KATETRIZAČNÍ ABLACE KOMOROVÝCH TACHYARYTMIÍ POMOCÍ DUÁLNĚ-ENERGETICKÉHO ABLAČNÍHO SYSTÉMU AFFERA PRO RADIOFREKVENČNÍ ABLACI A ABLACI PULZNÍM ELEKTRICKÝM POLEM

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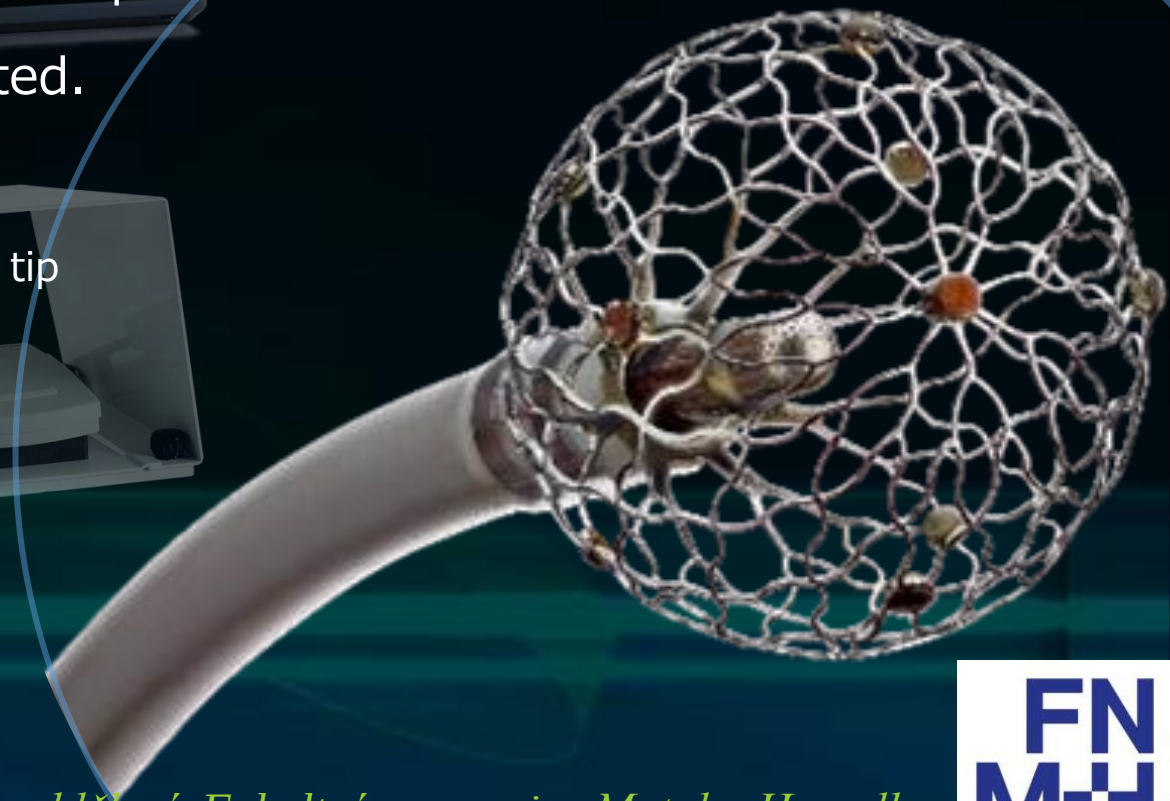
Affera System for Ventricular Arrhythmias

Backgrounds

- ✓ Ventricular arrhythmia ablation is still challenging, although AF ablation procedure became safe and simple.
- ✓ Affera system is mainly used for AF ablation procedures and clinical experience for VT ablation is limited.
- ✓ The advantages of this system are
  - ➢ Conformable 9mm large footprint of catheter tip
  - ➢ RF/PF dual energy capability
  - ➢ High density automated 3D mapping system



Sphere-9™ Catheter

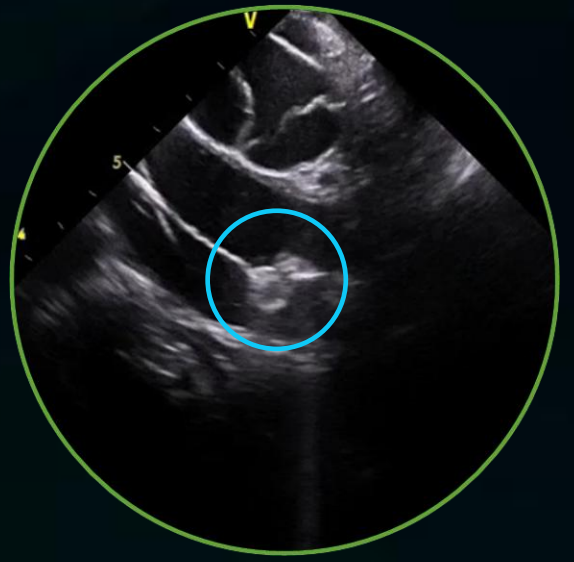
Technical capabilities

Innovative 9 mm, conformable lattice tip provides stability

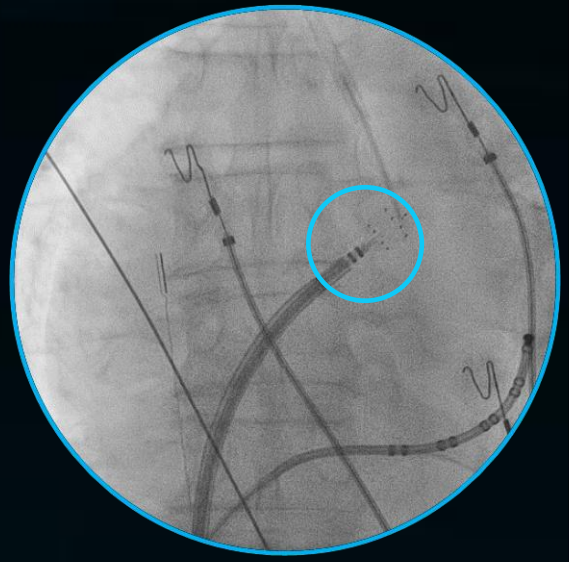
Visualization of Sphere-9 catheter by intracardiac echo and fluoroscopy

Stability[1]

Stability + Conformability[1]



Echogenicity[2]

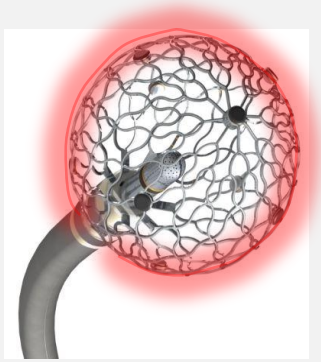


Opacity[3]

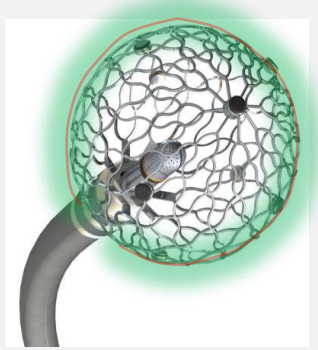
1. Medtronic data on file. Sphere-9 Visible Heart Lab Image
2. Anter E, et al. *JACC Clin Electrophysiol*. 2020; 6:507–519.
3. Medtronic data on file. Sphere-9 Fluoro Image February 2023.

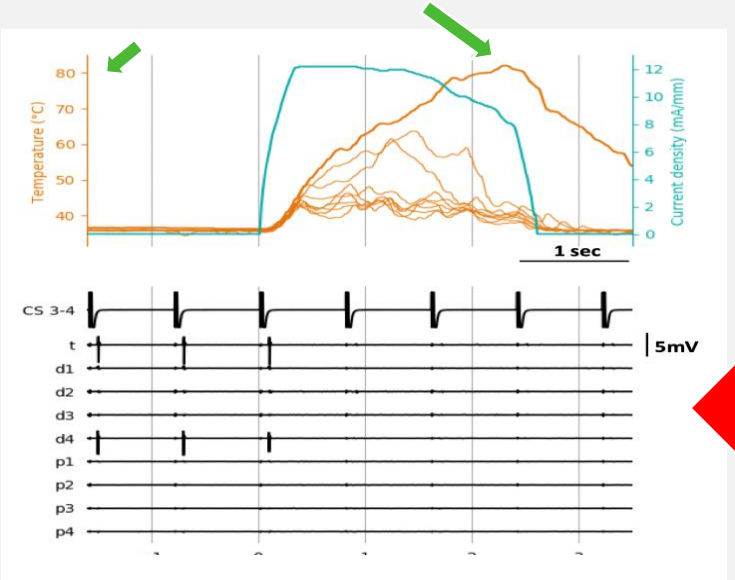
RF/PF Dual-energy Delivery

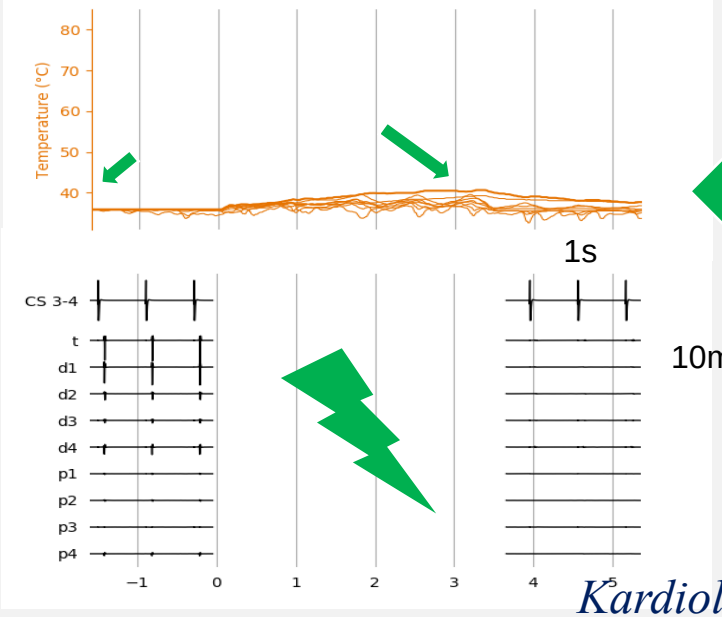
RF Ablation

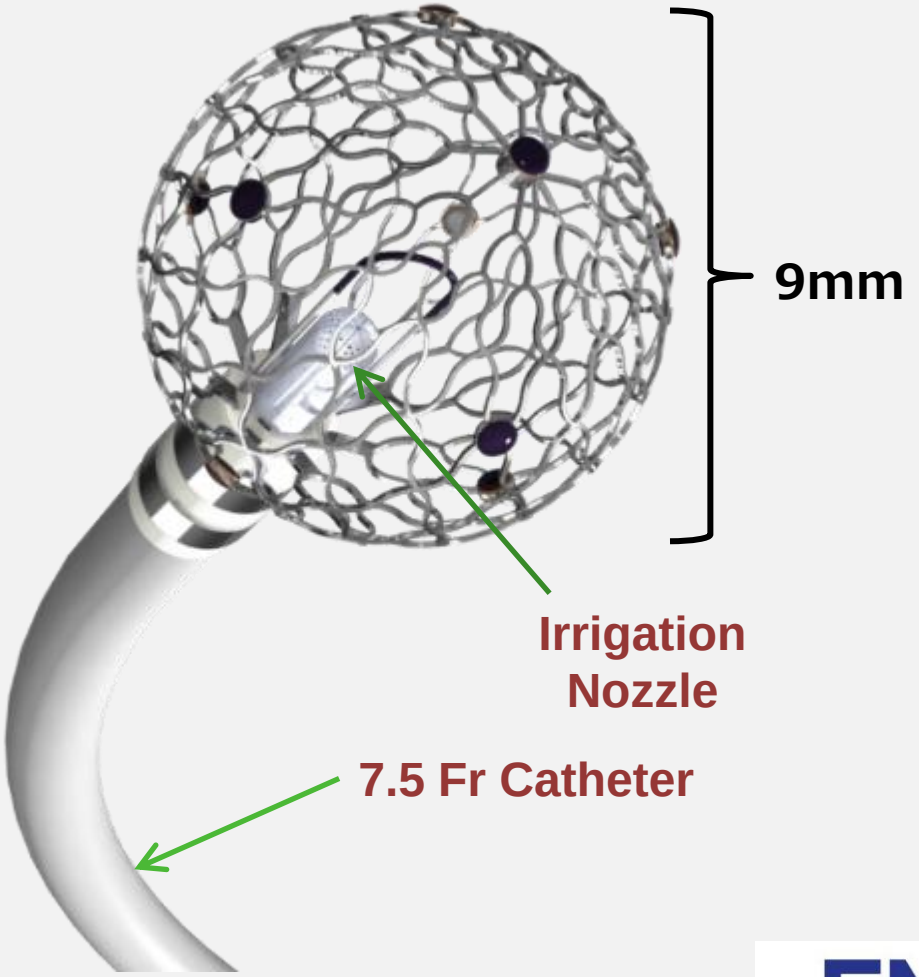


PF Ablation









Lesion Characteristics of Sphere-9 RF/PF applications

Safely deliver energy from the entire lattice in shorter ablation times[1]

Specific RF/PF Settings for VT ablation

PFA:

Same output as AF PFA

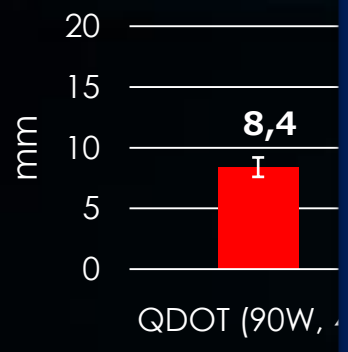
Longer duration compared to AF PFA

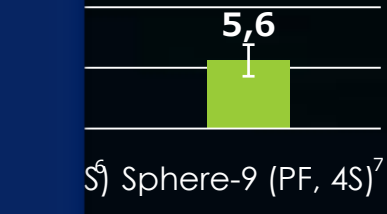
RFA:

Lower output compared to AF RFA

Lower temperature-controlled compared to AF RFA

Longer duration (30 sec or 60 sec.) compared to AF RFA





Radiofrequency

- **Temperature-controlle**
- **Ablation electrode has ablation catheters[2]**
- **Lattice behaves as a c than 3.5 mm catheter with similar lesion depths**

e cell death by

phere-9 RF

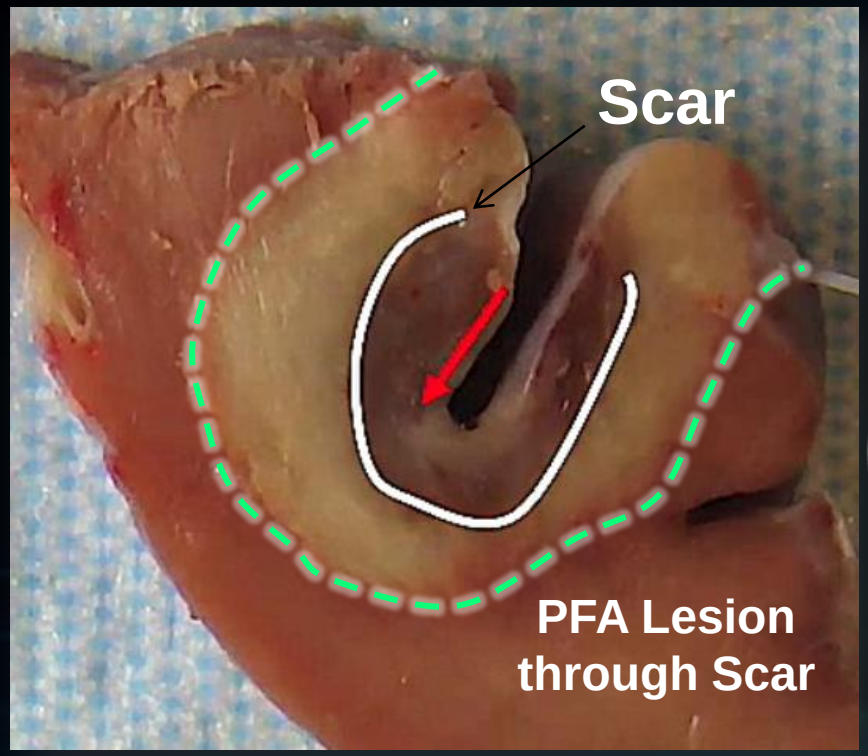
applications with the added potential safety benefits of PF[1,3,4]

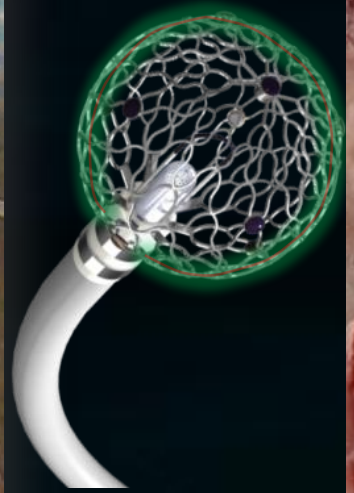
- **As with RF, the entire ablation electrode delivers the PF energy**
- **Consists of a train of microsecond-scale pulses**

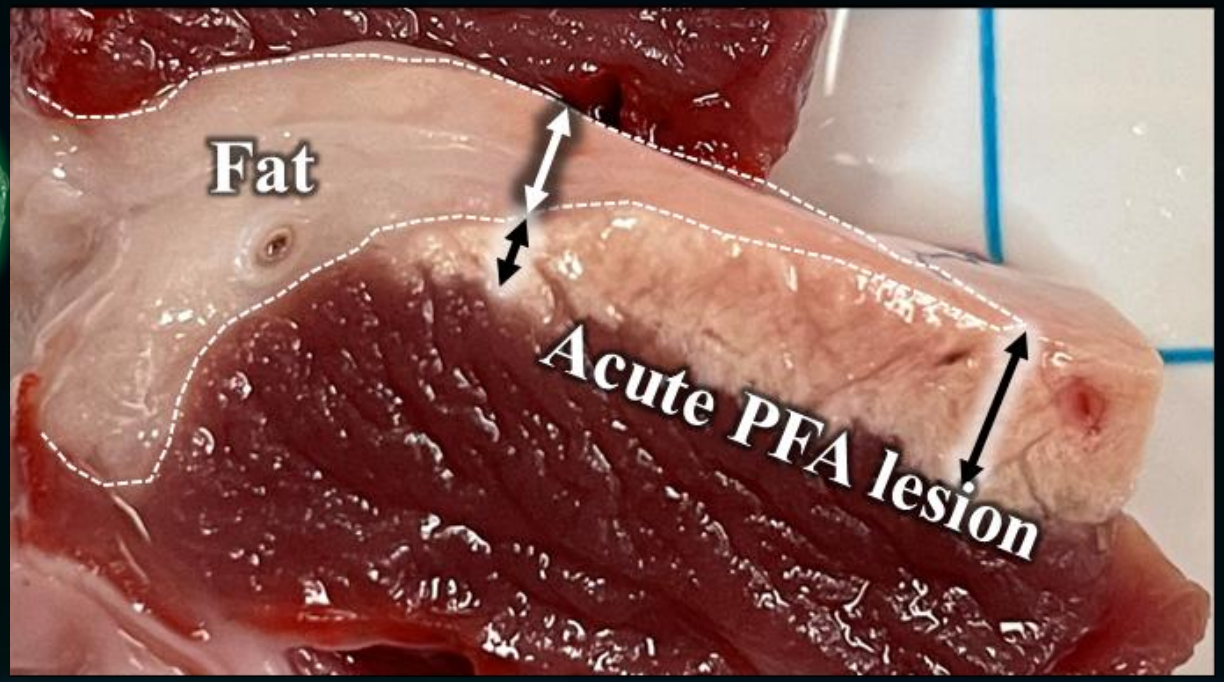
1. *Anter E, et al. Nat Med. 2024; 30:2303-2310.*
2. *Barkagan M, et al. Circ Arrhythm Electrophysiol. 2019; 12(4):e007090.*
3. *Yavin H, et al. Circulation: Arrhythmia and Electrophysiology. 2020; 13(6):e008580.*
4. *Reddy V, et al. JACC: Clinical Electrophysiology. 2023; 9(8):1786–1801.*
5. *Nakagawa H, et al. Circ Arrhythm Electrophysiol. 2021;14(7):e009899.*
6. *Medtronic data on file, S6585 GLP Study.*
7. *Yavin H, et al. Circulation: Arrhythmia and Electrophysiology. 2021; 14(9):e010375.*

Future of Substrate Modification

Technical Improvements Critical → PFA







*Off-label use, investigational use only.

Koruth JS, Kuroki K, Iwasawa J, … Reddy VY. Europace 22, 434–439 (2020)
JS.Koruth / I.Kawamura / VY.Reddy (HRS – 2021)

Kardiologické oddělení, Fakultní nemocnice Motol a Homolka

Affera VT Ablation @ NNH

Patient Characteristics (2019-2024)

Characteristic	Overall cohort
Patients (n)	26
VT ablation procedures	27
Age, years	62.9 ± 14.7
Male sex	68%
BMI, kg/m²	27.5 ± 4.3
VT storm at presentation	4 / 26, 15.4%
Ischemic cardiomyopathy	17 / 26, 65.4%
Arrhythmogenic right ventricular cardiomyopathy	4 / 26, 15.4%
Hypertrophic cardiomyopathy	3 / 26, 11.5%
Idiopathic VT	2 / 26, 7.7%

*Values are shown as mean ± SD or n / N, %.
*The cohort includes 26 patients undergoing 27 VT ablation procedures, with ischemic cardiomyopathy as the dominant substrate.

Affera VT Ablation @ NNH

Acute Ablation Results by Underlying Heart Disease (1)

Underlying disease	*Procedures (n)*	*VT storm (n)*	*GA (n)*	*Procedure time (min.)*	*Fluoroscopy time (min.)*	*Energy modality*	*RF applications (n)*	*RF time (min.)*	*PFA applications (n)*	*PFA time (min.)*
Ischemic cardio-myopathy	18	3/18 (16.7%)	13/18 (72.2%)	144.3 ± 46.5	5.2 ± 3.8	RF 5; PFA 5; RF+PFA 7; None 1*	19.2 ± 14.5	7.9 ± 5.7	51.1 ± 35.2	4.3 ± 2.9
ARVC	4	0/4 (0.0%)	1/4 (25.0%)	138.5 ± 56.3	5.1 ± 1.7	RF 3; PFA 1	9.3 ± 7.4	6.6 ± 4.2	27.0	2.2
Hypertrophic cardio-myopathy	3	1/3 (33.3%)	3/3 (100.0%)	232.0 ± 54.7	15.8 ± 4.9	RF 2; PFA 1	8.0	2.4 ± 1.2	19.0	1.6
Idiopathic VT	2	0/2 (0.0%)	0/2 (0.0%)	130.0 ± 42.4	1.3 ± 1.8	RF 2	3.5 ± 0.7	1.4 ± 0.3	—	—

*Values are shown as mean ± SD or n / N, %.

*One ICM patient did not undergo ablation procedure due to lack of substrate

Affera VT Ablation @ NNH

Acute Ablation Results by Underlying Heart Disease (2)

Underlying disease	***Final inducibility testing performed***	***Clinical VT/PVC residual after ablation***	***Non-clinical VT inducible at final testing***	***Complete non-inducibility***	***Major acute complication***
Ischemic cardiomyopathy	17/18 (94.4%)	0/17 (0.0%)	3/17 (17.6%)	14/17 (82.4%)	*1/18 (5.6%)*
ARVC	4/4 (100.0%)	0/4 (0.0%)	0/4 (0.0%)	4/4 (100.0%)	0/4 (0.0%)
Hypertrophic cardiomyopathy	3/3 (100.0%)	0/3 (0.0%)	1/3 (33.3%)	2/3 (66.7%)	0/3 (0.0%)
Idiopathic VT	2/2 (100.0%)	0/2 (0.0%)	0/2 (0.0%)	2/2 (100.0%)	0/2 (0.0%)

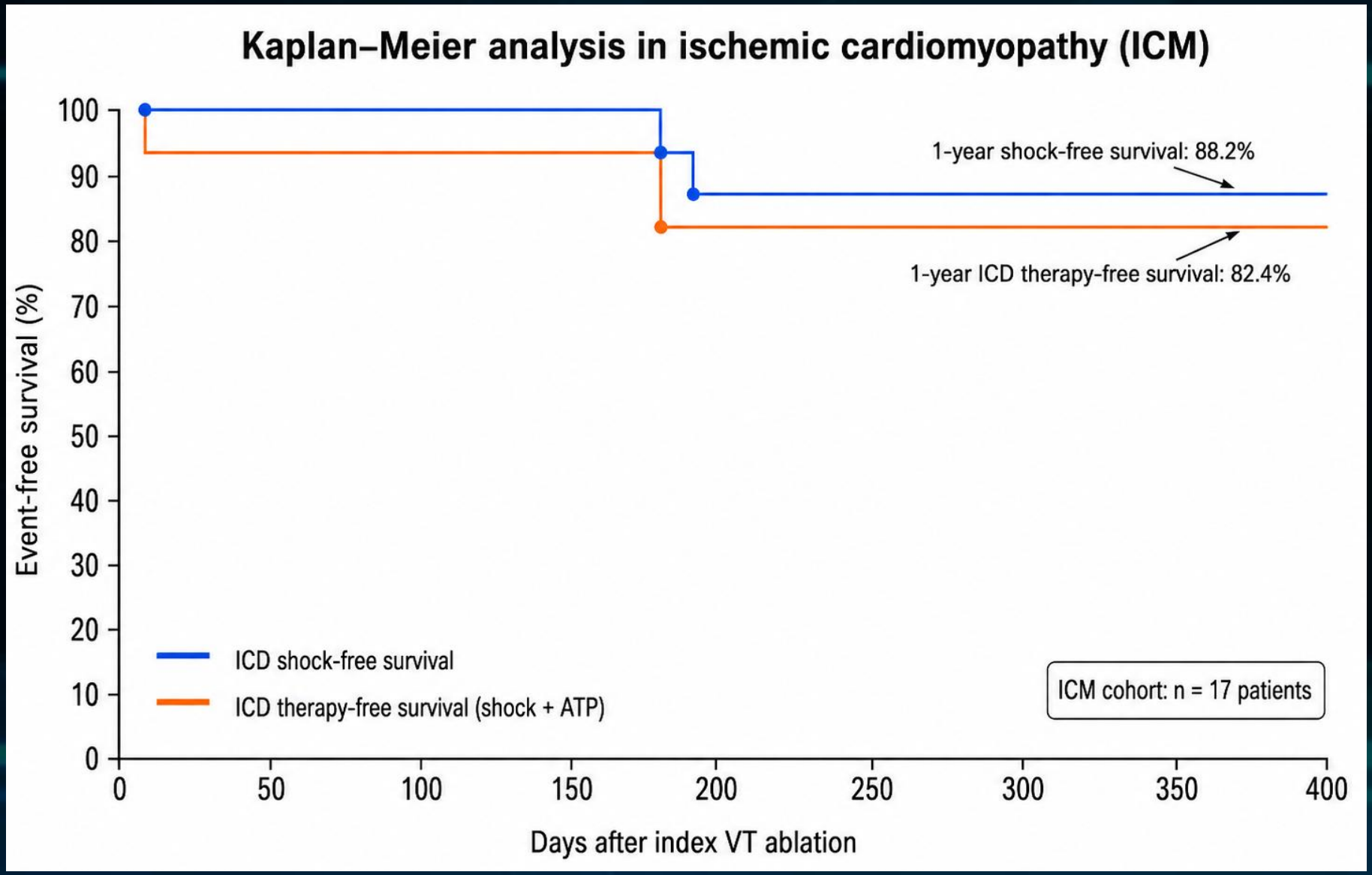
Affera VT Ablation @ NNH

Long-term Ablation Results by Underlying Heart Disease

Underlying disease	**Patients, n**	**Follow-up, days median [IQR]**	**Any recurrence**	**ICD therapy (ATP+CV)**	**Reablation**	**Death**
Ischemic cardiomyopathy	17	182 [137–274]	8/16 (50.0%)	5/16 (31.2%)	1/16 (6.2%)	1/17 (5.9%)
ARVC	4	1494 [824–2015]	3/4 (75.0%)	3/4 (75.0%)	2/4 (50.0%)	1/4 (25.0%)
Hypertrophic cardiomyopathy	3	188 [160–245]	2/3 (66.7%)	1/3 (33.3%)	0/3 (0.0%)	0/3 (0.0%)
Idiopathic VT	2	128 [85–172]	0/2 (0.0%)	0/2 (0.0%)	0/2 (0.0%)	0/2 (0.0%)

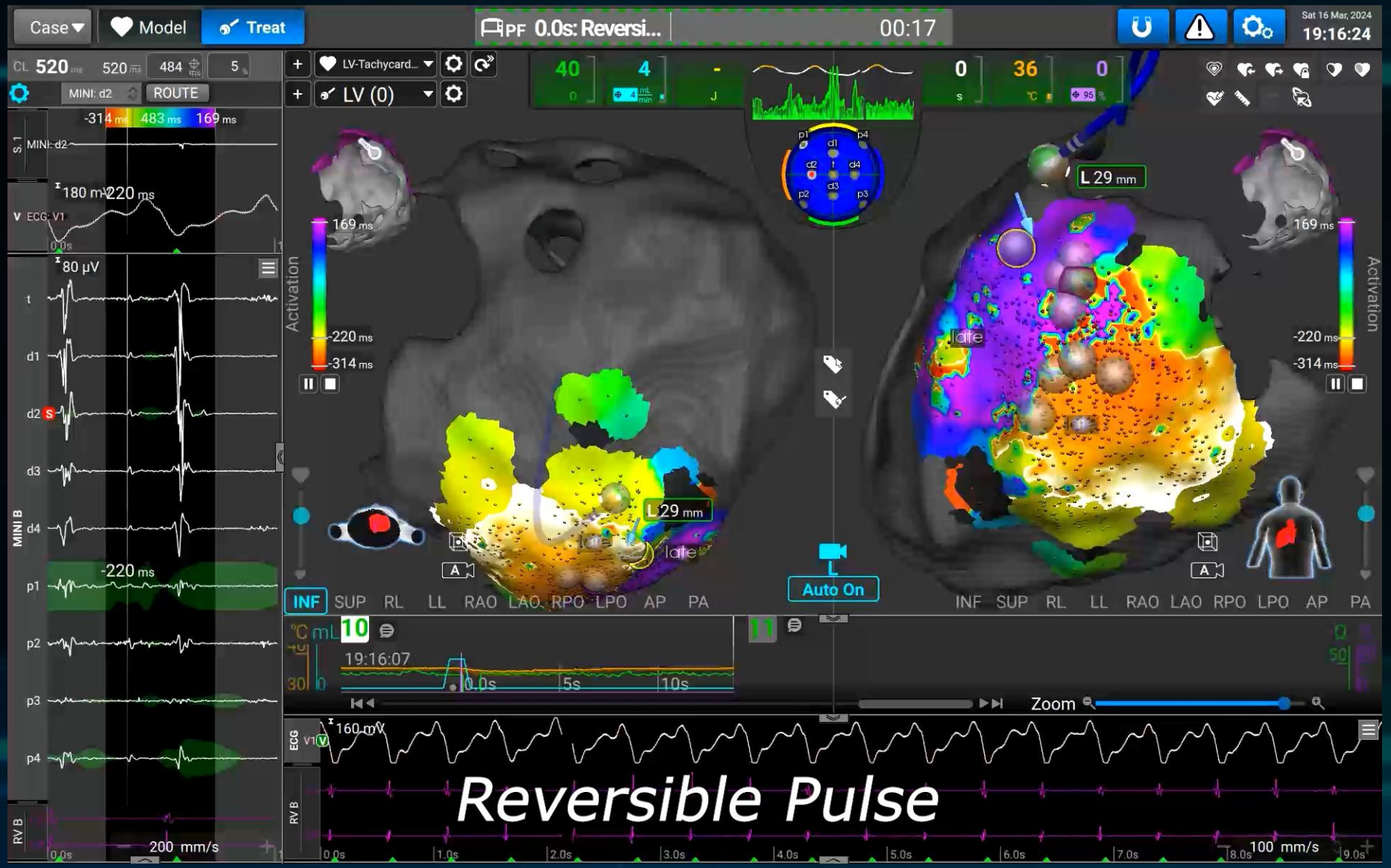
One Year Result after Affera VT ablation for ICM

ICD event-free survival rate per patient (n=17)



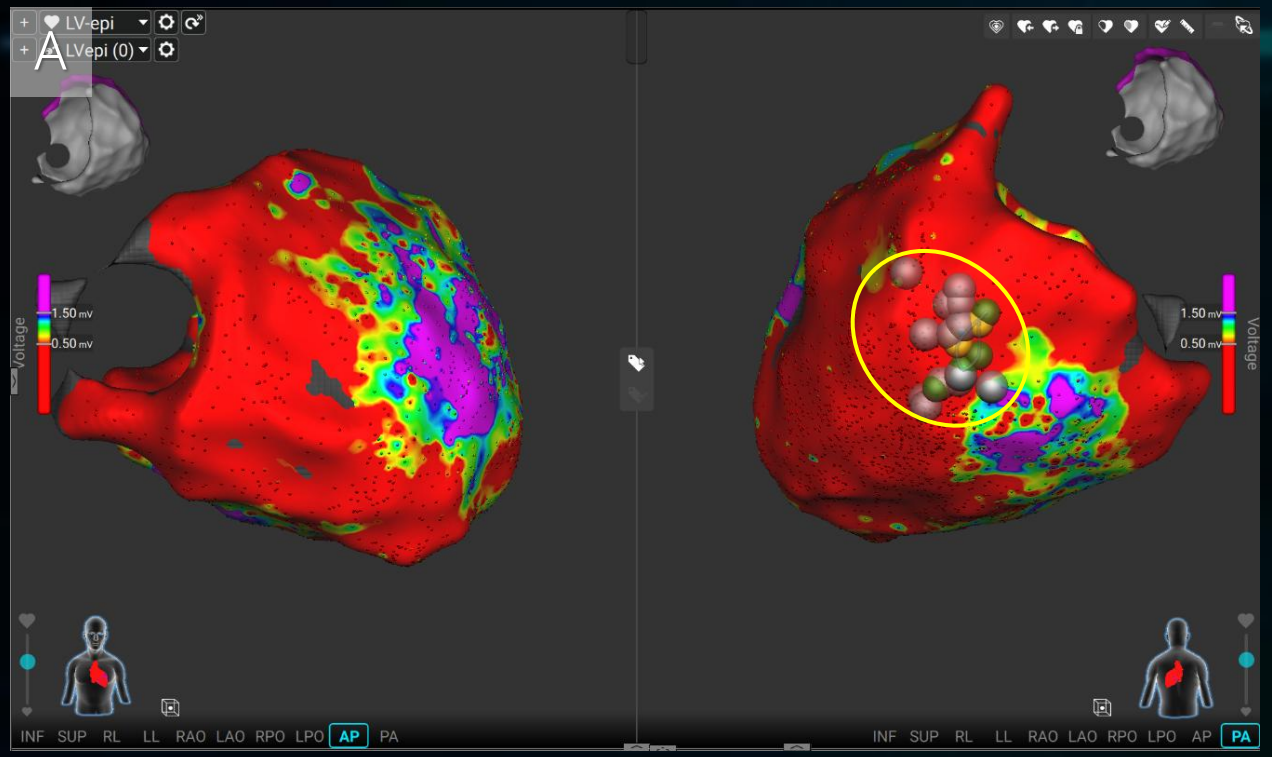
Strategy for Epicardial PFA

Reversible PFA for Critical Isthmus Diagnosis

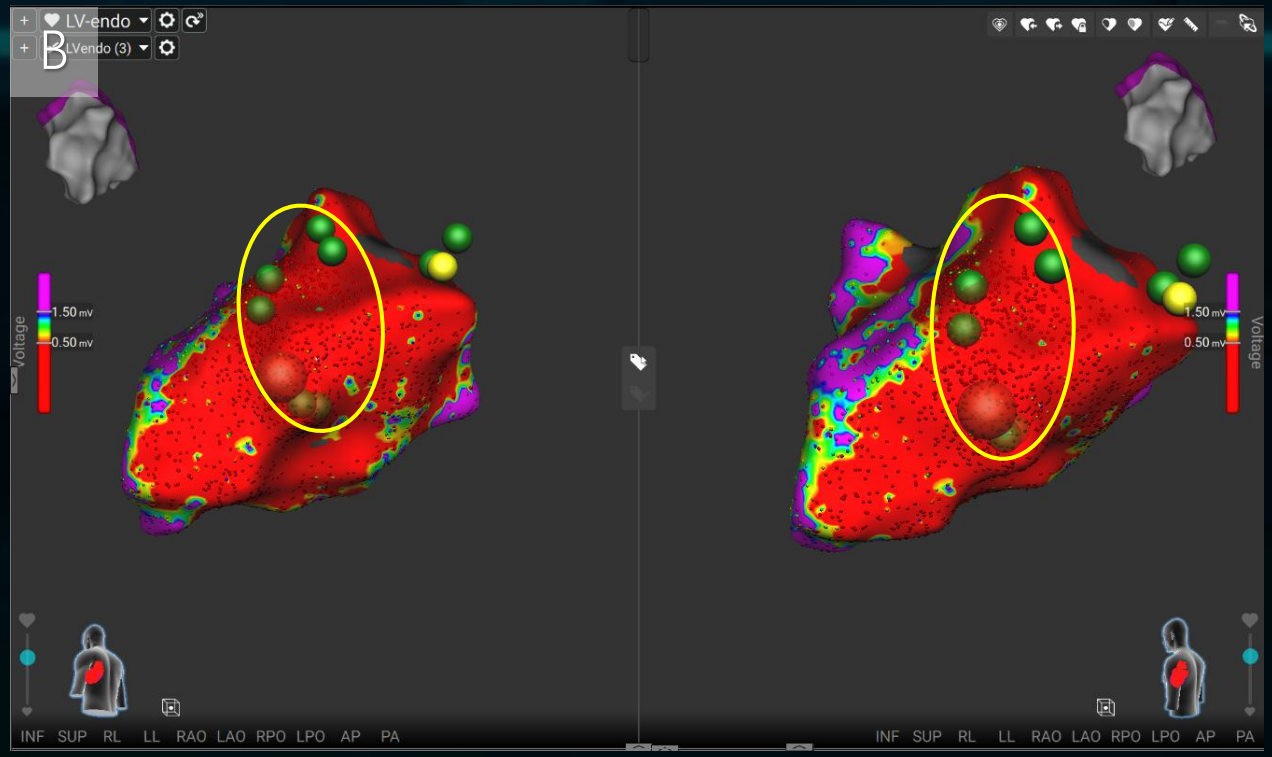


Strategy for Epi/Endo PFA

A Lesson from Recurrent ICM Epi/Endo Ablation Case



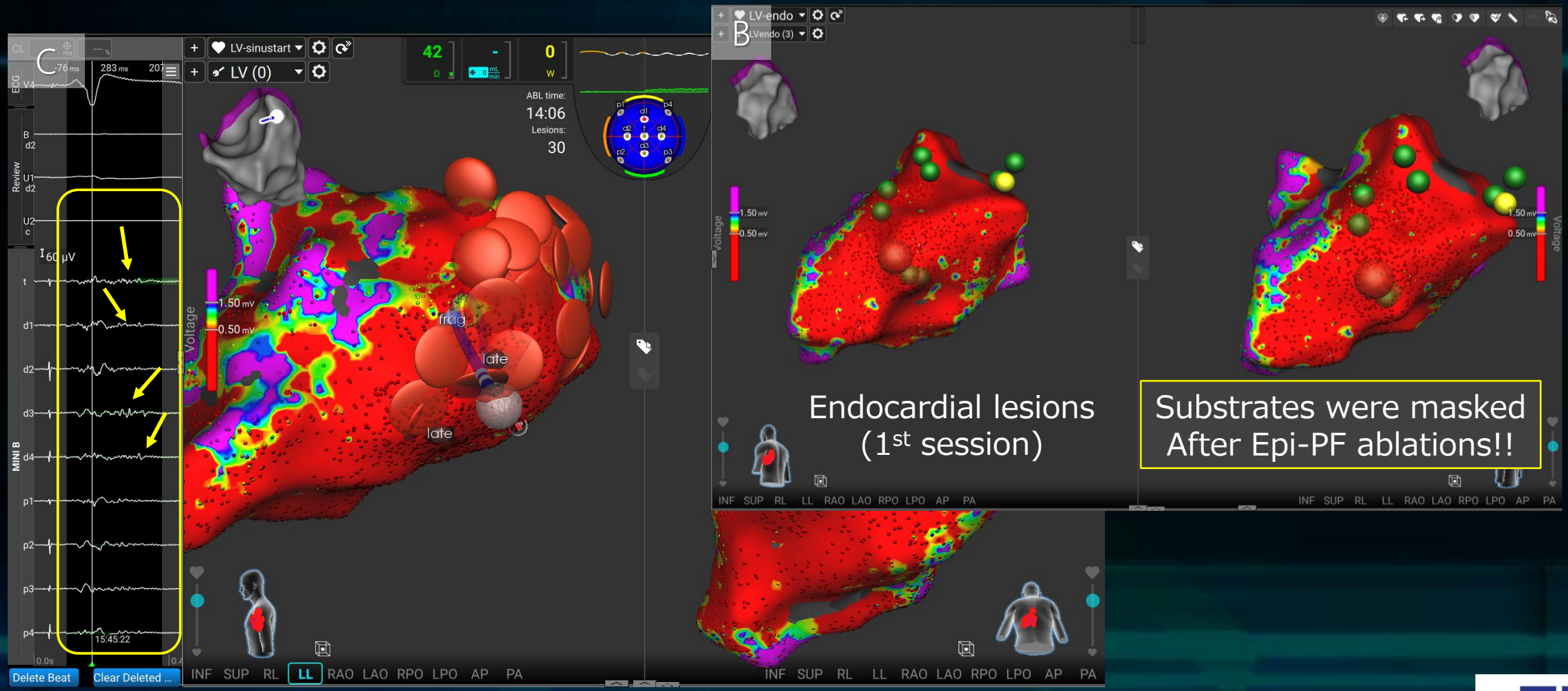
Epicardial PF lesions
(1st session)



Endocardial PF lesions
(1st session)

Strategy for Epi/Endo PFA

A Lesson from Recurrent ICM Epi/Endo Ablation Case



Endocardial RF lesions
(2nd session)

Kardiologické oddělení, Fakultní nemocnice Motol a Homolka

Limitations

- ✓ Single-center, single-arm, non-randomize study.
- ✓ Small number of the cases, although typical types of VT were included.
- ✓ Mixed RF/PF strategies especially for ICM patients.
- ✓ Uniform RF/PF strategy with a randomized trial (vs. conventional RF) should be considered.

Summary

AFFERA: Possible Future for VT Ablation

- ✓ VT ablation using Affera dual-energy RF/PF system is feasible.
- ✓ Some cases were completed without GA.
- ✓ “Mapping first” strategy may be required as PFA can mask substrates on the other surface of the heart structure.

Nothing ventured, nothing gained..