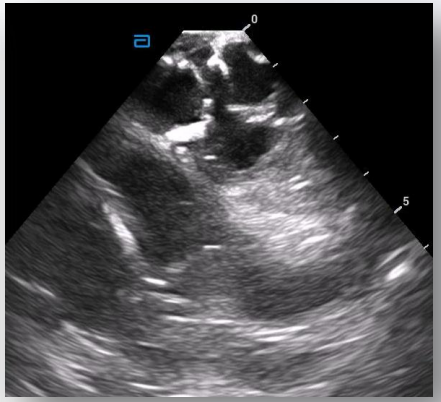
All-in-One Mapping and Ablation

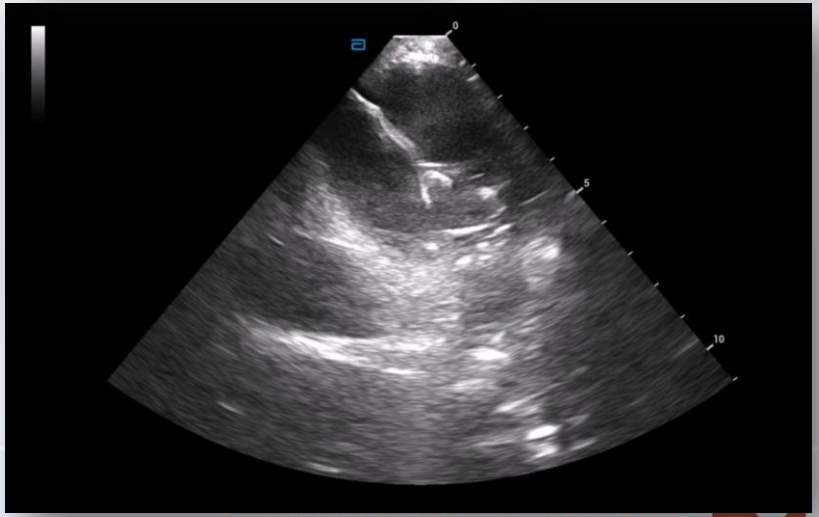
- 6 bipolar electrode pairs for mapping and pacing
- Local impedance assessment
  - Assess catheter proximity to tissue
- Single transeptal puncture

8F, non-steerable, no irrigation

- Over-the-wire design





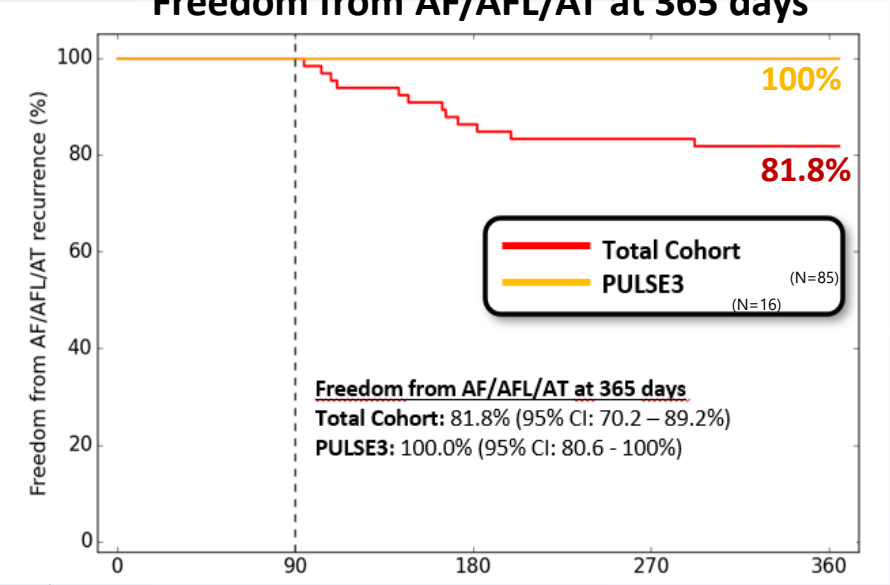


Ukázka pacienta ze studie

CP-00013-02-015 – 11-Mar-2024

First-in-Human Study
Efficacy and Safety

Freedom from AF/AFL/AT at 365 days

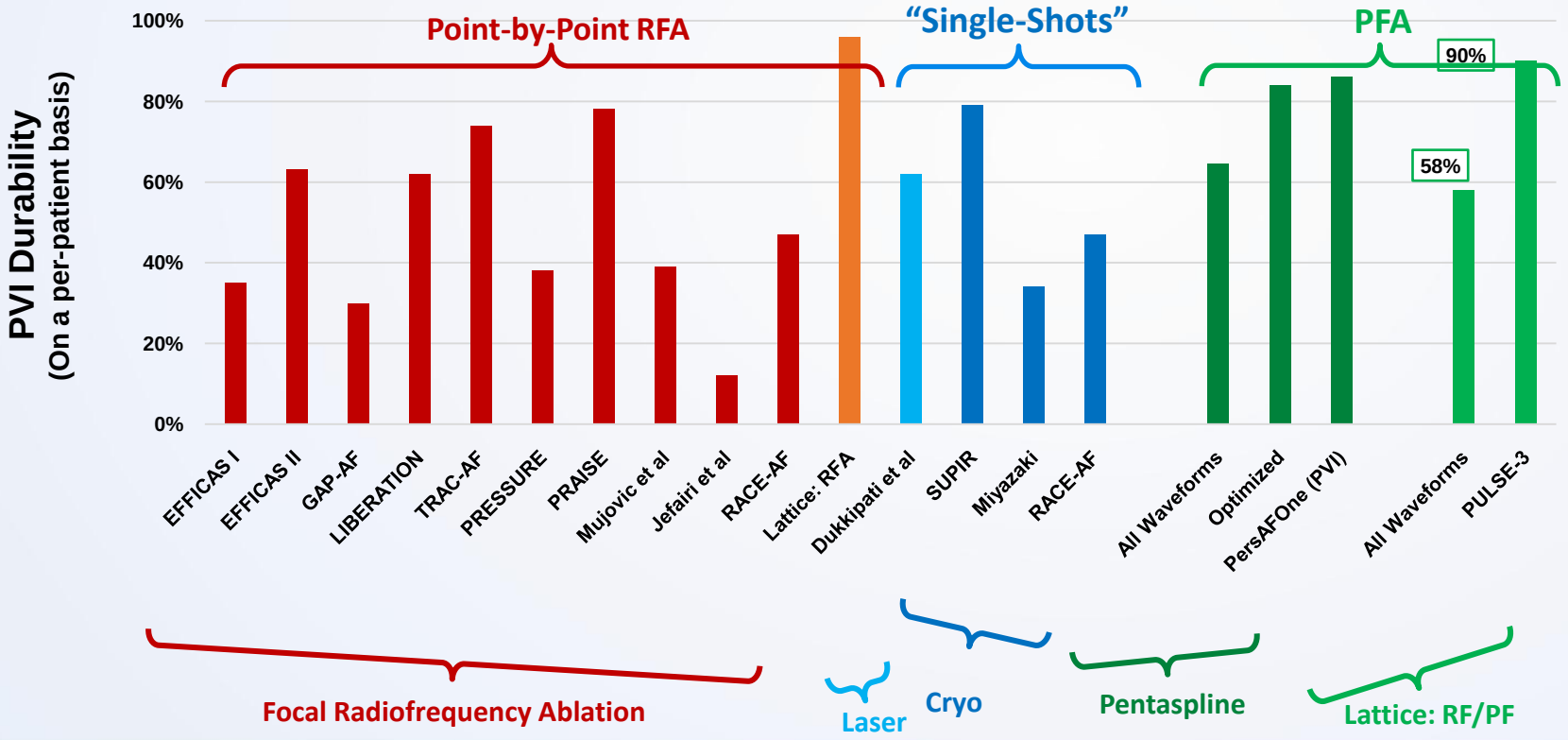


Number At Risk					
Total Cohort	85	66	57	55	54
PULSE3	35	16	16	16	16

	Primary Safety Events	Total Cohort (N=85)
SAEs included in primary safety endpoint (within 7 days)	**Total subjects with primary safety events**	**0**
	Death	0
	Myocardial infarction	0
	Persistent phrenic nerve palsy	0
	Transient ischemic attack	0
	Stroke/cerebrovascular accident	0
	Thromboembolism	0
	Major vascular access complications/bleeding	0
	Heart block	0
	Gastroparesis	0
	Severe pericarditis	0
	Hospitalization (initial and prolonged) due to cardiovascular or pulmonary AE *	0
	Cardiac tamponade/perforation†	0
	Pulmonary vein stenosis ‡	0
	Atrio-esophageal fistula ‡	0
Serious device / procedure-related AEs		1 (1.2)

** Excludes hospitalization due to AF/AFL/AT recurrence*
† Occurring up to 180 days after index ablation is considered primary safety event
‡ Occurring up to 180 days after index ablation is considered primary safety event
 # Symptom remission in 2 days. MRI evaluation - ruled out embolic event

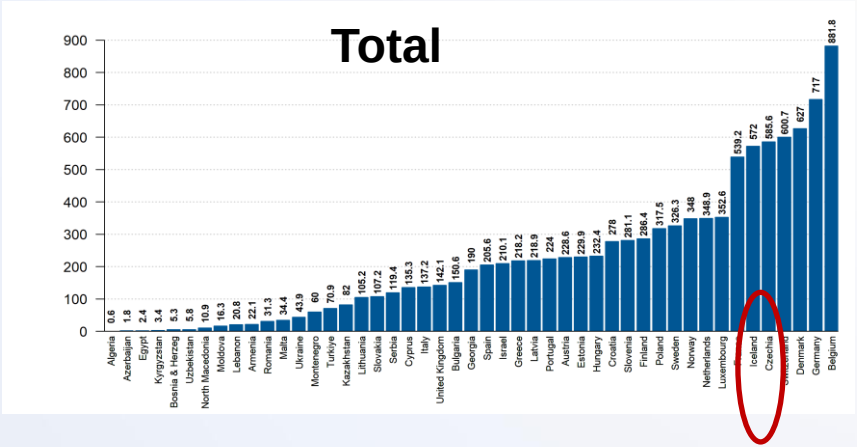
Trvanlivost léze: srovnání technologií

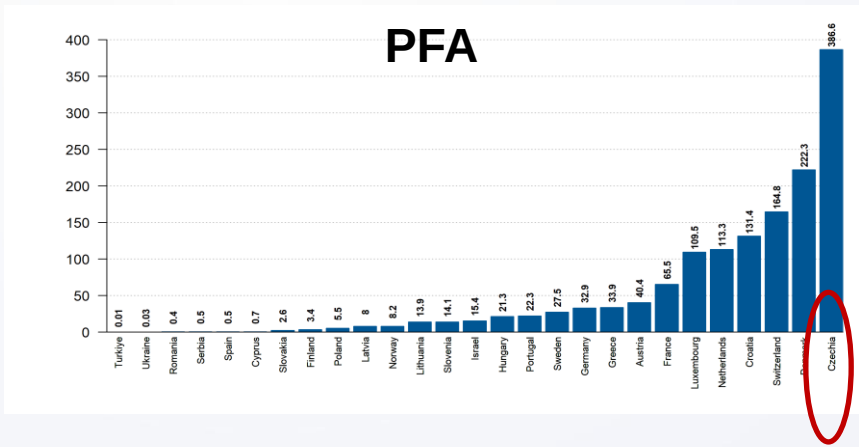


VY.Reddy, et al. *JACC EP* (2023)

Ablace FS v Evropském regionu

(na 1 million 2023)





ESC-EHRA Atlas 1st edition

M. Farkowski et al. 2025, Arrhythmia care in ESC member countries – the 2025 ESC-EHRA Atlas on Heart Rhythm Disorders.
Europace 2025.

INSTITUT KLINICKÉ A EXPERIMENTÁLNÍ MEDICÍNY
KLINIKA KARDIOLOGIE
IKEM

Závěry

- Ablace pulzním polem je netermální druh ablace, kdy je dosaženo selektivního ničení kardiomyocytů destabilizací buněčné membrány s následnou apoptózou
- Existují 3 hlavní typy katetrů pro PFA – regionální, fokální velký půdorys, fokální pevná elektroda
- Katetr Pulse Select dovoluje účinnou a bezpečnou izolaci plicních žil
- Nový katetr Sphere 360 dovolí ještě jednodušší izolací plicních žil

SAVE THE DATE

PRAGUE RHYTHM

PRAGUE RHYTHM 2026

Prague, May 17-19,2026

www.prague-rhythm.cz

IKEM

NEMOCNICE NA HOMOLCE

SRDCE