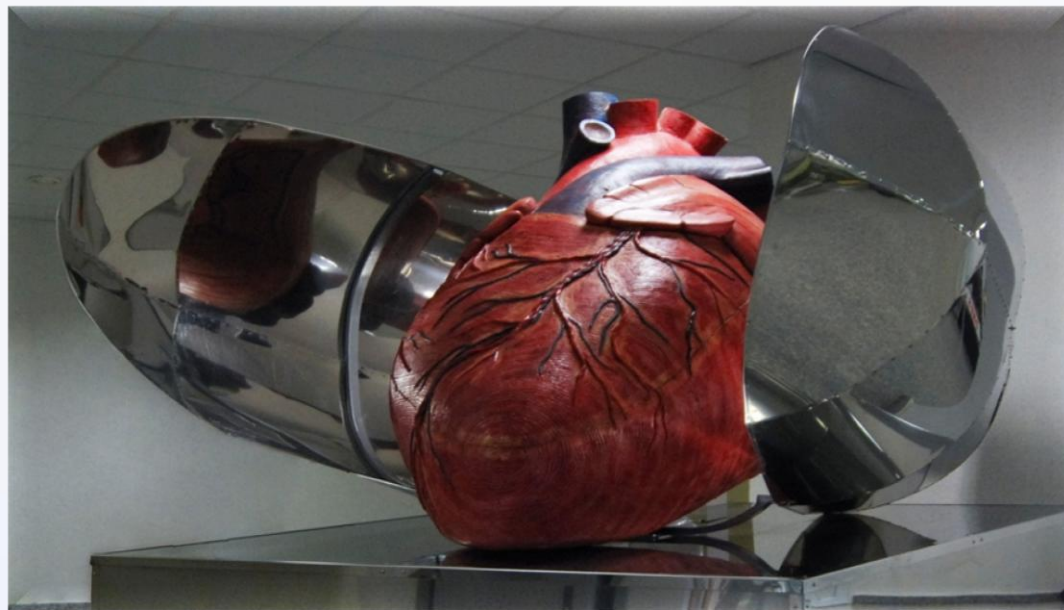


# Co můžeme dnes nabídnout pacientům s fibrilací síní?



*Josef Kautzner*

*Institut Klinické a experimentální medicíny, Praha*

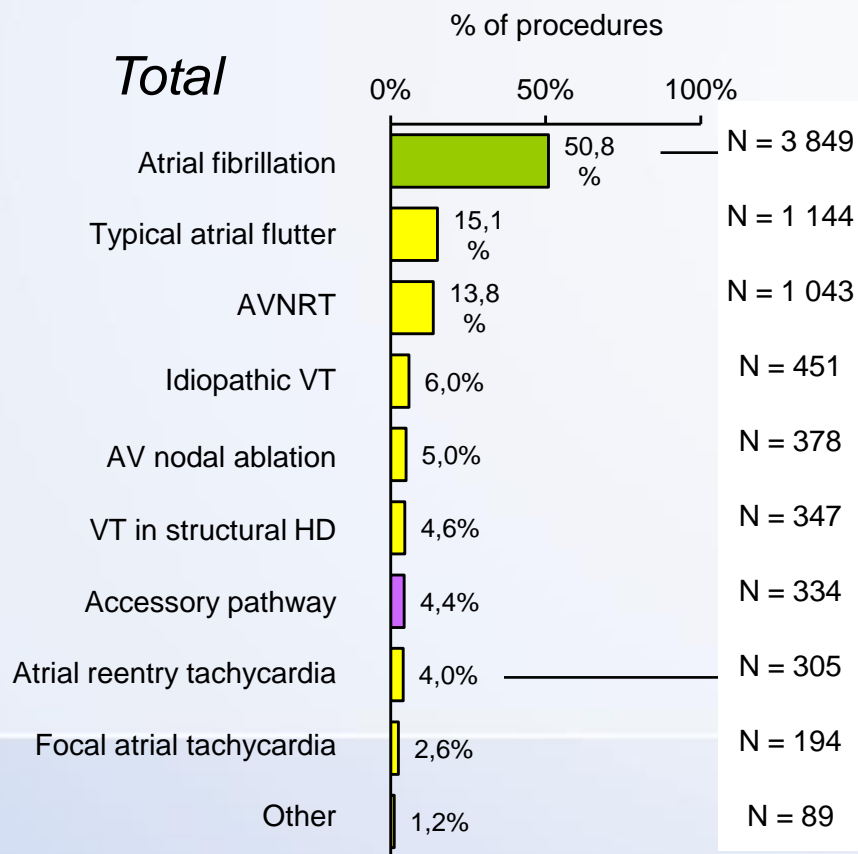
**e-mail: [joka@ikem.cz](mailto:joka@ikem.cz)**  
**[www.ikem.cz](http://www.ikem.cz)**

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KLINIKA KARDIOLOGIE

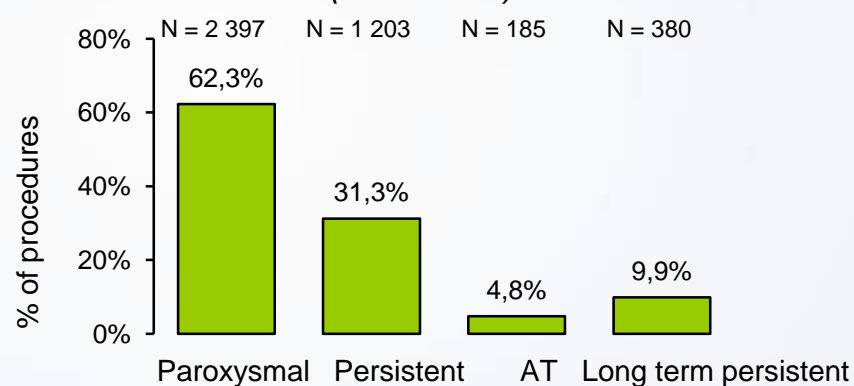


**IKEM**

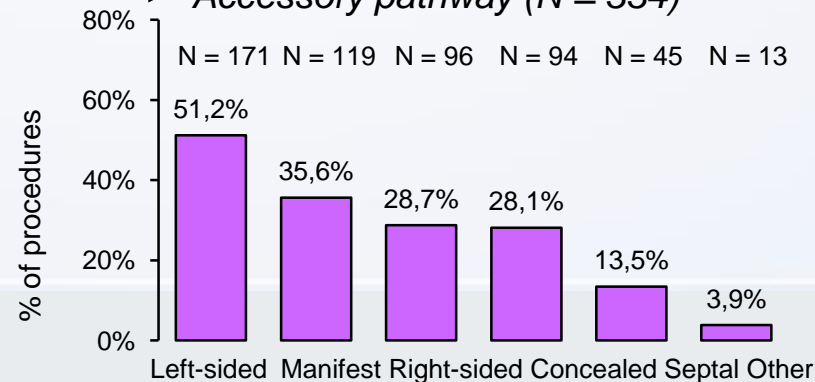
# Ablace FS je nejčastější ablační procedurou v ČR: Czech Ablation Registry 2020



## Atrial fibrillation (N = 3 849)

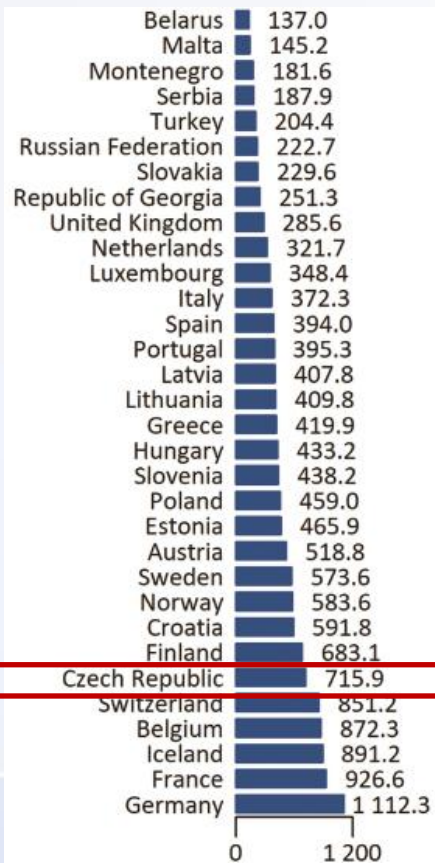


## Accessory pathway (N = 334)



## Czech registry on catheter ablation

### Number of catheter ablation procedures per million people in ESC member countries, 2021



Ablation procedures per million inhabitants in the European Society of Cardiology member countries, 2021

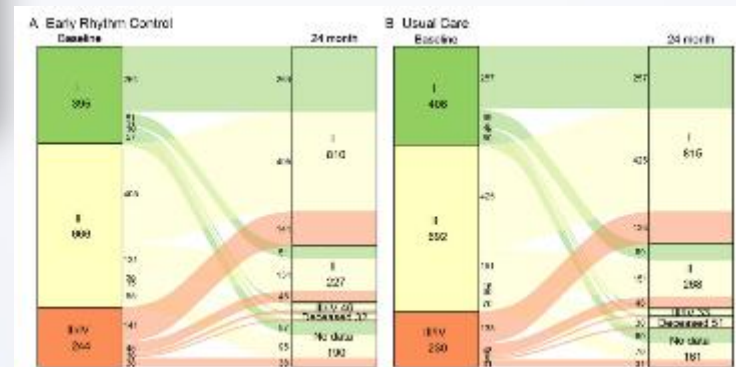
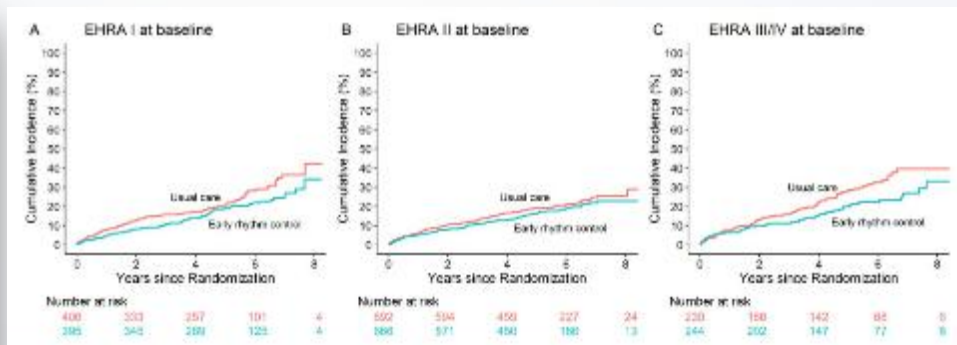
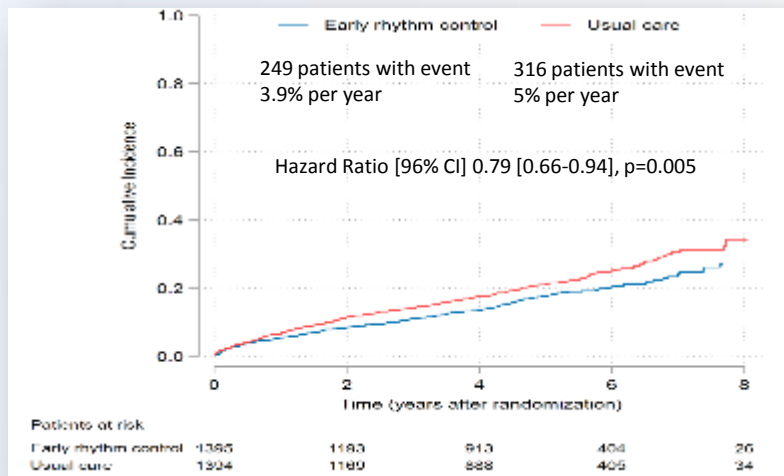
\* In CR - number for 2020



**Nová data ukazují, že snaha o udržení sinusového rytmu přináší lepší prognózu (bez ohledu na symptomy)**



# EAST – AFNET 4 study: časná vs obvyklá léčba FS



2789 pts, 135 míst, 11 zemí

**Pacienti s rizikem KV událostí** ( $\approx$

CHA<sub>2</sub>DS<sub>2</sub>VASc skóre  $\geq 2$ )

a recentně vzniklou FS ('**časná FS**',  $\leq 1$  rok trvání dle EKG dokumentace)

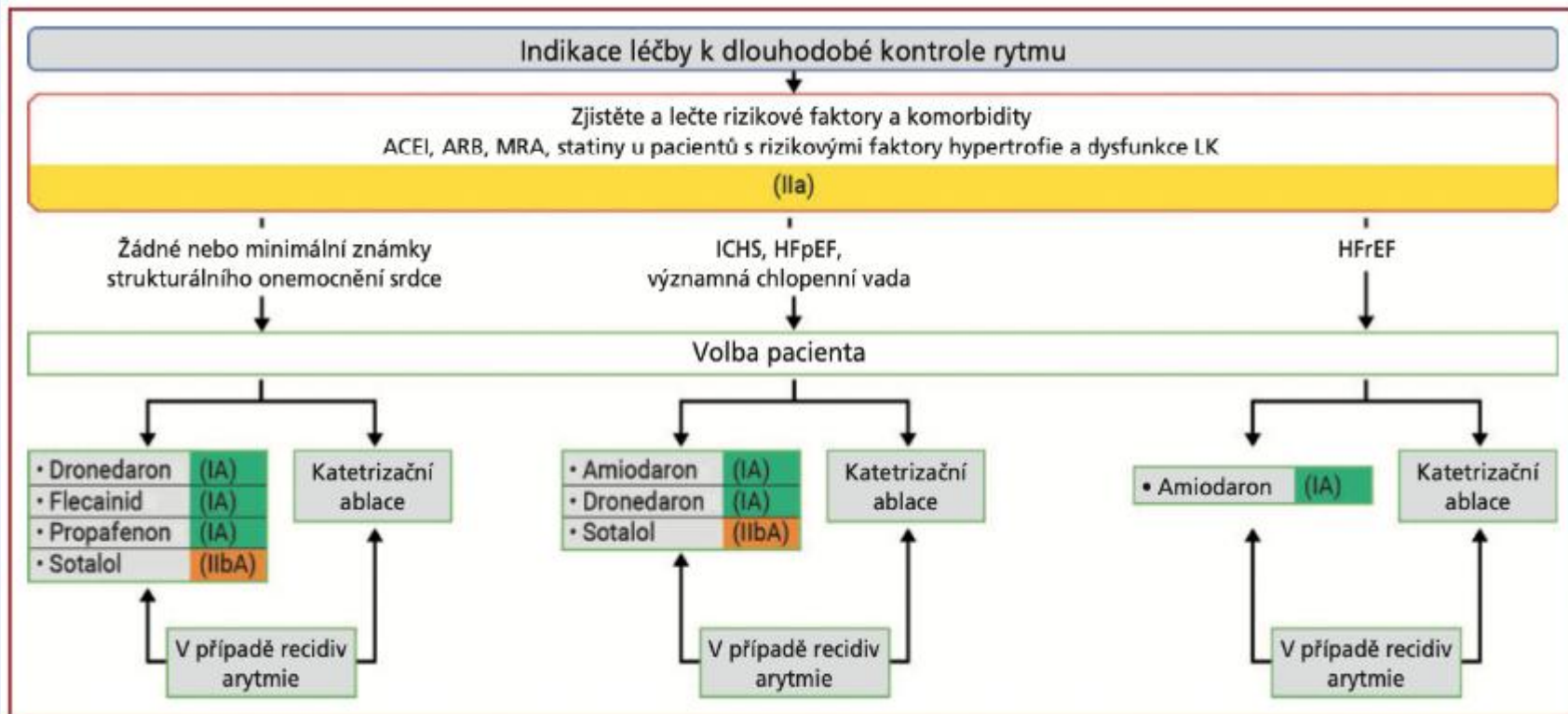
# EAST – AFNET 4 – komponenty primárního endpointu

	Patients with event in Early Rhythm Control (n=1395)	Patients with event in Usual Care (n=1394)	Uncorrected Hazard Ratio [95% CI]
Cardiovascular death	67 / 6915 (1.0)	94 / 6988 (1.3)	0.72 [0.52-0.98]
Stroke	40 / 6813 (0.6)	62 / 6856 (0.9)	0.65 [0.44-0.97]
Hospitalization with worsening of heart failure	139 / 6620 (2.1)	169 / 6558 (2.6)	0.81 [0.65-1.02]
Hospitalization with acute coronary syndrome	53 / 6762 (0.8)	65 / 6816 (1.0)	0.83 [0.58-1.19]

# Jak toho dosáhnout?



# Dlouhodobá kontrola rytmu

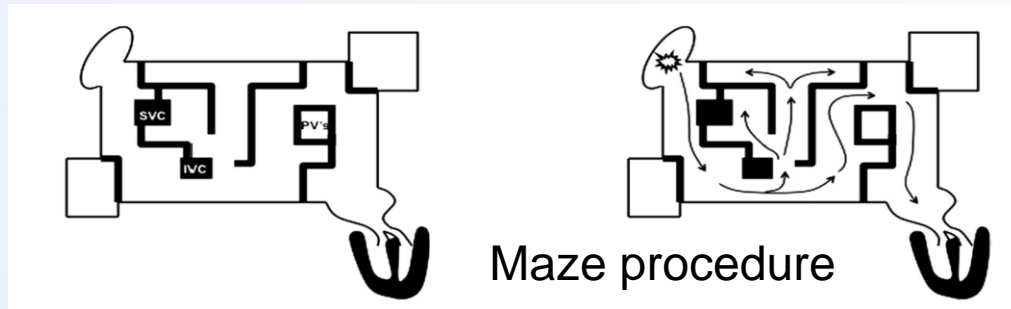




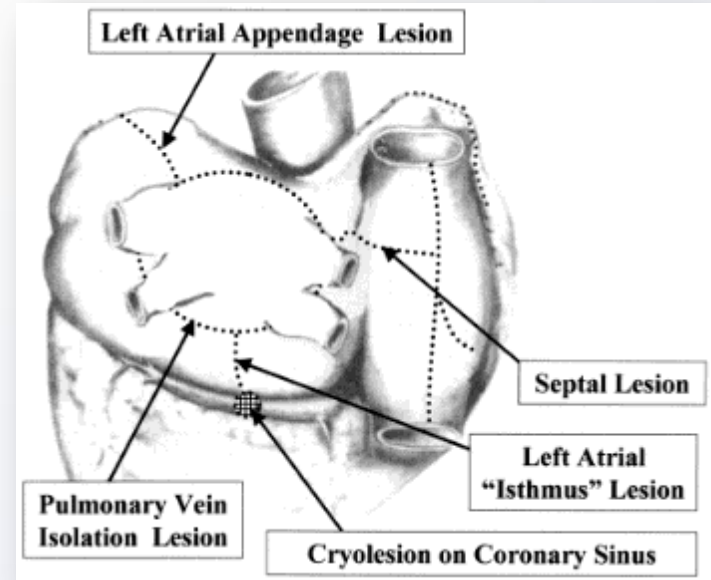
# Revoluční metoda léčby FS – časná 90. léta

If we were going to treat atrial fibrillation surgically, it was now apparent that we had to develop a procedure that made it impossible for the atrium to fibrillate at all.

JL Cox

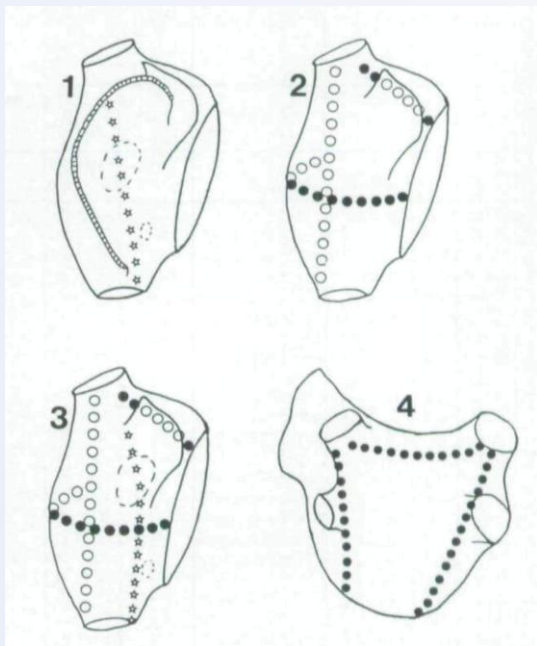


Maze I-III, 168 pts,  
93 % úspěšnost

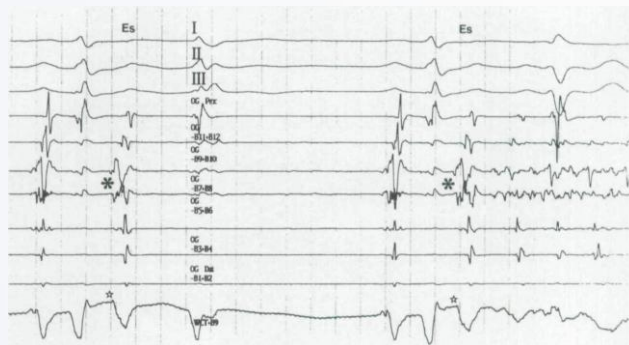


Cox JL, et al. J Thorac Cardiovasc Surg 1991;101:....  
Cox JL, et al. Ann Surg 1996;224:267-275  
Cox JL. J Thorac Cardiovasc Surg 2011;141:1093-7

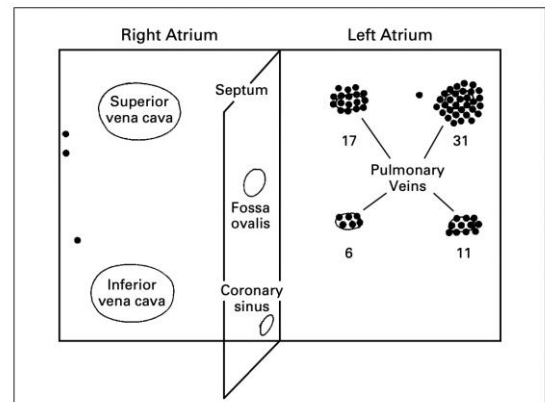
# Snahy replikovat tento výkon Maze vedly k objevu fokálních spouštěčů v plicních žilách



Progressive Anatomically Directed Ablation



Triggering foci unmasked during linear ablations

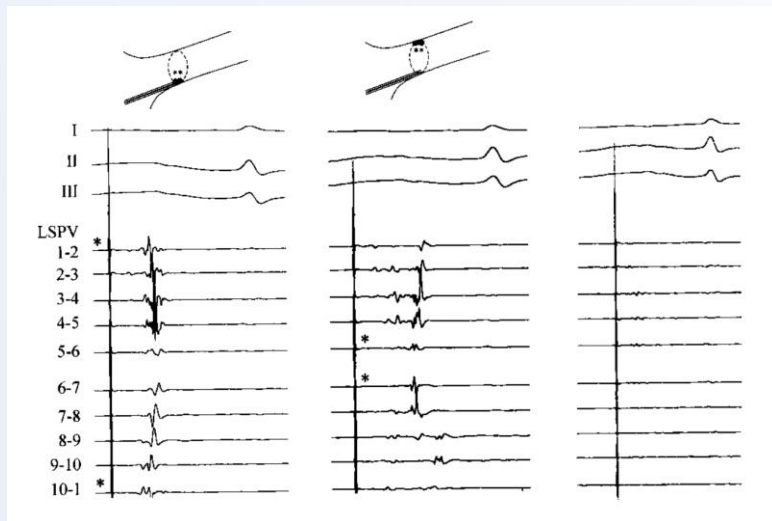


Predominant location in PVs

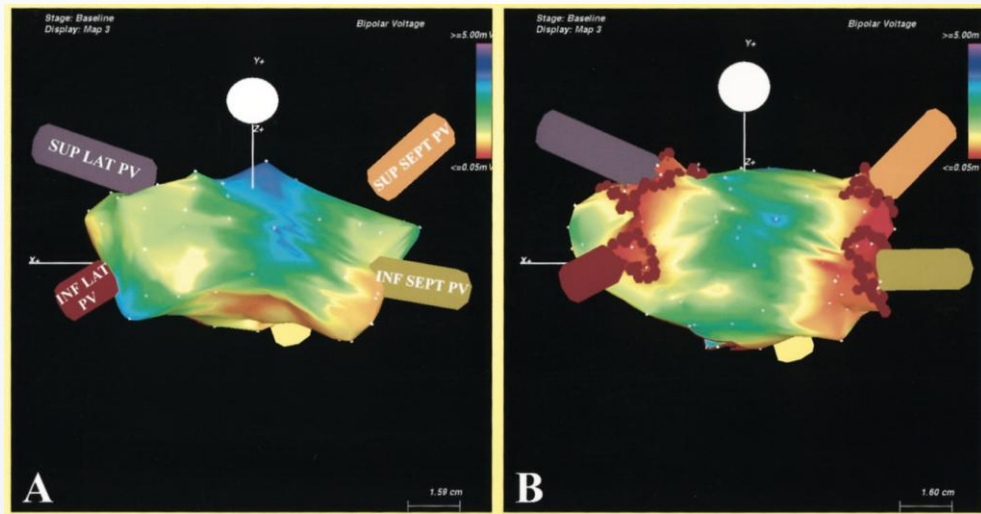
Haissaguerre M, et al. JCE 1996;7:1132-44

Haissaguerre M, et al. N Engl J Med 1998;339:659-66

# Ablace fokálních zdrojů vedla k rozvoji strategií izolace plicních žil



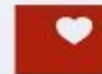
Lasso-guided segmental isolation



EAM-guided circumferential ablation

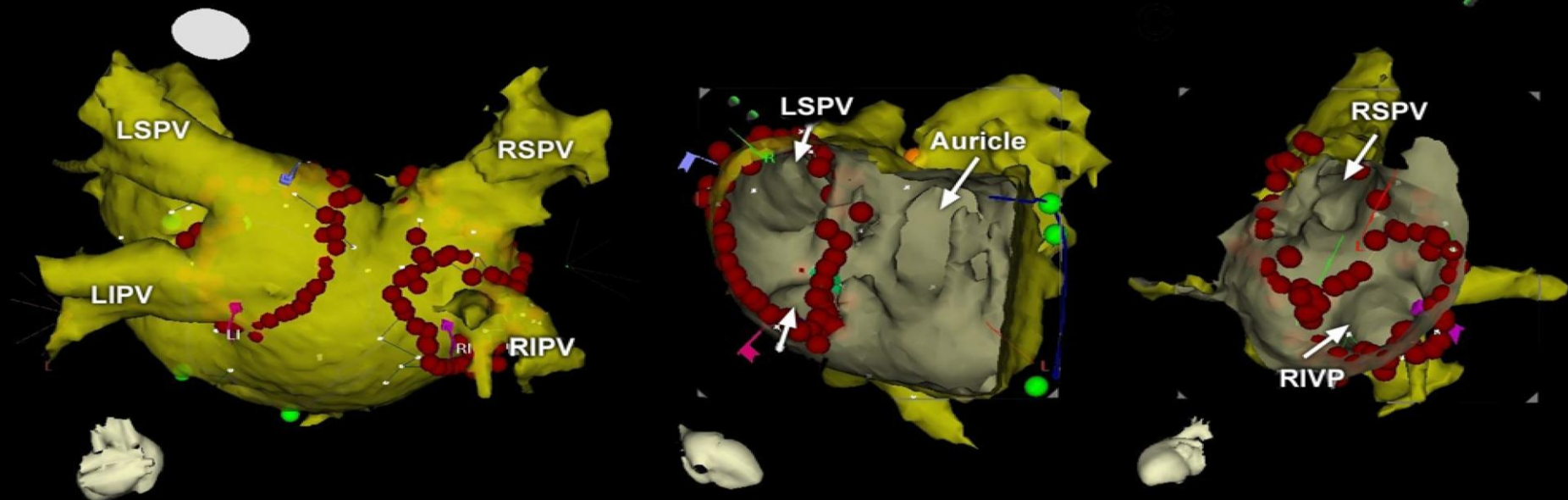
Haissaguerre M, et al. *Circulation*. 2000;102:2463–2465  
Pappone C, et al. *Circulation*. 2000;102:2619-2628.)

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KLINIKA KARDIOLOGIE



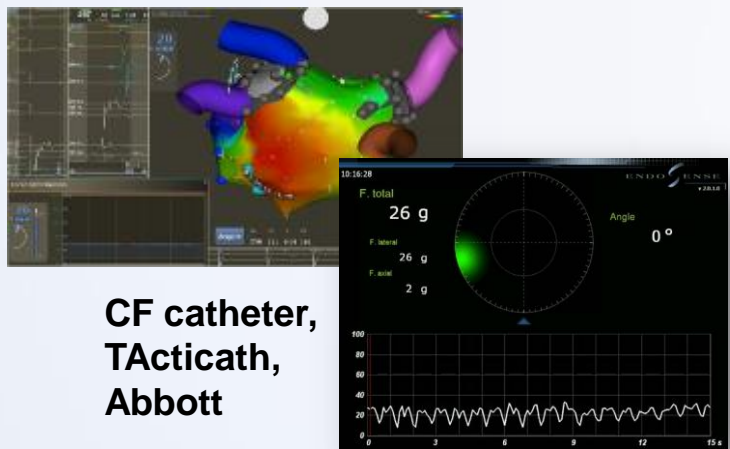
IKEM

# Izolace plicních žil = základ katetrizační ablace FS



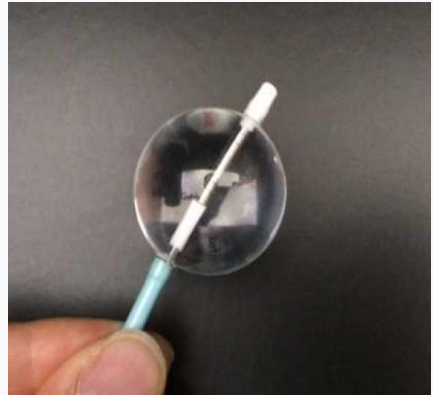
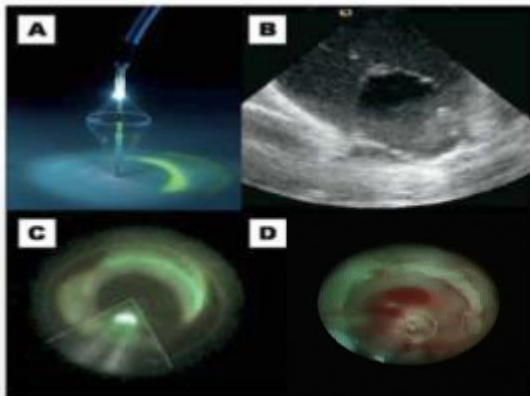
# Do současnosti bylo testováno mnoho technologií a strategií

CF catheter,  
Smart Touch, Biosense Webster



CF catheter,  
TActicath,  
Abbott

Laser balloon, Cardiofocus

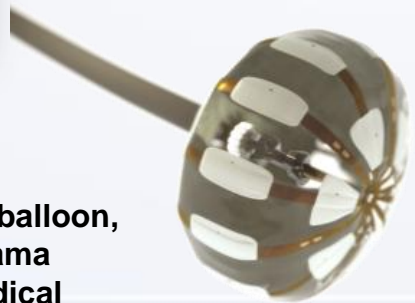


Hot balloon Toray

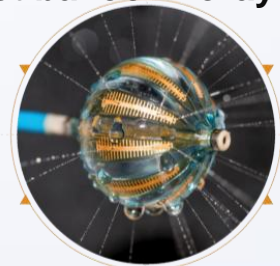
Cryoballoon  
Cryocath,  
Medtronic



RF balloon,  
Apama  
Medical



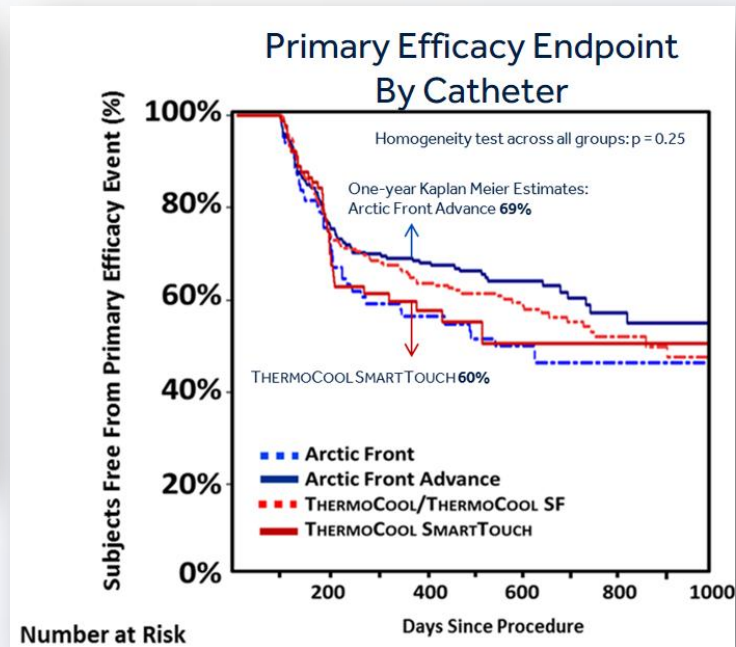
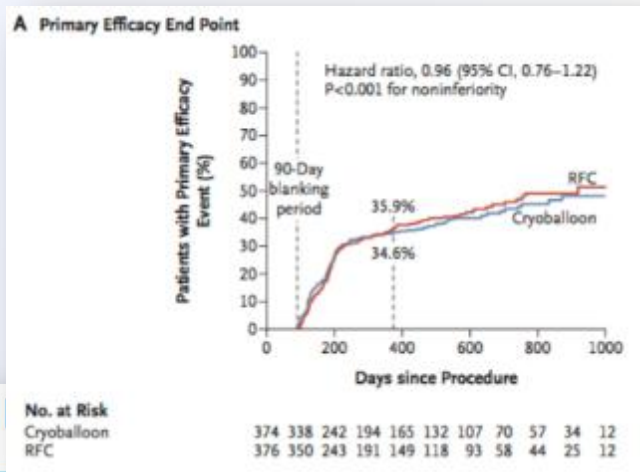
RF balloon, Helios  
Biosense Webster



# Studie FIRE and ICE

## Primární endponty (recidiva FS, AADs, re-ablace)

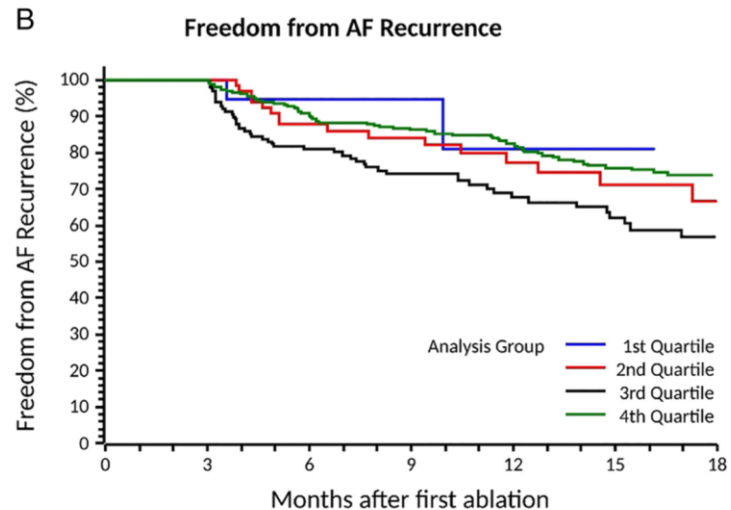
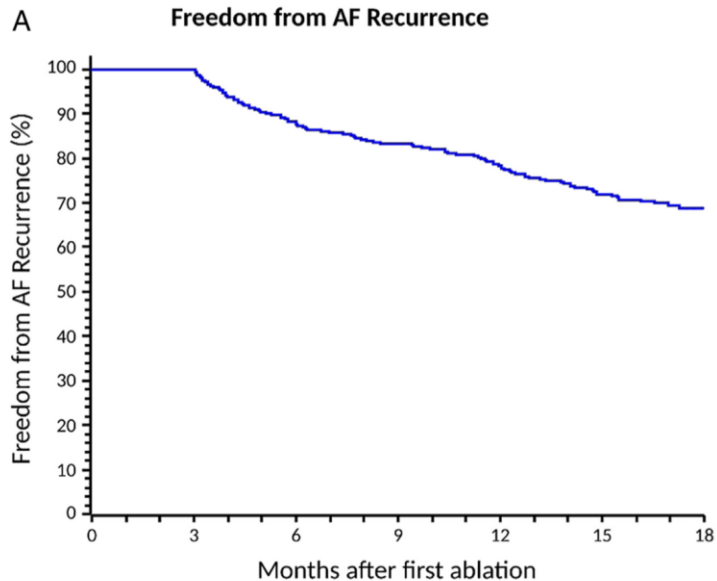
376 RF  
374 CR



Kuck KH, et al. *N Engl J Med.* 2016; 374(23): 2235-45.

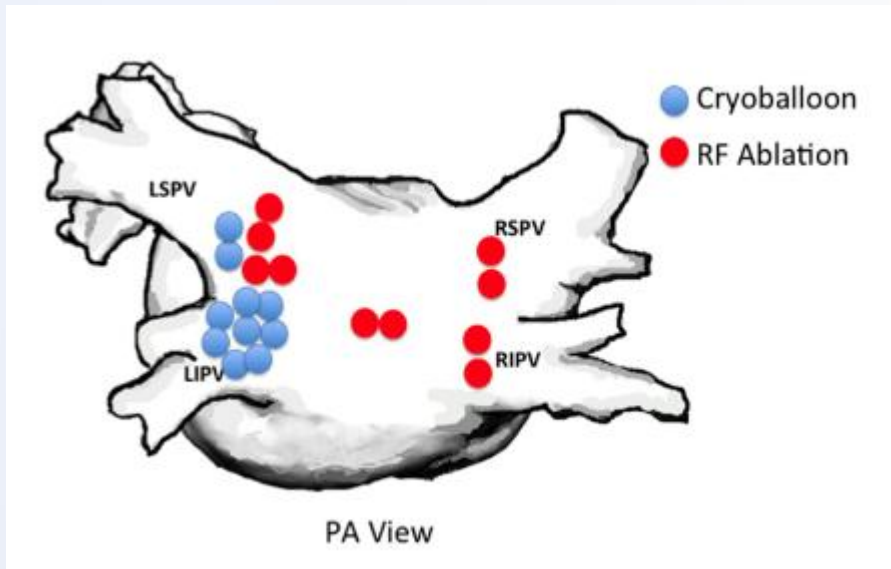
Time Measurement (minutes)	RFC (n=376)	Cryoballoon (n=374)	p-value**
Procedure Time***	140.9 ± 54.9	124.4 ± 39.0	<0.0001
LA Dwell Time***	108.6 ± 44.9	92.3 ± 31.4	<0.0001
Fluoroscopy Time	16.6 ± 17.8	21.7 ± 13.9	<0.0001

# Kryoablace je jednodušší, rychlejší a méně závislá na zkušenostech centra (operatéra)



No. at Risk	0	3	6	9	12	15	18
1st Quartile	27	19	11	7	4	3	2
2nd Quartile	91	72	53	43	30	20	13
3rd Quartile	195	163	108	80	57	39	26
4th Quartile	547	432	299	218	173	125	91

# Riziko kolaterálního poškození je i u kryoablace



Atrioezofageální píštěl

- AE píštěl u kryoablace (1 na 10 000 výkonů)
- častěji paréza freniku, která je přechodná
- Perzistující paréza při kryoablaci 1,41% (vzorek 7433 procedur z Holandska 2016-17)

John RM, et al. Heart Rhythm 2017;14:184–189)

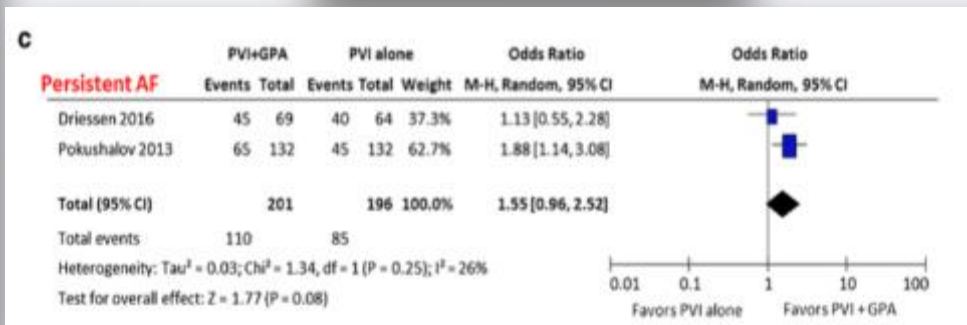
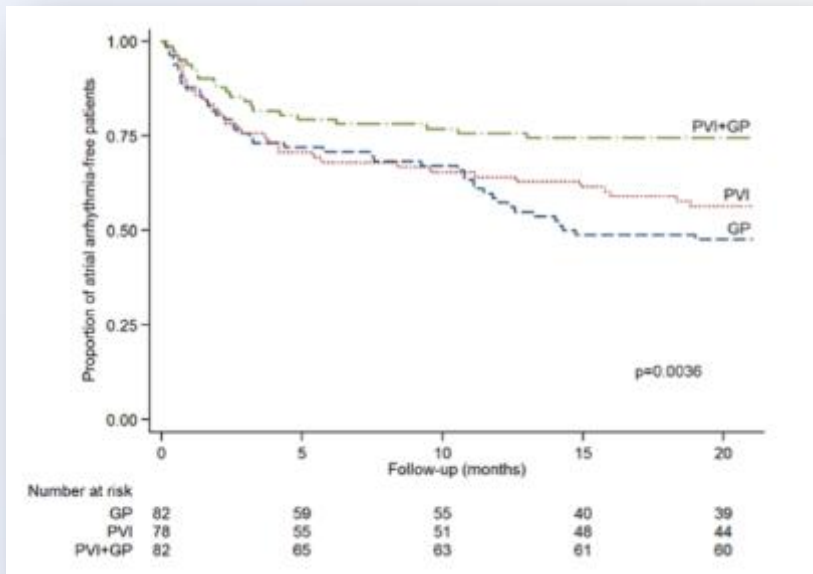
Mol D, et al. J Cardiovasc Electrophysiol

2022;33(3):559-564



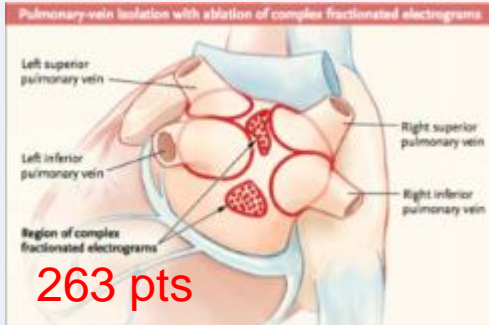
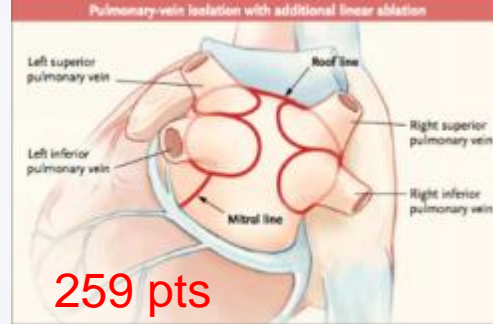
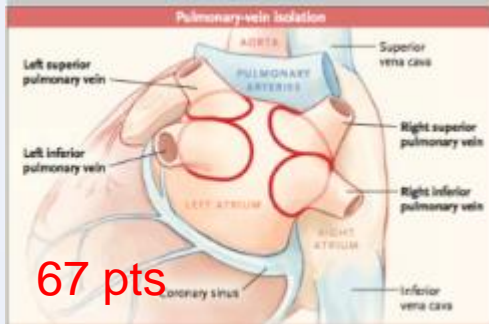
# Některé studie prokázaly zlepšení výsledků při ablaci autonomních plexů

- 242 pts, symptomatic paroxysmal AF
- Randomisaton: PVI, anatomic GP ablation, PVI plus anatomic GP ablation



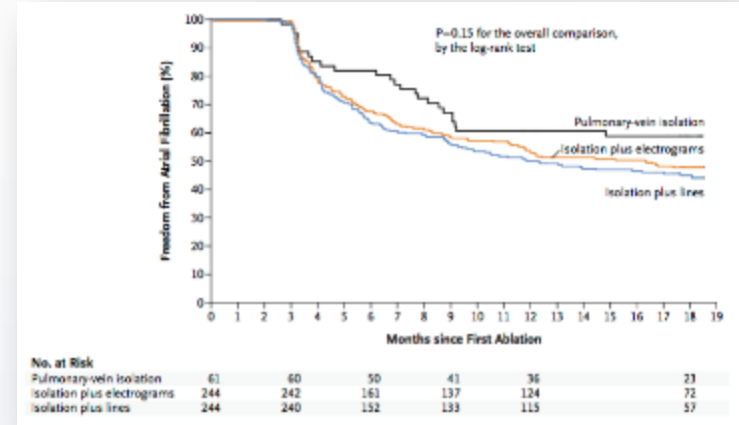
Kampaktsis PM, et al. JICE DOI 10.1007/s10840-017-0285-z

# Mnoho ablačních strategií bylo testováno..

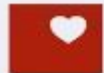


589 pts, 2010-2012  
 Vysoká zátěž FS (80-83  
 hod/měs)  
 Perzistence více jak 6 měsíců  
 (72-78 %)

## Přežití bez FS



**Dosud jsme nevěděli, zda jde  
o špatný koncept nebo o  
nedokonalost technologií  
provést to, co mělo být  
provedeno...**



# Nyní se doba mění...

- A disruptive technology – pulse field ablation (PFA)
- Historical excursion
- Two concepts of AF ablation (with PFA)

## What Is Disruptive Technology?

Disruptive technology is an innovation that significantly alters the way that consumers, industries, or businesses operate.

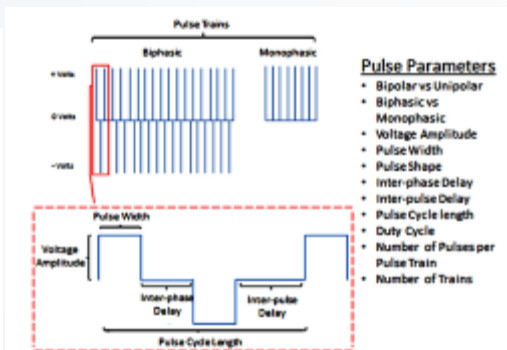
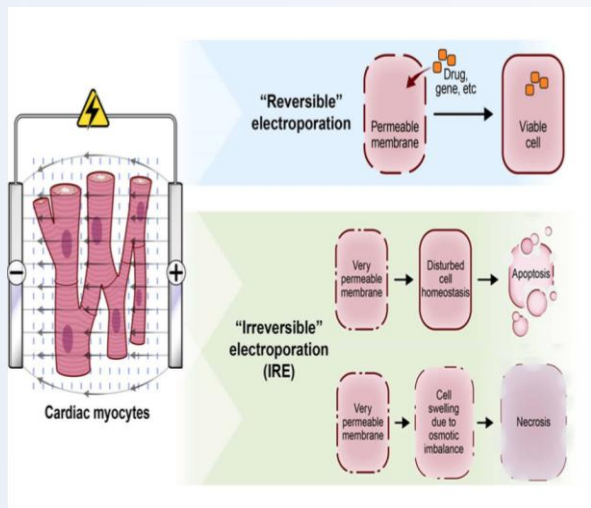
A disruptive technology sweeps away the systems or habits it replaces.

<https://www.investopedia.com/terms/d/disruptive-technology.asp>

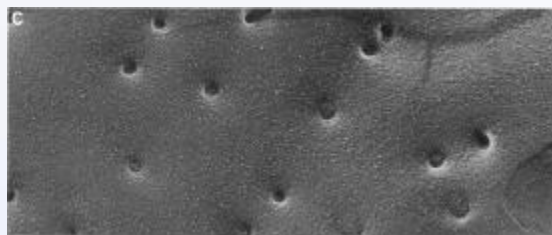


# Ablace pomocí pulzního elektrického pole (PEFA nebo PFA)

- Elektroporace... ultrakrátké pulzy stejnosměrného proudu vedoucí k destabilizaci buněčných membrán (póry)

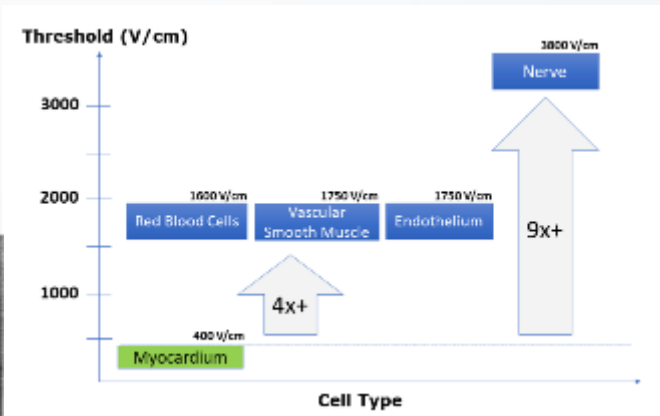


Bradley CJ, Haines DE. JCE 2020



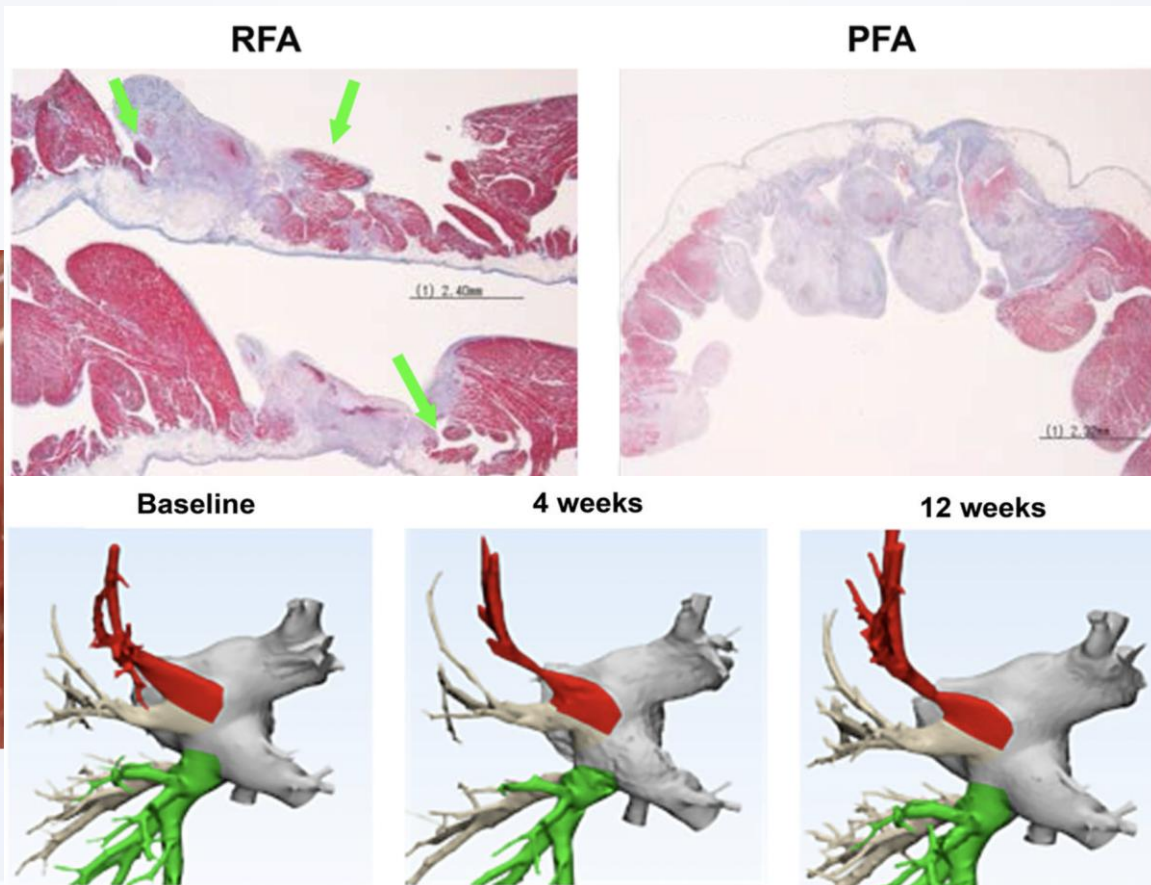
Chang DC Reese TS. Biophys J 1990;58:1-12,

Vysoká senzitivita kardiomyocytů – PFA je ničím selektivním způsobem bez poškození okolí

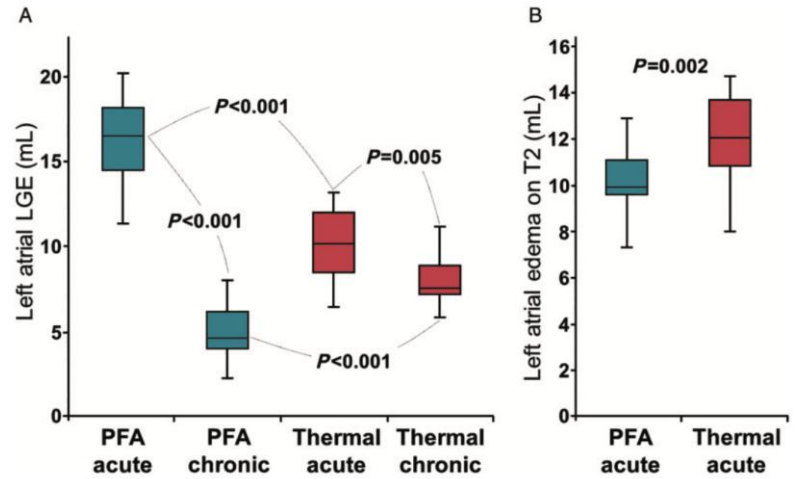
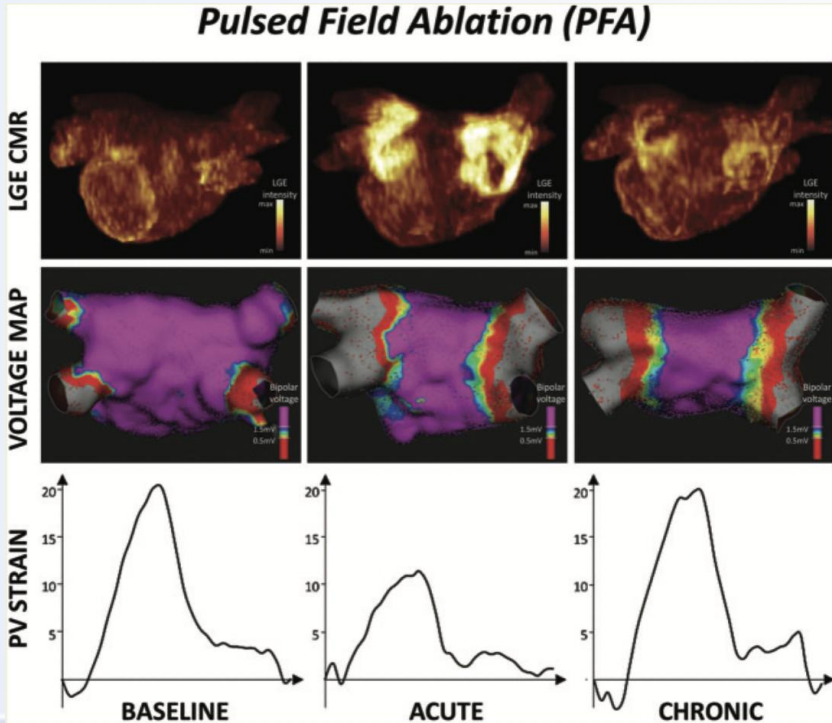


Reddy VY, et al. J Am Coll Cardiol 2019;74:315–26.

# Tkáňový efekt PFA vs RFA



# PFA zabraňuje vzniku chronické fibrózy a restriktivních změn



Množství LGE po PFA vs RFA

41 PAF pts, 18 PFA, 16 RFA, 7 cryo

# PFA „single-shot“ katetr

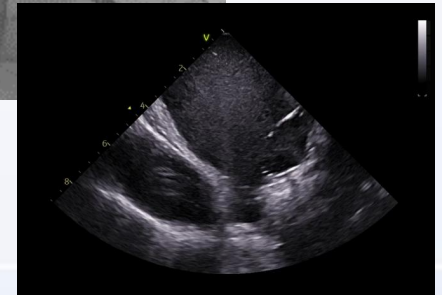
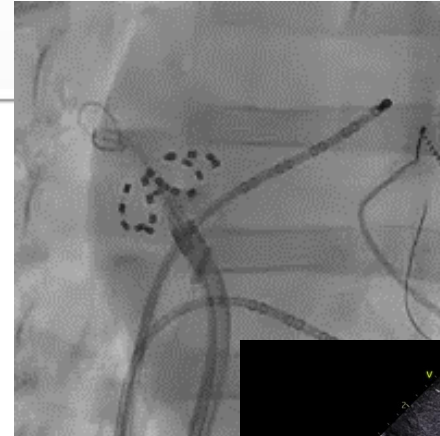
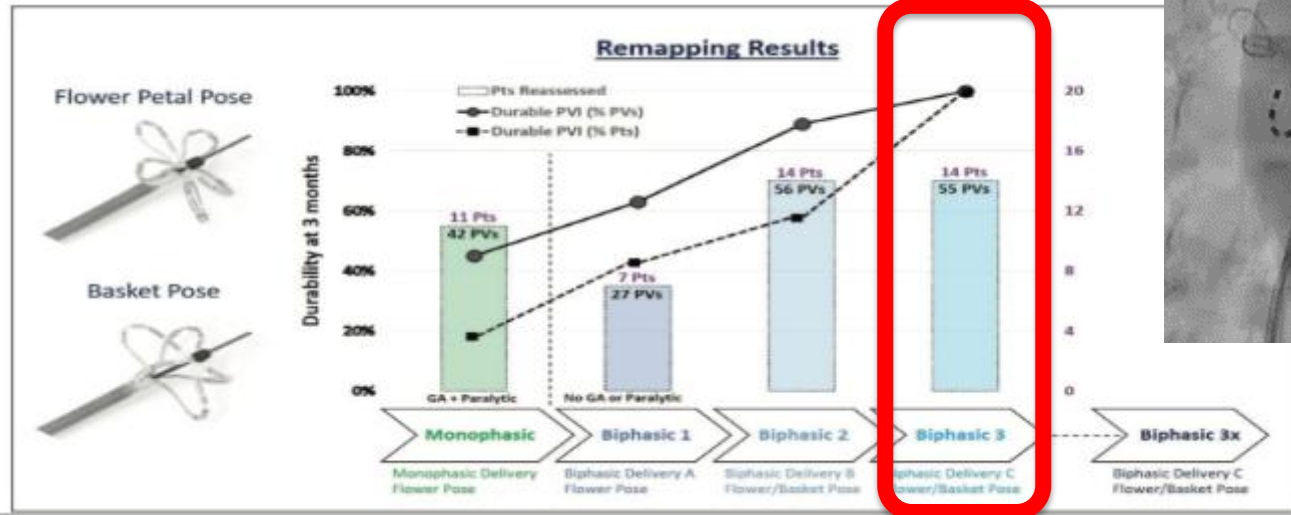
- 81 PAF, monofazická (n=15) → bifazická konfigurace (n=66)
- Čas výkonu 92±27min (vč. 20min na remapování)
- Posledních 14pts 100% trvalá izolace po 3 měsících
- Žádné léze na MRI 13pts, bez stenoz PŽ, bez poranění jícnu (endoskop+MRI)
- 6 a 12 měs absence FS u 90% a 87% případů

## Pulsed Field Ablation for Pulmonary Vein Isolation in Atrial Fibrillation



Vivek Y. Reddy, MD,<sup>a,b</sup> Petr Neuzil, MD, PhD,<sup>a</sup> Jacob S. Koruth, MD,<sup>b</sup> Jan Petru, MD,<sup>a</sup> Moritoshi Funosako, MD,<sup>a</sup> Hubert Cochet, MD,<sup>c</sup> Lucie Sediva, MD,<sup>a</sup> Milan Chovanec, MD,<sup>a</sup> Srinivas R. Dulkipati, MD,<sup>b</sup> Pierre Jais, MD<sup>a</sup>

JACC VOL. 74, NO. 3, 2019 JULY 23, 2019:315–26





Catheter insertion

Basket in LSPV ostium

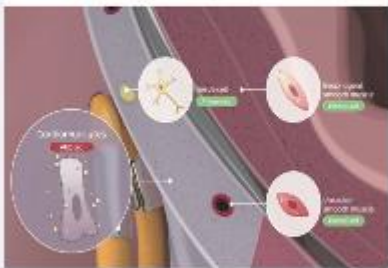
flower

Flower in LSPV ostium

PF energy application

# Jednoroční výsledky single-shot PFA

## PFA Catheter & Mechanism of Ablation



## Safety

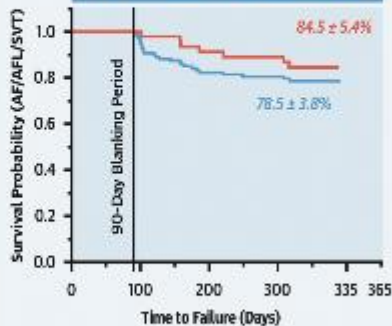
- Esophageal Damage 0%
- Esophageal Dysmotility 0%
- Atrioesophageal Fistula 0%
- Pulmonary Vein Stenosis 0%
- Phrenic Nerve Injury 0%
- Stroke 0%
- Transient Ischemic Attack 0.9%
- Pericardial Effusion 0.8%
- Vascular injury 1.7%
- Death 0%

## Efficacy

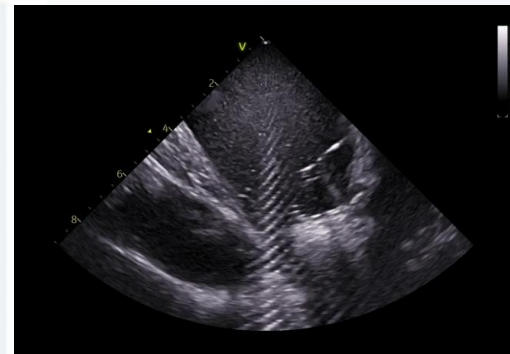
### Durability of PV Isolation (Invasive Remapping)

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	0	100	200	300	335	365
Entire Cohort	114	97	89	81		
PFA-OW	46	43	40	36		



3 multicentre studies  
 IMPULSE (Iowa)  
 PEFCAT (Farapulse)  
 PEFCAT II (Farapulse)

Reddy, V.Y. et al. J Am Coll Cardiol EP. 2021;7(5):614-27.

**TABLE 3 Primary and Secondary Endpoints (N = 25)**

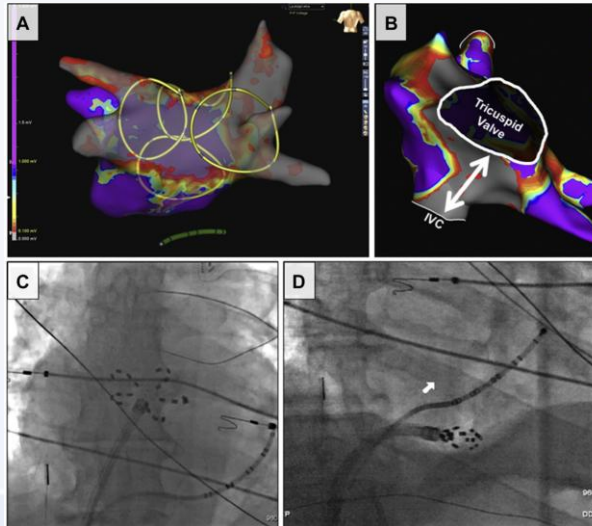
Primary feasibility endpoint (n = 25)	
Acute PV isolation	96/96 (100)
Secondary feasibility endpoints (n = 25)	
Chronic PV isolation (n = 22)	82/85 (96)
Chronic LAPW isolation (n = 22)	
Full cohort (n = 22)	21/22 (95)*
Treated using pentaspline catheter only (n = 21)	21/21 (100)*
Acute CTI block (n =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

Values are n/N (%). \*The lone reconnected LAPW was in the first patient receiving linear PFA using the initial Focal-1 dose. In patients undergoing posterior wall ablation with the pentaspline PFA catheter, all LAPWs remained durably ablated. †Pericardial effusion without tamponade occurred during remapping using radio-frequency only; clinical events committee adjudication pending.

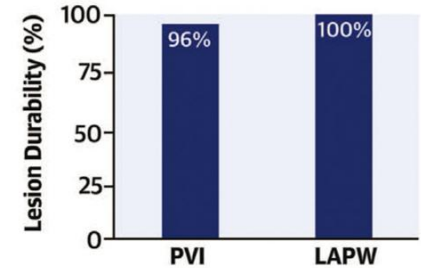
Abbreviations as in [Tables 1 and 2](#).

## Pulsed Field Ablation in Patients With Persistent Atrial Fibrillation

Vivek Y. Reddy, MD,<sup>a,b</sup> Ante Anic, MD,<sup>c</sup> Jacob Koruth, MD,<sup>b</sup> Jan Petru, MD,<sup>a</sup> Moritoshi Funasako, MD,<sup>a</sup> Kentaro Minami, MD,<sup>a</sup> Toni Breskovic, MD, PhD,<sup>c</sup> Ivan Sikiric, MD,<sup>c</sup> Srinivas R. Dukkupati, MD,<sup>b</sup> Iwanari Kawamura, MD,<sup>b</sup> Petr Neuzil, MD, PhD<sup>a</sup>



### Outcomes Upon Invasive Remapping



## MANIFEST-PF Survey

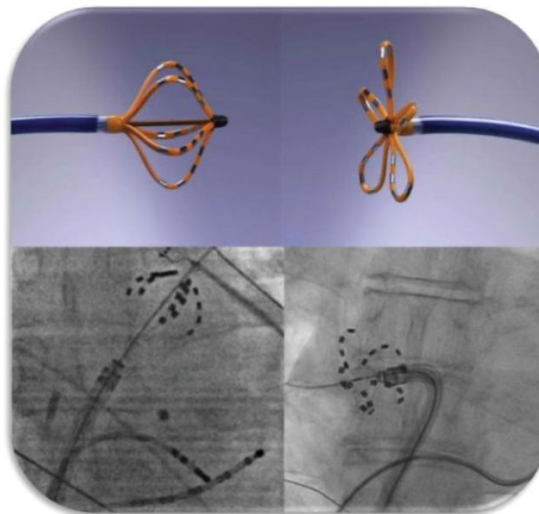
Real-World Outcomes of PFA for AF

24 centers in Europe

90 Operators

1,758 Patients

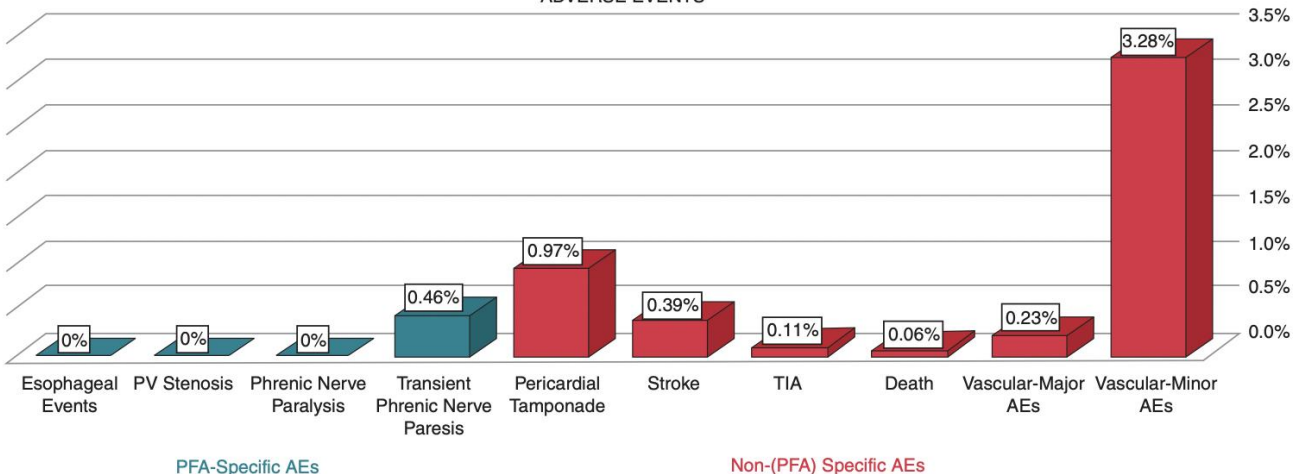
99.9% Acute PVI Success Rate



# Real-life data (MANIFEST PF Survey)

Clinical Site Characteristics	N (24)
Practice type	
Academic (%)	70.8
Semi-academic (%)	8.3
Private (%)	20.8
No. of operators, mean (min-max)	3.8 (2-11)
Years in practice, mean (min-max)	13.2 (5.3-22.5)
Annual no. of AF ablations, mean (min-max)	704 (300-2200)
No. of PFA cases in past year, mean (min-max)	73.3 (7-291)
Date of first PFA case, month/year (earliest-latest)	7/2021 (3/2021-12/2021)

### ADVERSE EVENTS



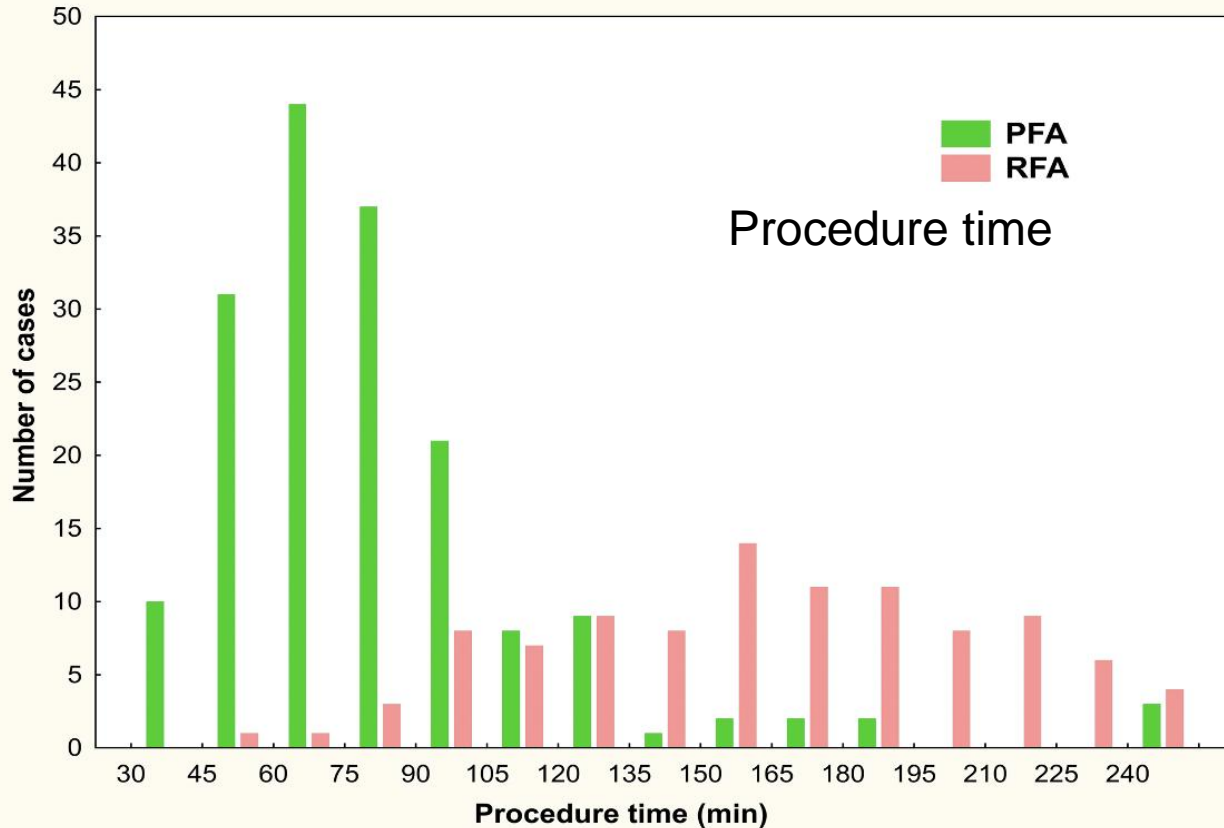
Ekanem E, et al.  
Europace. 2022 Jun 1:euac050.

# Naše letošní zkušenost (1-7/2022)

Parameter	PFA (170)		RFA (100)		p<
	Mean	SD	Mean	SD	
Age (y)	65	9	64	10	0.71
Procedure time (min)	84	38	165	46	0.00001
Fluoro time (min)	10	5	6	3	0.00001
Rad. Dose (Gy.cm <sup>2</sup> )	1.5	1.7	1.3	2.3	0.005
Persistent AF	49%		28%		0.0007
Re-do	19%		24%		0.37
Posterior wall	53%		9%		0.00001
Anterior wall	4%		19%		0.00002
Mi isthmus	9%		3%		0.06
CTI	25%		40%		0.01



# PFA vs RFA



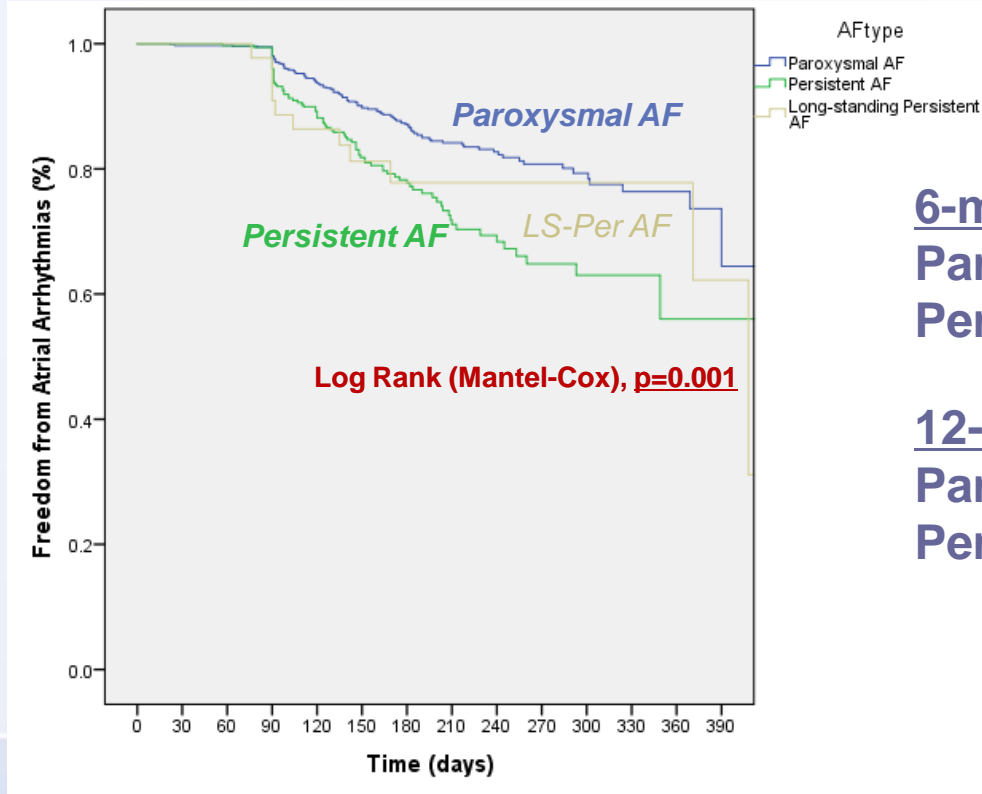
270 pts dohromady

Žádná embolická  
příhoda

1 hemoperikard s  
drenáží u případu  
kombinované ablace  
PFA a RFA

# 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%**

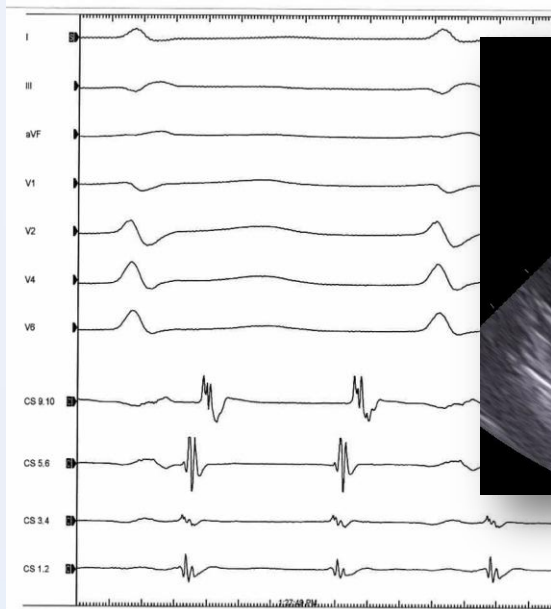
### 12-month Estimate

**Paroxysmal AF: 73.4%**

**Persistent AF: 58.2%**

# S tímto katetrem lze provést i komplexní ablaci

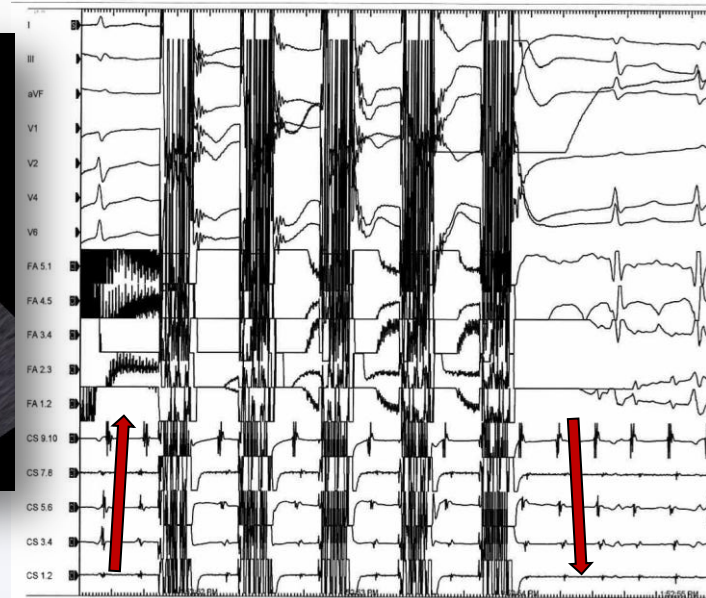
- 70letý pacient, PVI + CTI před 6 lety
- Re-do ablace s PFA



Perimitrální flutter



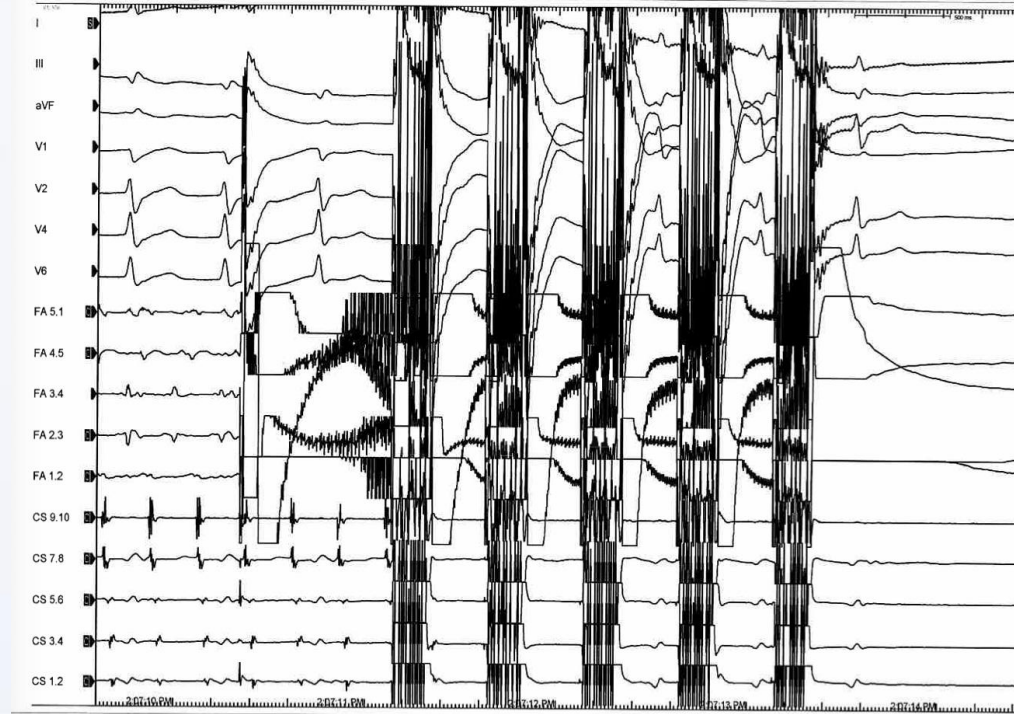
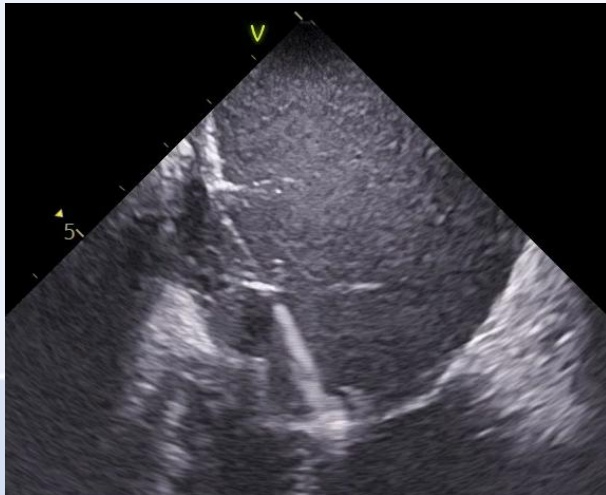
PFA na mi isthmu



Změna aktivace (na typický flutter)



# Ablace na CTI laterálně



# Potvrzení bloku na mi isthmu (stim ouška)



80 min čas skin-to-skin, skia 7.2 min, rad. dávka 3 Gy.cm<sup>2</sup>

# Vize ...

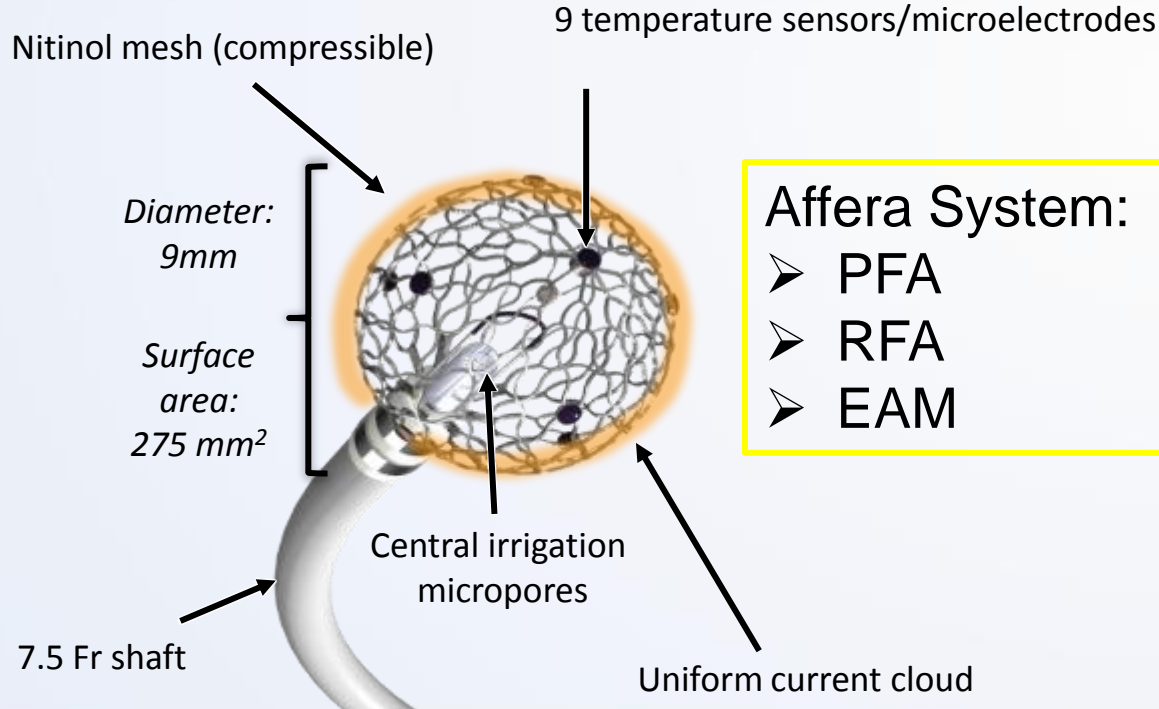
- Trvání výkonu do 1 hodiny
- Nízké riziko komplikací – propuštění stejný den odpoledne
- Prakticky každý, kdo umí udělat bezpečně transseptální punkci a manipulovat s katetrem a vodičem může tuto ablaci udělat ...

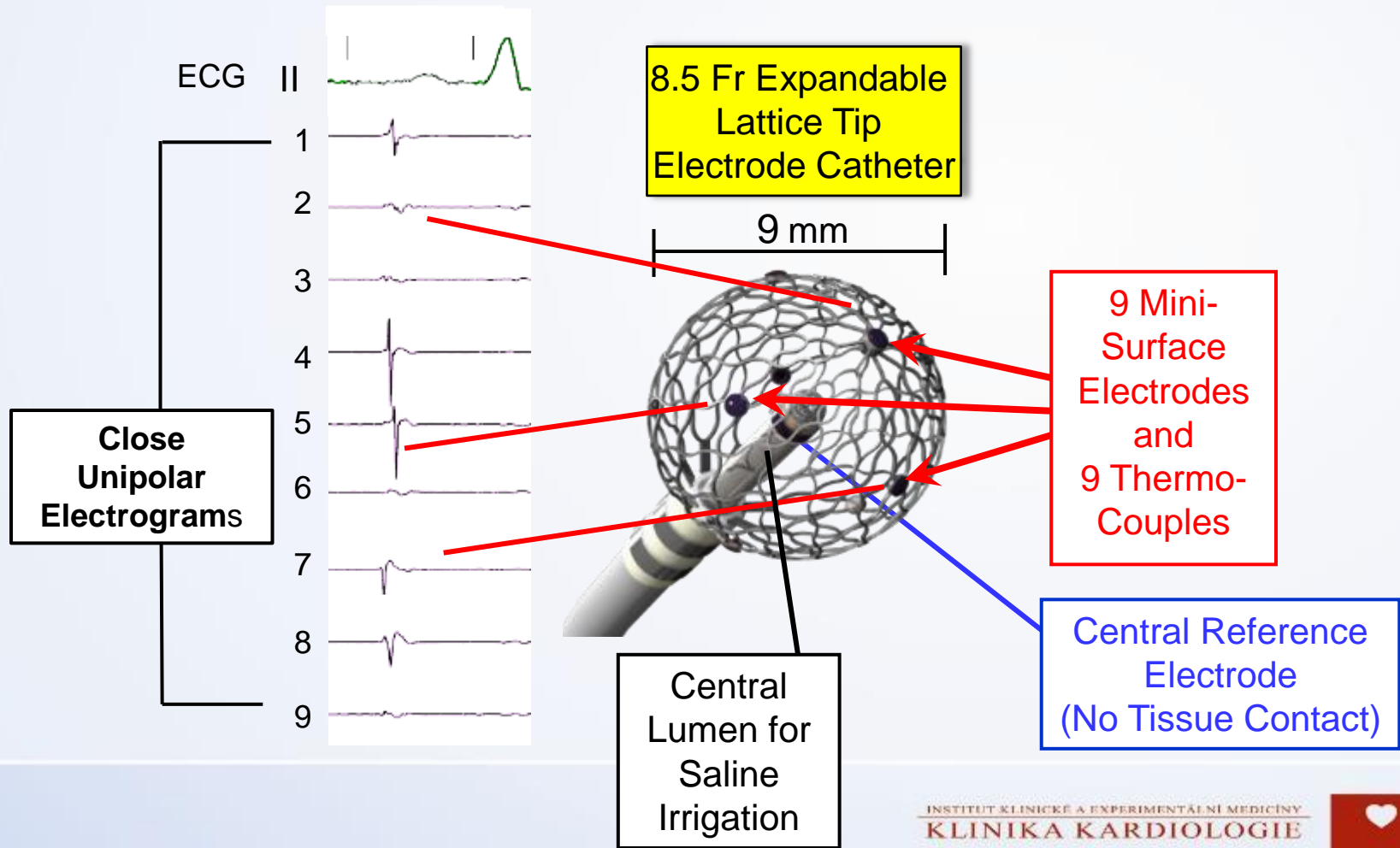
# Koncept sofistikovaného mapovacího a ablačního systému pro lineární léze (k replikaci procedury Maze)

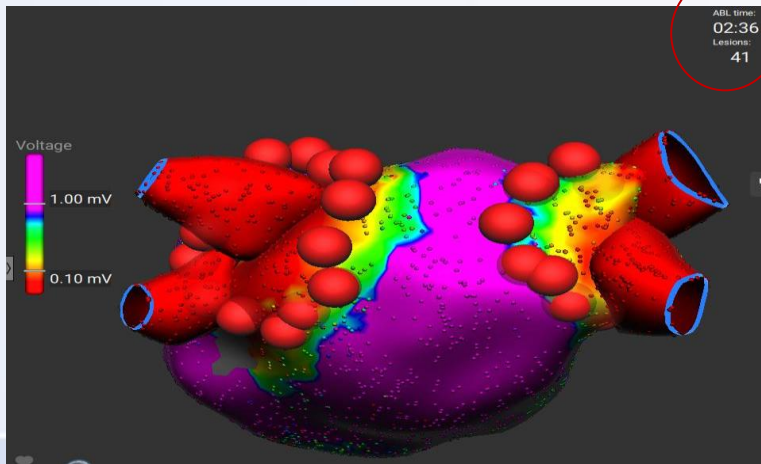


# AFFERA mapping and ablation system

Affera, Inc., Watertown, MA, získal Medtronic







# První zkušenosti IKEM s RF s vysokou energií (2018)

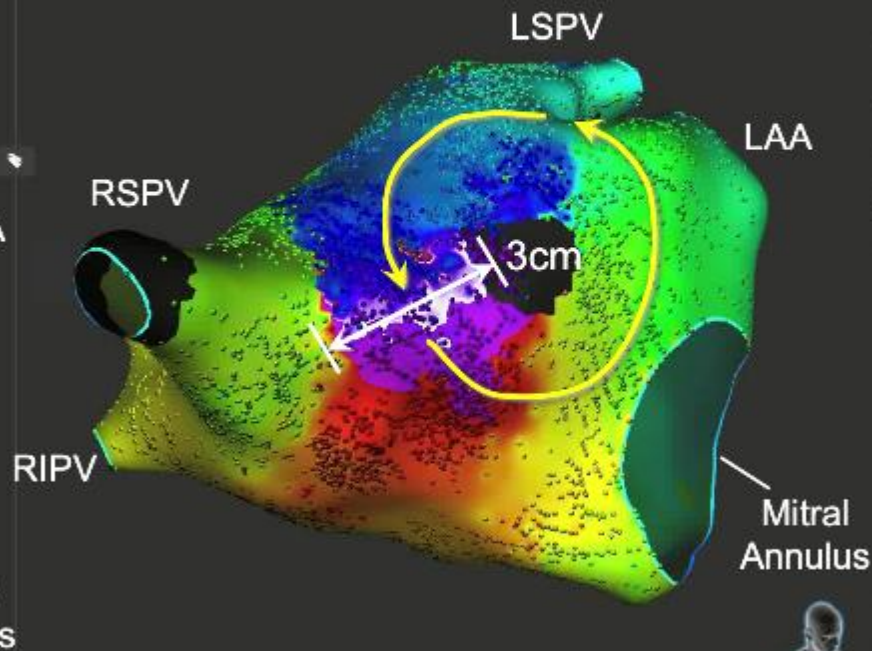
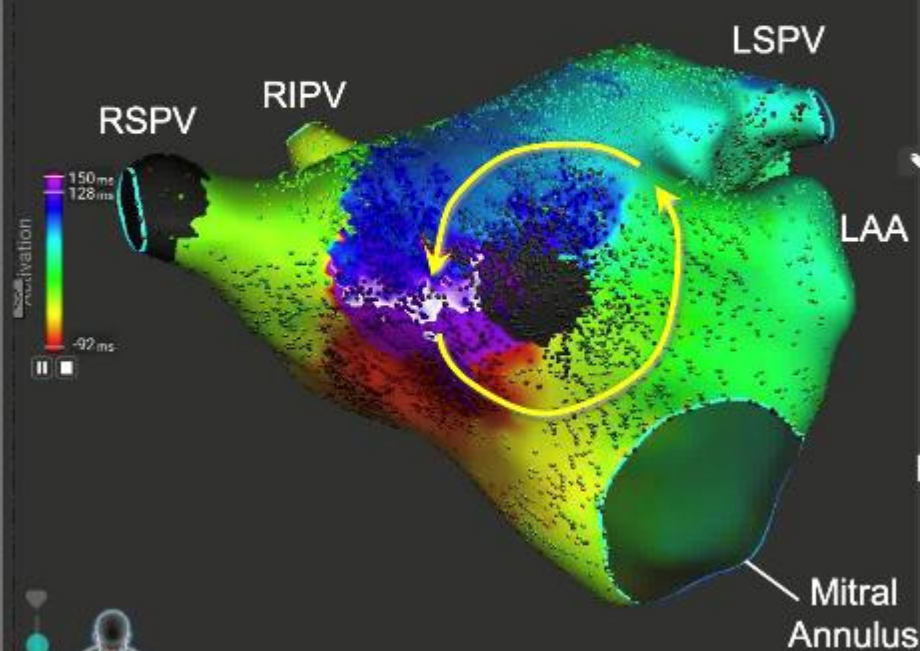
- 8pts ( $67 \pm 7$ let) s FS/flutterem
- Průměr  $38 \pm 7$  aplikací (3-5sec) pro IPŽ
- $4.5 \pm 1.7$  aplikací (5sec) pro lineární léze
- Celková anestezie
- **Žádné**



IKEM Case

High-Density Close Unipolar Activation Map

Small Macroreentrant AT



INF SUP RL LL RAO LAO RPO LPO AP PA

INF SUP RL LL RAO LAO RPO LPO AP PA



# První zkušenosti s (HPSD RF) a mřížkovou elektrodou

JACC: CLINICAL ELECTROPHYSIOLOGY

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VOL. 6, NO. 5, 2020

## ATRIAL FIBRILLATION

### A Lattice-Tip Temperature-Controlled Radiofrequency Ablation Catheter for Wide Thermal Lesions

#### First-in-Human Experience With Atrial Fibrillation

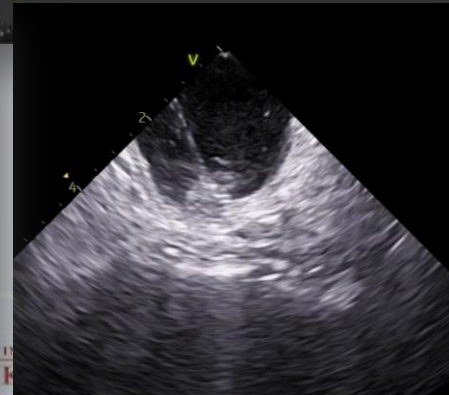
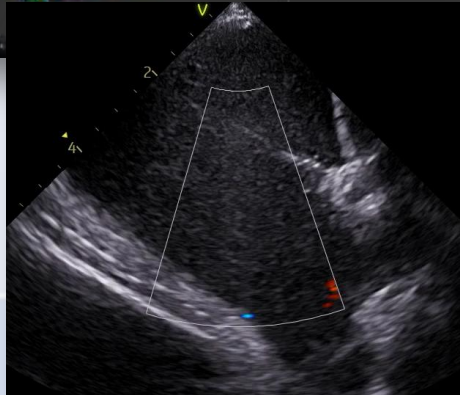
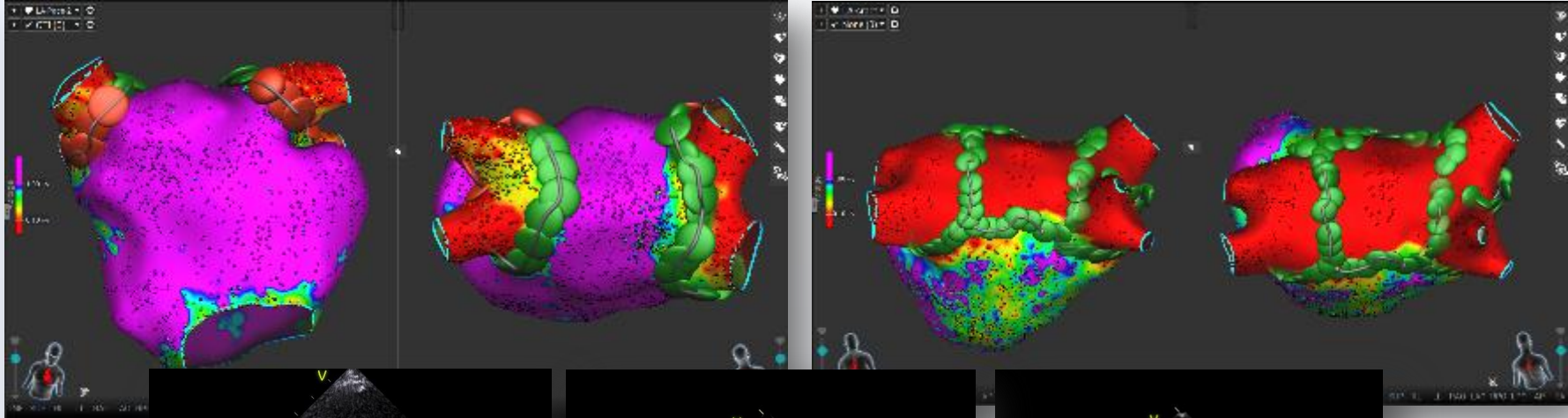
Elad Anter, MD,<sup>a</sup> Petr Neuzil, MD, PhD,<sup>b</sup> Gediminas Rackauskas, MD, PhD,<sup>c</sup> Petr Peichl, MD, PhD,<sup>d</sup> Audrius Aidietis, MD, PhD,<sup>e</sup> Josef Kautzner, MD, PhD,<sup>d</sup> Hiroshi Nakagawa, MD, PhD,<sup>e</sup> Warren M. Jackman, MD,<sup>f</sup> Andrea Natale, MD,<sup>g</sup> Vivek Y. Reddy, MD<sup>h,i</sup>



**TABLE 2** Procedural Details (N = 71)

Cavotricuspid isthmus line	
Successful linear lesion	48/48 (100)
Success using lattice catheter only	48/48 (100)
Number of RF applications	5.9 ± 3.1
Total RF time, min	0.5 ± 0.24
Transpired ablation time, min*	2.3 ± 1.6
Fluoroscopy time, min†	4.8 ± 2.2
Pulmonary vein isolation	
Successful lesion set	130/130 (100)
Success using lattice catheter only	129/130 (99.2)
Number of RF applications	39.5 ± 8.9
Total RF time, min	2.7 ± 0.70
Transpired ablation time, min*	21.8 ± 12.1
Total left atrial dwell time, min‡	43.0 ± 18.4
Fluoroscopy time, min§	7.0 ± 6.7
Mitral isthmus line	
Successful linear lesion	22/22 (100)
Success using lattice catheter only	21/22 (95.5)
Number of RF applications	11.5 ± 10.7
Total RF time, min	1.0 ± 0.92
Transpired ablation time, min	5.8 ± 6.4
Roof line	
Successful linear lesion	23/24 (95.8)
Success using lattice catheter only	23/24 (95.8)
Number of RF applications	4.9 ± 1.9
Total RF time, min	0.4 ± 0.16
Transpired ablation time, min	3.0 ± 4.4

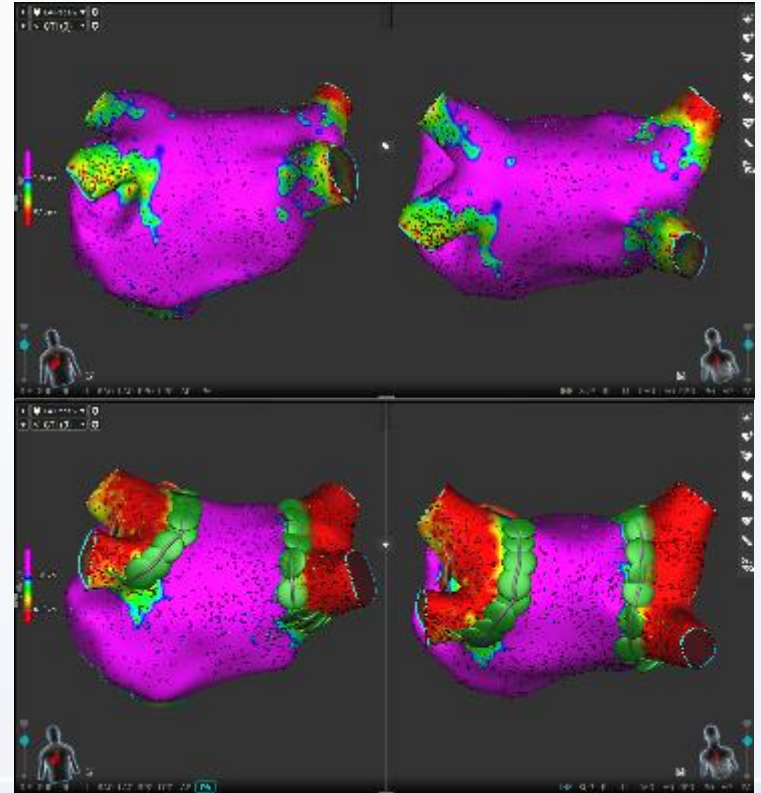
# Dnes, systém dovoluje přepnutí mezi RF a PF a kombinovaný výkon



# Naše zkušenosti s Affera

Sphere 9	Total	RF/PF PVI +	PF only PVI +
TOTAL	44	8	36
CTI	29	6	23
MI	14	1	13
ROOF	34	5	29
Posterior Inferior Line	18	1	17
Anterior ablation	9	0	9

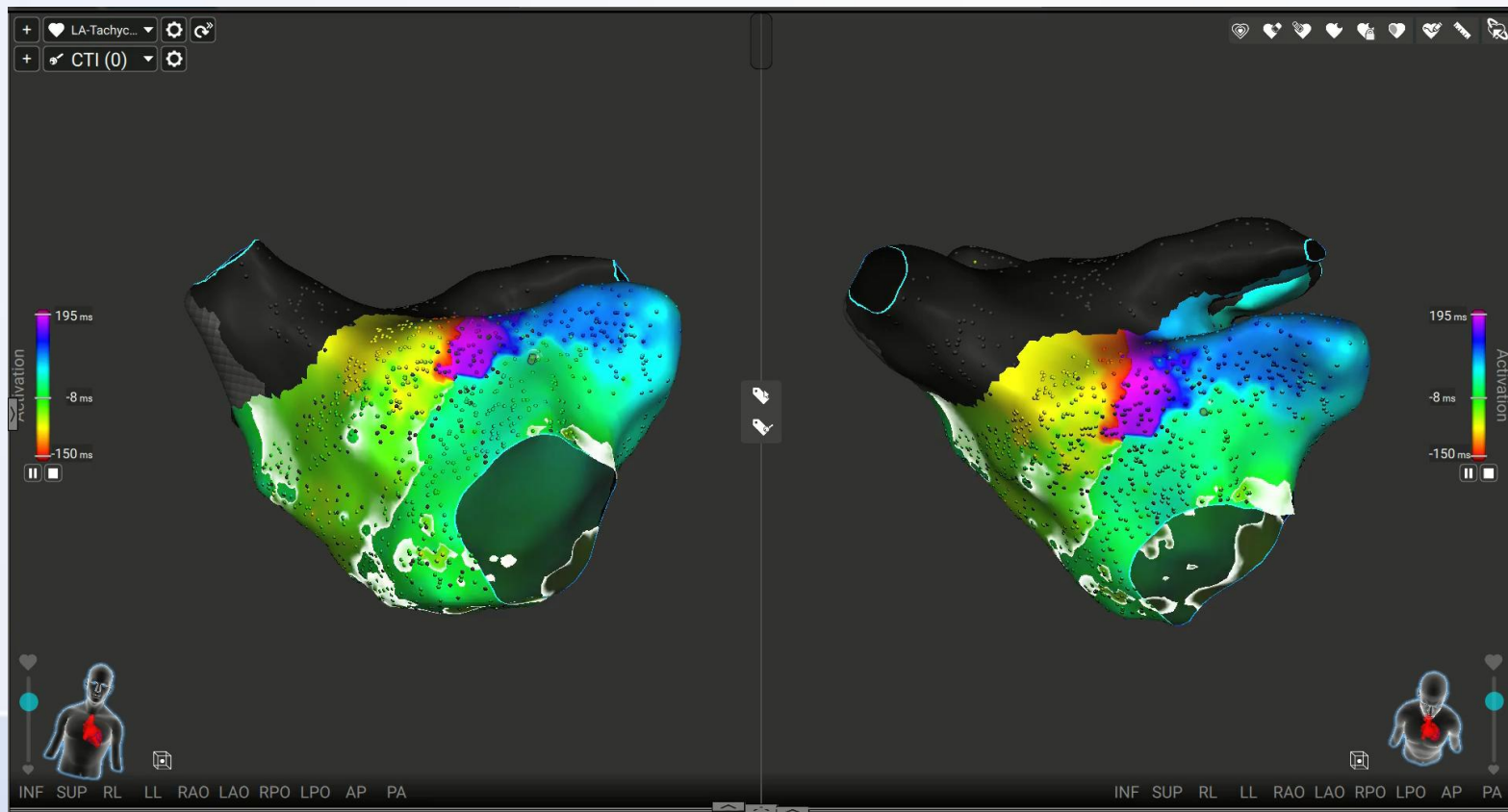
Sphere PVI	PF PVI
TOTAL	11



# Ilustrativní případ

- 69letý muž, BMI 34, persistující FS
- Ablace v rámci randomizované studie, celková anestezie
- Mapa LS, izolace PŽ a zadní stěny, indukce typického flutteru, přechod do LS flutteru při entrainmentu
- Aktivační mapa LS, ablace flutteru v LS a nakonex linie na CTI, neindukovatelnost
- Trvání výkonu 150 min, skia 3.3 min, rad dávka 0.38 Gy.cm<sup>2</sup>

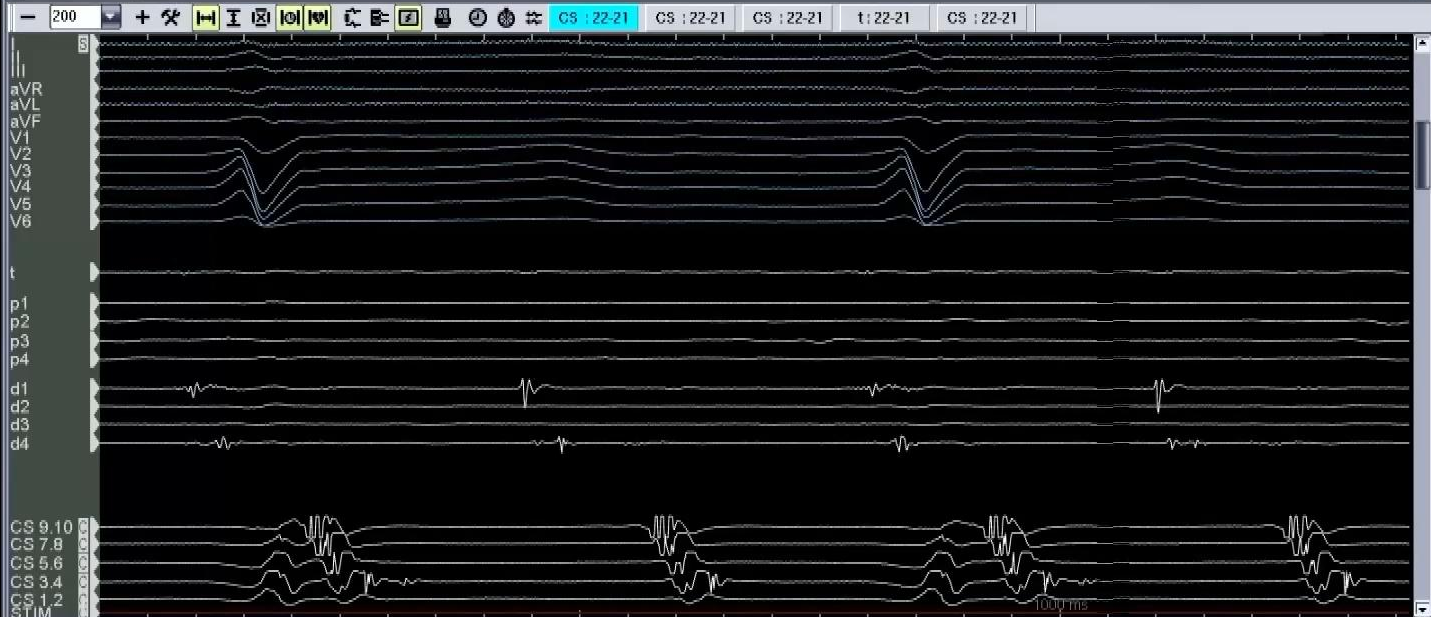
# Fast mapping of left-sided flutter



Ablation



Real-Time: Page 2



x, y BSA 2.29    110.0 Kg	HR 1 <b>83</b>	HR 2 0	BP <b>ZERO</b>	SpO2 :	Temp	<b>1:06:57 PM</b> 7/21/2022
	cl <b>716</b>	cl	P2 <b>ZERO</b>	RR :		

# První zkušenosti u člověka (lattice-tip electrode, RF/PF or PF/PF)

	RF / PF Cohort * (n = 40)	PF / PF Cohort (n = 36)	RF Only † (n = 71)
<b>Fluoroscopy Time, min</b>	5.6 ± 4.1	2.7 ± 2.4	7.0 ± 6.7
<b>Saline Infusion, mL</b>	444 ± 189	452 ± 233	432 ± 147
<b>Energy Application Time, min ‡</b>			
<b>PV Isolation</b>	3.3 ± 1.1	3.2 ± 0.9	2.7 ± 0.7
<b>Mitral Isthmus Line</b>	1.3 ± 0.5	0.9 ± 0.6	1.0 ± 0.9
<b>LA Roof Line</b>	0.3 ± 0.2	0.4 ± 0.2	0.4 ± 0.2
<b>CT Isthmus Line</b>	0.5 ± 0.3	0.5 ± 0.2	0.5 ± 0.2
<b>Transcatheter Ablation Time, min §</b>			
<b>PV Isolation</b>	23.3 ± 9.5	22.0 ± 6.8	21.8 ± 12.1
<b>Mitral Isthmus Line</b>	7.8 ± 4.3	3.5 ± 1.8	5.8 ± 6.4
<b>LA Roof Line</b>	2.2 ± 3.1	1.4 ± 0.7	3.0 ± 4.4
<b>CT Isthmus Line</b>	2.2 ± 2.2	2.6 ± 2.1	2.3 ± 1.6

# Vize blízké budoucnosti

- Trvání výkonu do 1 hodiny
- Nízké riziko postprocedurálních komplikací – ambulantní výkon
- Kdokoliv, kdo provede bezpečně transeptální punkci a je schopen manipulovat vodiči a katetry bude schopen dělat iniciální izolaci plicních žil
- Pro komplexní ablaci bude možno využít sofistikovanějších mapovacích a ablačních systémů



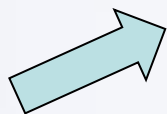
# Vize ...

- Unverzální mapovací a ablační systémy jako tento dovolí ušít ablaci na míru konkrétnímu pacientovi a nakonec umožní i provedení procedury MAZE
- Katetrizační MAZE by měla maximalizovat účinnost v udržení sinusového rytmu

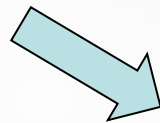
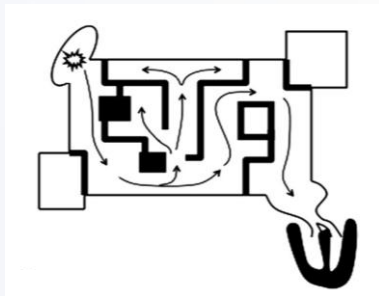
# Okruh se uzavírá...

Rychlá, bezpečná, účinná metoda izolace PŽ

Nová technologie - PFA



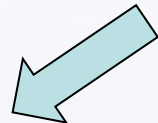
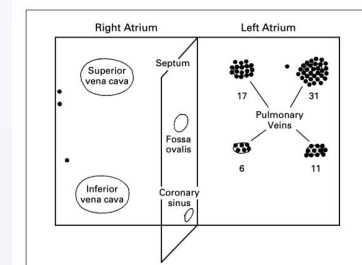
Chirurgická procedura Maze  
(časná 90 léta)



Snaha reprodukovat katetry  
(polovina 90tých let)



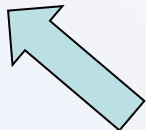
Objev spouštěčů v PŽ  
(konec 90tých let)



Nové techniky a technologie izolace PŽ



Rozvoj strategií pro modifikaci substrátu



# Co si odnést domů?

- Katetrizační ablace má největší potenciál k udržení SR
- ČR je v počtu ablací na milion obyvatel na jednom z předních míst na světě
- Situace se ještě dál zlepší - PFA je nová netermální technologie katetrizační ablace, která je vysoce selektivní
- Rozšíření PFA má potenciál učinit katetrizační ablaci účinnější, bezpečnější a rychlejší (a tím zlepšit časnou kontrolu rytmu u mnohem většího počtu nemocných)





**PRAGUE  
RHYTHM**

25<sup>th</sup>

# **PRAGUE RHYTHM**

With live demonstrations  
(Novel Technology Forum)

**MARCH 19 - 21, 2023,  
Prague, Czech Republic**

