DOPLŇKOVÉ LINEÁRNÍ LÉZE NAD RÁMEC IZOLACE PLICNÍCH ŽIL A IZOLACE ZADNÍ STĚNY PŘI PULZNÍ ABLAČNÍ TERAPII FIBRILACE SÍNÍ

Funasako M.[1], Petrů J.[1], Lekešová V.[1], Škoda J.[1], Hála P.[1], Janotka M.[1], Chovanec M.[1], Šedivá L.[1], Reddy V.[2], Neužil P.[1]

1. Kardiologie, Fakultní nemocnice Motol a Homolka, PRAHA, CZE

2. Cardiology, Mt Sinai, New York, United States

Farapulse System for Atrial Fibrillation

Backgrounds

- ✓ Farapulse system is widely used for AF ablation procedures, especially in Czech Republic since 2021.
- ✓ The advantages of this system are
  - ➢ The largest clinical evidence since FIH
  - ➢ Effective basket/flower configuration
  - ➢ Possibility to combine with contact-sensing 3D mapping system
- ✓ PVI+ procedures including PWI, MI, and CTI are also clinically performed.
- ✓ However, clinical evidence for non-PV lesion is limited.

First-In-Human "Commercially Available" Pulsed Field Ablation Registry

ESC European Society of Cardiology
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Multi-national s efficacy, and saf clinical use of pu (MANIFEST-PF

Emmanuel Ekanem[1], Viv
Kars Neven[5,6], Andreas
Philippe Maury[10,11], Thoma
Frederic Anselme[15], Serge
Pepijn van der Voort[20], Rol
Daniel Scherr[25], Reza Waki
Johan Vijgen[29], Pierre Jais
Anna Füting[5,6], Andreas
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[30], Mohit K. Turagam[1], and Petr Neuzil[2]* (for the MANIFEST-PF Cooperative)

Overall Non-PV PFA Experience in the first year

Posterior Wall Isolation	= 75%
Roof Line	= 50%
Lateral Mitral Isthmus	= 37.4%
Anterior Line	= 25%
CTI	= 31%*

*Data from MANIFEST-US

			Frequently	Always
			12.5	25
			12.5	33.3
			4.2	0
			0	8.3
			0	21.7
			4.3	91.3
			4.3	0
			0	0
			0	0
			8.3	33.3
			20.8	41.7
			8.3	41.7
			12.5	12.5
			4.2	0
			16.7	12.5
Anterior line (%)	75	25	0	0
SVC isolation (%)	95.8	4.2	0	0
CFAE (%)	95.8	4.2	0	0
LAA isolation (%)	93.8	6.2	0	0
Non-PV trigger (%)	79.2	20.8	0	0

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Baseline Patient Characteristics

Characteristics	Overall	Paroxysmal AF	Non-paroxysmal AF	P value
N, patients	**1,048**	**234**	**814**	—
Age, years	**68.0 ± 9.9**	**65.9 ± 10.5**	**68.6 ± 9.6**	**<0.001**
Female sex	369 (35.2%)	90 (38.5%)	279 (34.3%)	0.245
BMI, kg/m²	29.7 ± 5.5	29.2 ± 5.0	29.8 ± 5.6	0.105
Hypertension	793/1046 (75.8%)	167 (71.4%)	626/812 (77.1%)	0.083
Diabetes mellitus	250/1047 (23.9%)	50 (21.4%)	200/813 (24.6%)	0.339
Renal failure	**119/1047 (11.4%)**	**18 (7.7%)**	**101/813 (12.4%)**	**0.047**
Heart failure	**206/1047 (19.7%)**	**31 (13.2%)**	**175/813 (21.5%)**	**0.005**
Oral anticoagulation	1015 (96.9%)	223 (95.3%)	792 (97.3%)	0.137
Class I/III AAD recorded*	**531 (50.7%)**	**141 (60.3%)**	**390 (47.9%)**	**0.001**
Class I AAD, propafenone	306/1047 (29.2%)	94 (40.2%)	212/813 (26.1%)	<0.001
Class III AAD, amiodarone	225 (21.5%)	47 (20.1%)	178 (21.9%)	0.589
LVEF, %	**56.9 ± 9.6**	**58.0 ± 8.9**	**56.6 ± 9.8**	**0.043**
LAD, mm	**45.6 ± 6.8**	**43.5 ± 5.7**	**46.2 ± 7.0**	**<0.001**

*Values are mean ± SD or n/N (%).

*P values are Welch's t-test for continuous variables and Fisher's exact test for categorical variables.

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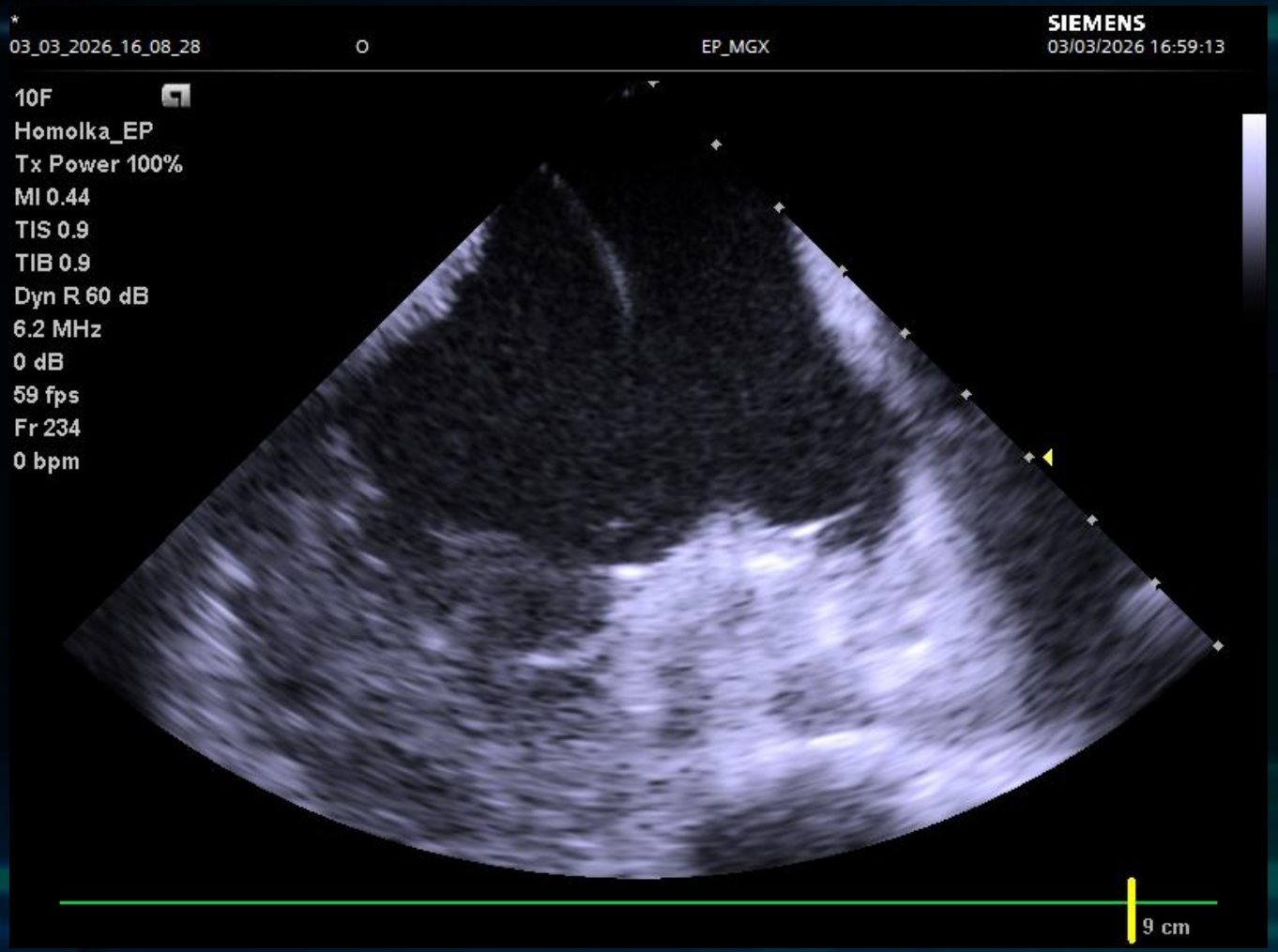
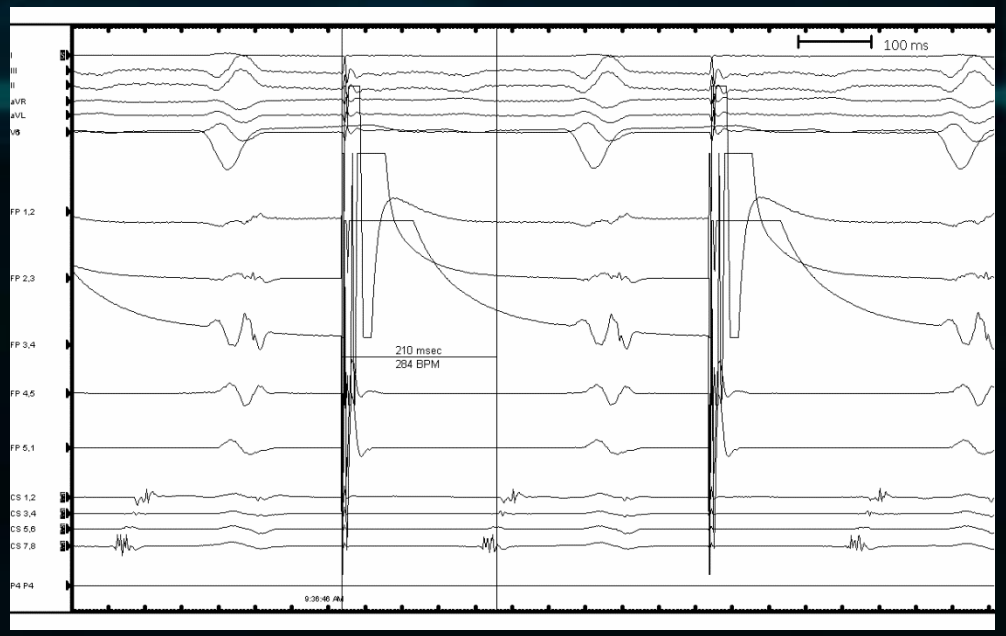
Example of Farapulse mitral isthmus ablation





- ✓ Anterolateral mitral isthmus linear lesion
- ✓ Flower configuration
- ✓ Tissue contact confirmation with ICE
- ✓ 3 applications per site
- ✓ 3 to 5 sites per line on average
- ✓ Block confirmation was not mandatory
- ✓ NTG not mandatory

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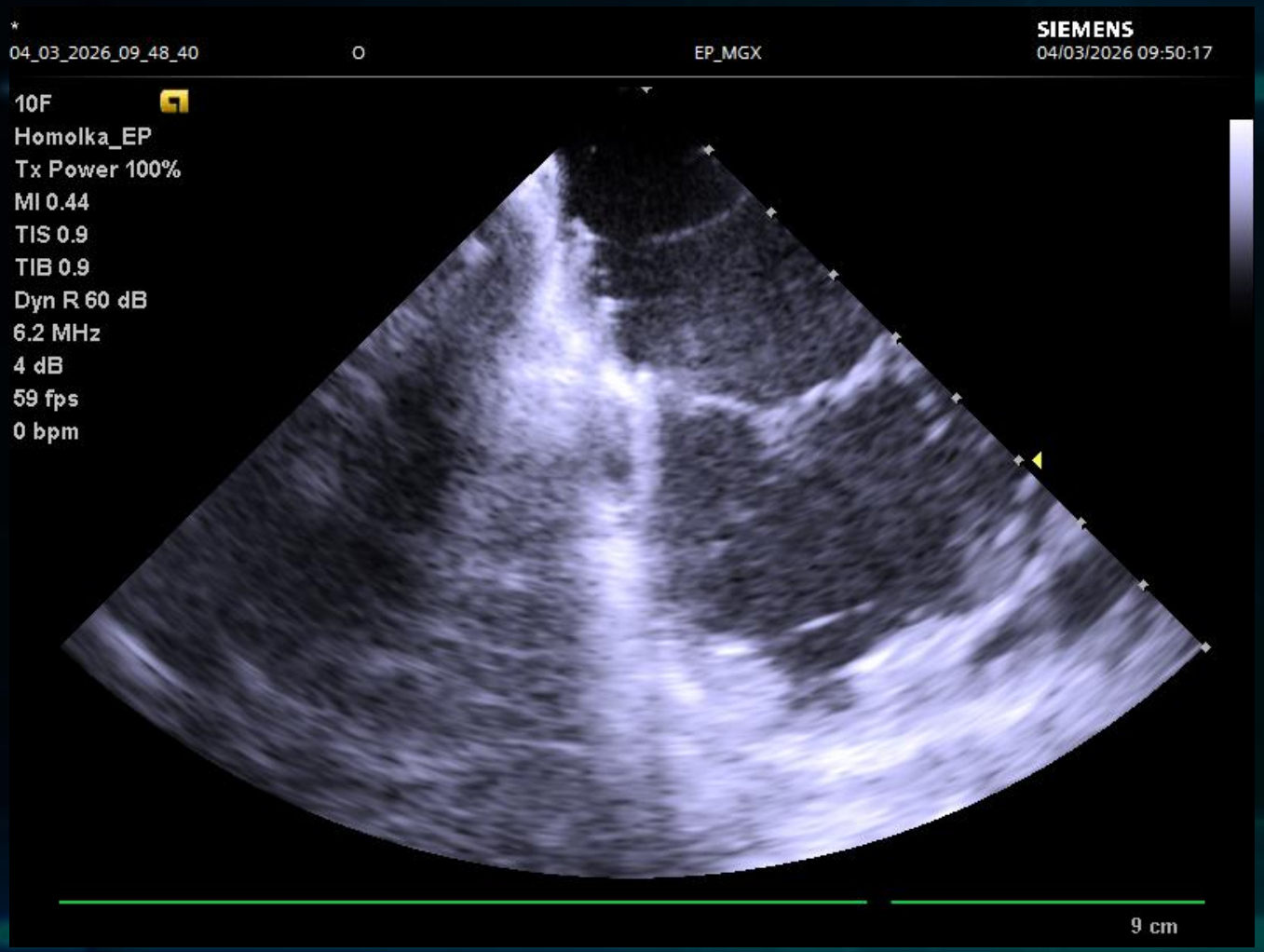
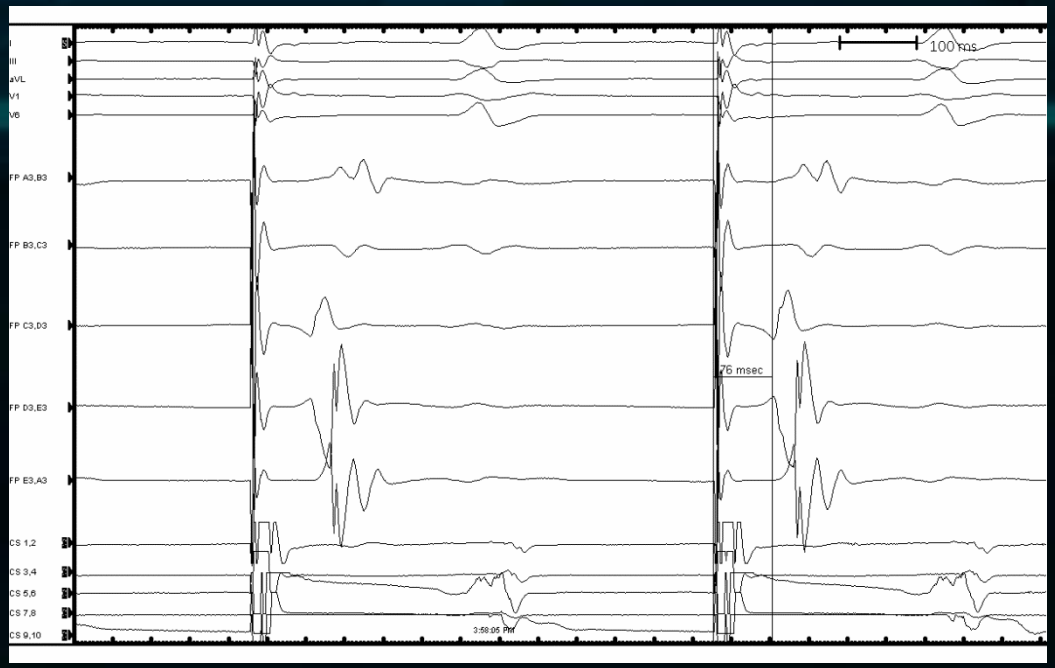
Example of Farapulse CTI ablation





- ✓ Lateral cavotricuspid isthmus lesion
- ✓ Flower configuration
- ✓ Tissue contact confirmation with ICE
- ✓ 3 applications per site
- ✓ 2 to 4 sites per line on average
- ✓ Block confirmation was not mandatory
- ✓ NTG not mandatory

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Acute Procedural Results (1)

Procedural characteristics	Overall	Paroxysmal AF	Non-paroxysmal AF	P value
N, procedures	**1,127**	**245**	**882**	—
Redo ablation procedures	188/1102 (17.1%)	46/236 (19.5%)	142/866 (16.4%)	0.283
Procedure time, min	**65.0 [51.0–90.0]**	**62.0 [50.0–85.0]**	**66.0 [51.0–92.0]**	**0.040**
Fluoroscopy time, min	6.1 [2.6–10.6]	6.0 [2.8–10.7]	6.2 [2.6–10.6]	0.884
PFA pulse count	**62.5 [45.0–83.0]**	**61.0 [45.0–79.0]**	**64.0 [45.0–84.0]**	**0.033**
Total PFA delivery time, sec	**167.4 [132.0–205.0]**	**145.8 [116.1–183.6]**	**175.8 [140.4–211.0]**	**<0.001**
DAP, Gy·cm²	2.90 [1.16–8.48]	2.40 [0.96–7.54]	3.00 [1.20–8.56]	0.102
Electrical cardioversion during procedure	**183 (16.2%)**	**17 (6.9%)**	**166 (18.8%)**	**<0.001**
3D mapping used	103 (9.1%)	20 (8.2%)	83 (9.4%)	0.617
Any complication	56/1127 (5.3%)	4.5%	5.6%	0.62

*Values are mean ± SD or n/N (%).

*P values are Welch's t-test for continuous variables and Fisher's exact test for categorical variables.

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Acute Procedural Results (2)

Lesion set / strategy	Overall	Paroxysmal AF	Non-paroxysmal AF	P value
PVI performed	1,127 (100%)	245 (100%)	882 (100%)	—
PVI only	**196 (17.4%)**	**153 (62.4%)**	**43 (4.9%)**	**<0.001**
PVI + PWI	240 (21.3%)	58 (23.7%)	182 (20.6%)	0.332
PVI + PWI + MI	**443 (39.3%)**	**34 (13.9%)**	**409 (46.4%)**	**<0.001**
PVI + PWI + MI + α	**131 (11.6%)**	**0 (0.0%)**	**131 (14.9%)**	**<0.001**
Other patterns*	**117 (10.4%)**	**0 (0.0%)**	**117 (13.3%)**	**<0.001**
CTI ablation performed	**943 (83.7%)**	**217 (88.6%)**	**726 (82.3%)**	**0.019**
CTI block documented †	231/509 (45.4%)	62/157 (39.5%)	169/352 (48.0%)	0.083

*Other patterns mainly reflect previously completed PVI and/or PWI and non-standard combinations.

† Among procedures with CTI ablation in which CTI block documentation was available in the adjudicated table.

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Periprocedural Complications

Complication	Overall
Any complication	**56/1127 (5.3%)**
Complications requiring surgical or invasive treatment*	**4/1127 (0.36%)**
Vascular access complications	34/1127 (3.0%)
└ **Vascular access complications requiring surgical repair**	**2/1127 (0.18%); 2/34 (5.9%)**
Pericardial effusion	10/1127 (0.9%)
└ **Pericardial drainage**	**1/1127 (0.09%)**
Bradycardia / conduction disturbance requiring temporary pacing	8/1127 (0.71%)
└ **Permanent pacemaker implantation**	**1/1127 (0.09%)**
Neurologic / embolic event	1/1127 (0.09%)
Coronary spasm during CTI with ST elevation and AV block	1/1127 (0.09%)
Hemolysis	2/1127 (0.18%)

*Defined as complications requiring **pericardial drainage, permanent pacemaker implantation, or suegical vascular repair**.

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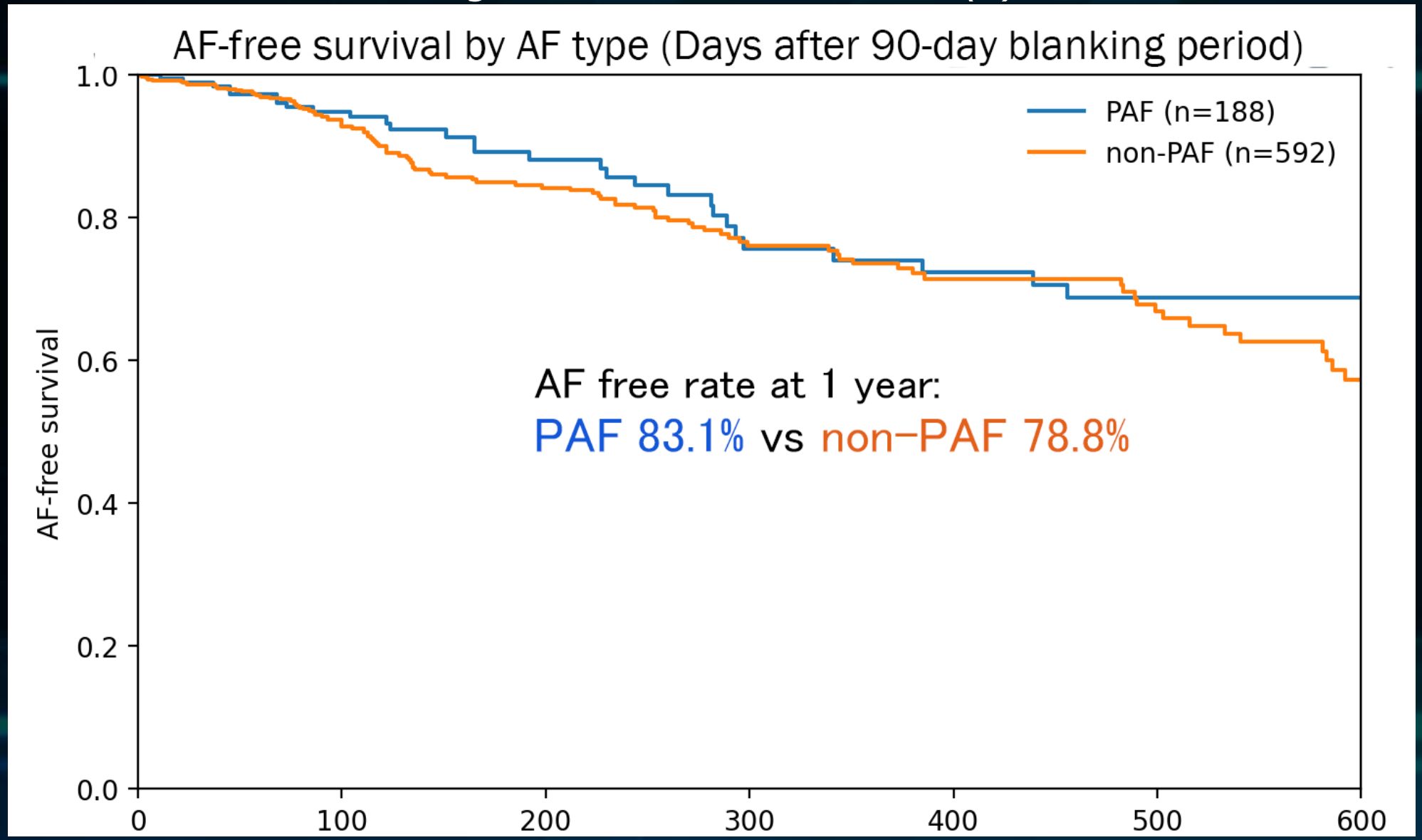
Long-term Procedural Results (1)



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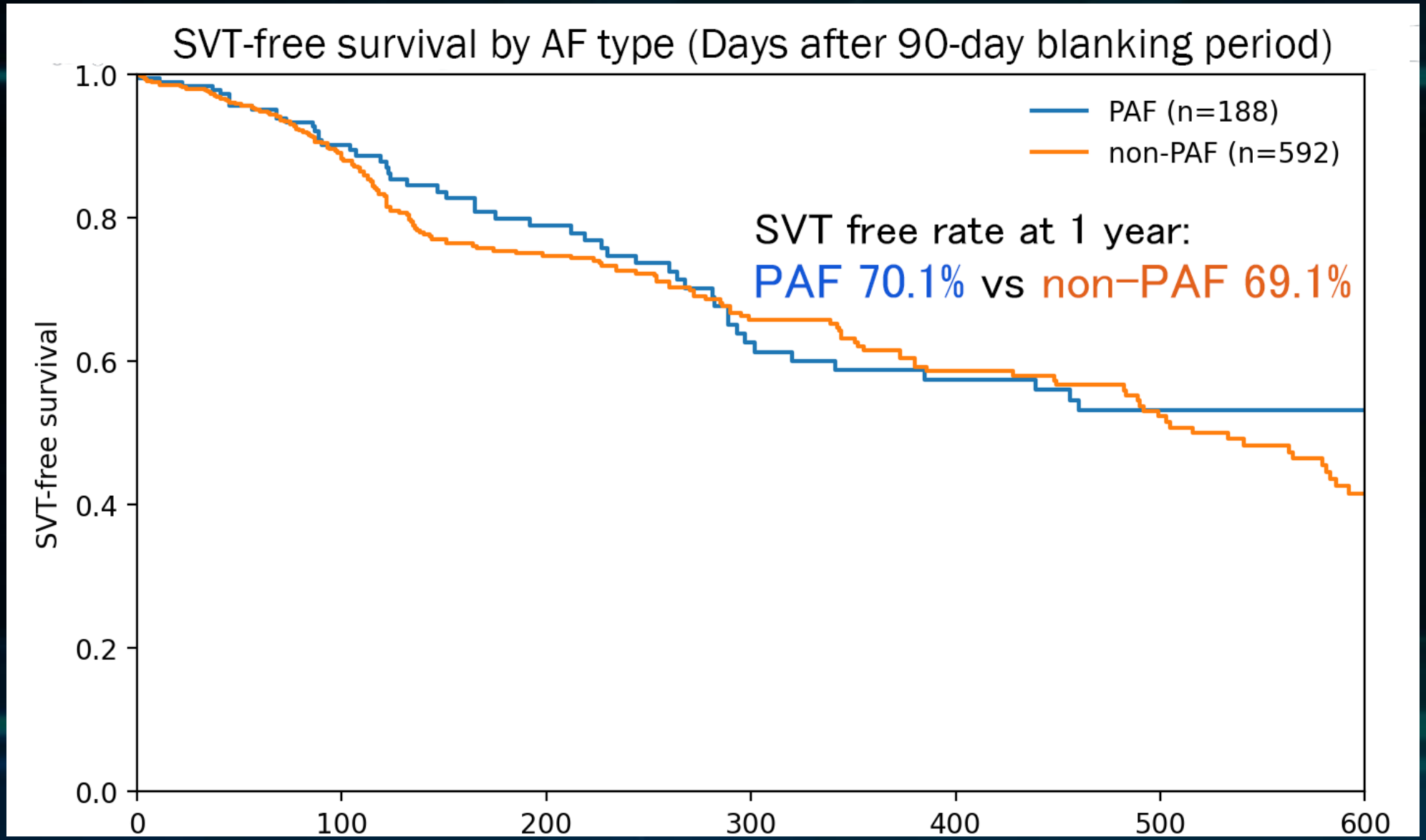
Long-term Procedural Results (2)



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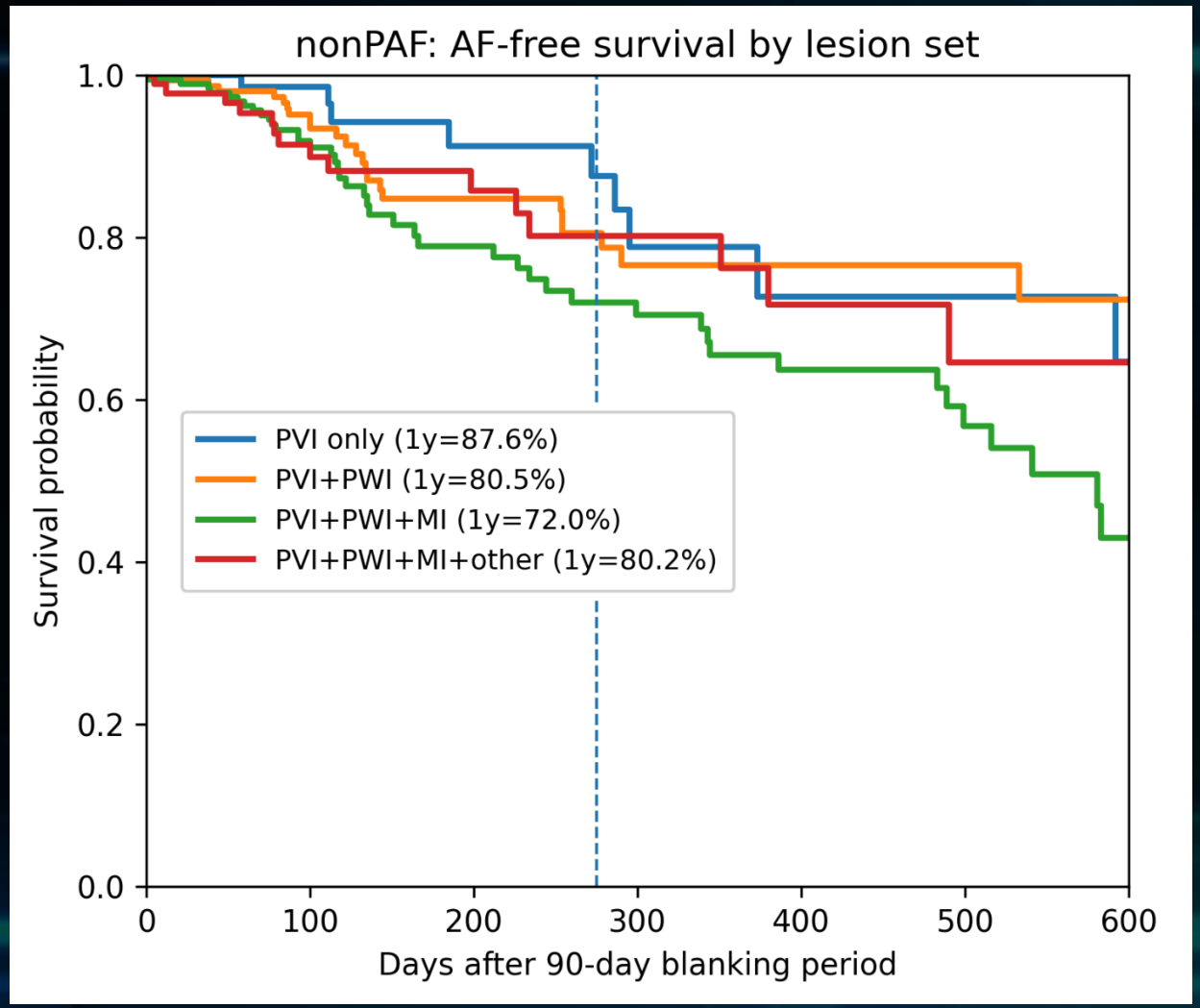
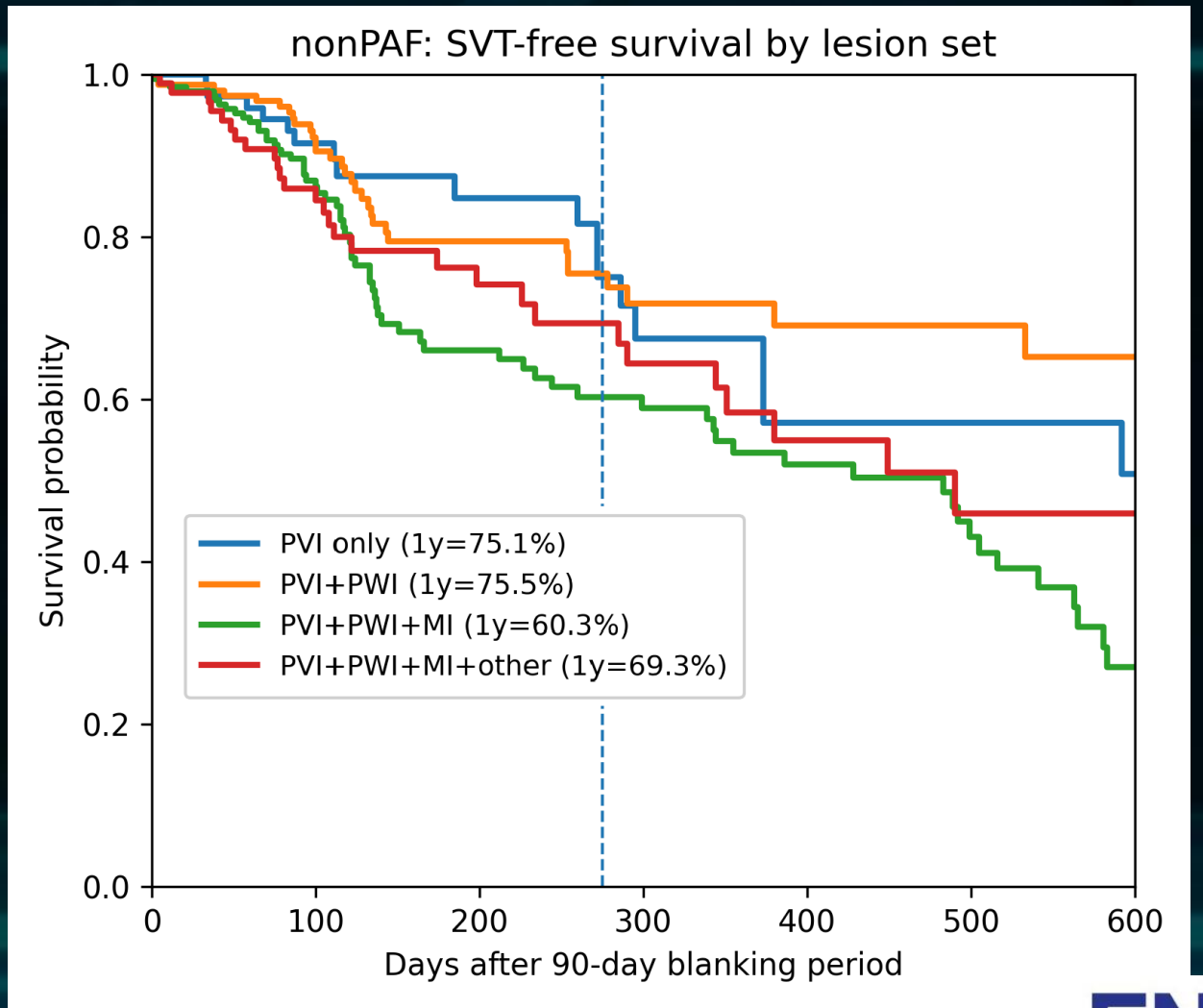
Long-term Procedural Results (3)





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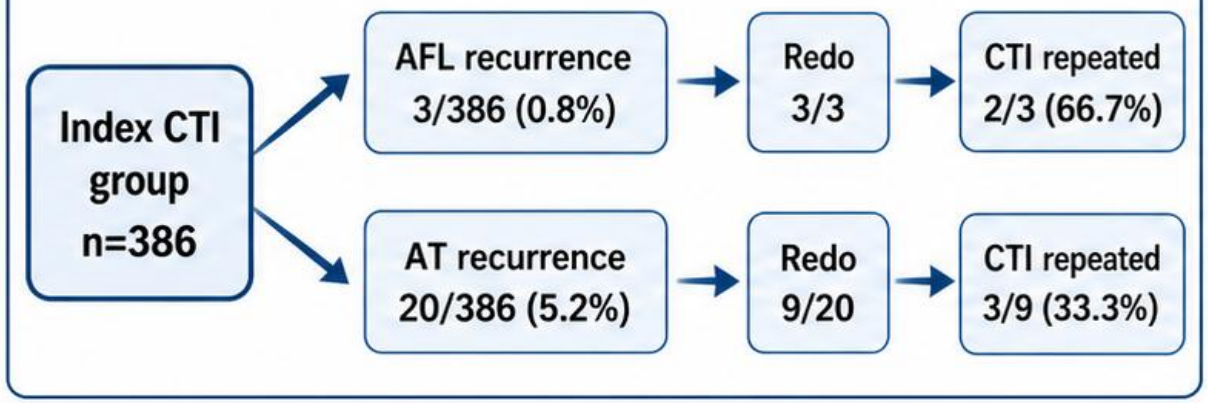
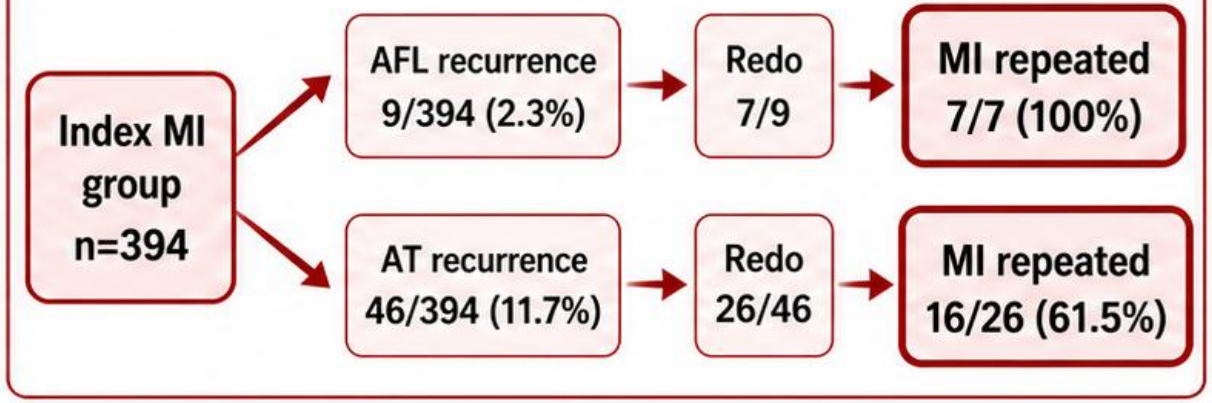
What we did in the Redo procedures?

Long-term cohort: 780 patients	Repeat ablation after index PFA: 128/780 (16.4%)	Redo date available: 119 cases	Median time to redo: 358 [142–582] days	At redo: CTI 62/128 (48.4%), MI 61/128 (47.7%), both 32/128 (25.0%)

A. Index CTI group



B. Index MI group



Key message: Organized AT/AFL recurrence was more frequent after index MI ablation, and MI was frequently retargeted at redo.

Interpretation: These redo findings support possible incomplete MI line durability or reconduction as a contributor to recurrence, but do not prove reconduction in every case.

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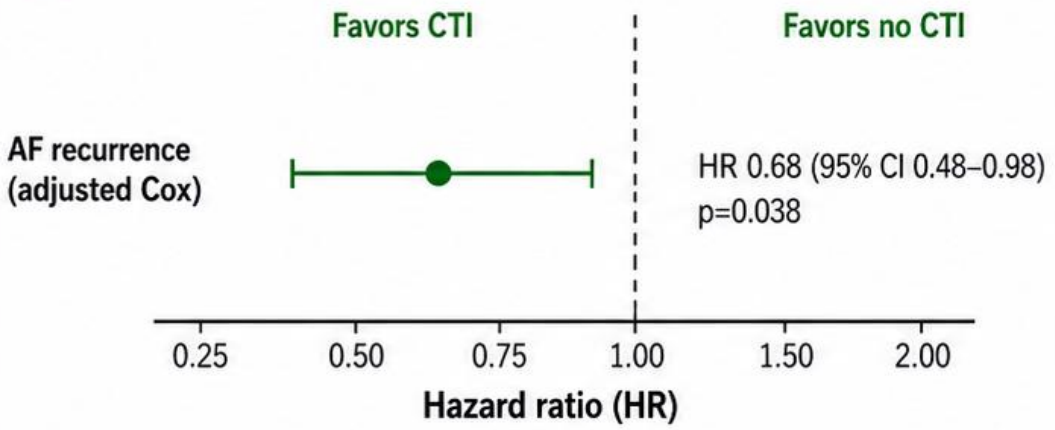
Clinical Effect of CTI and MI Ablation

Summary of adjusted and sensitivity analyses

A CTI ablation

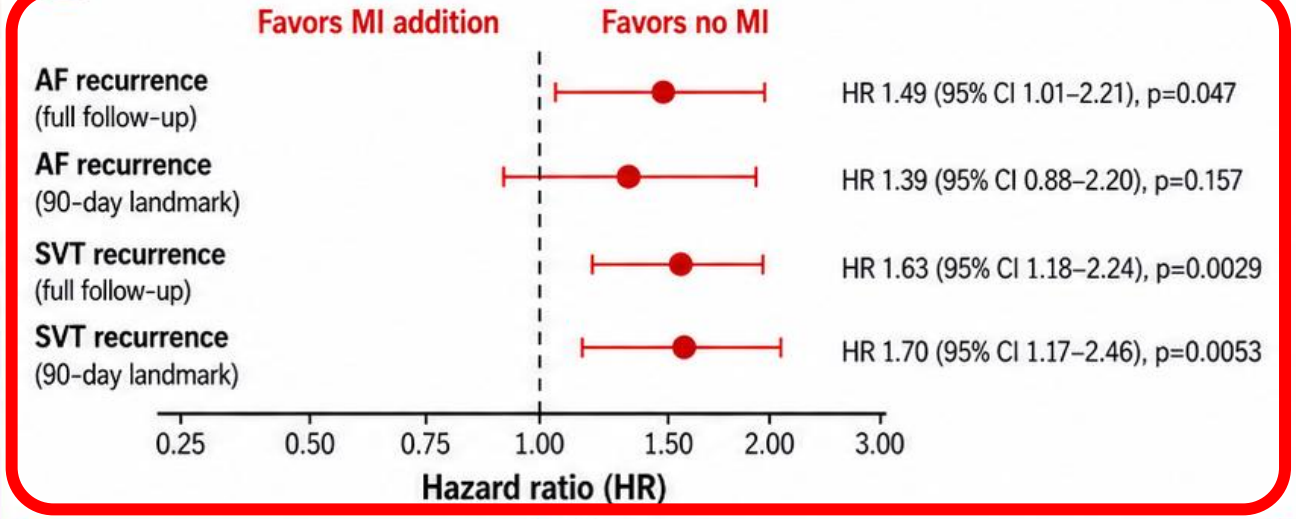


Key facts

- CTI performed overall: 943/1,127 procedures (83.7%)
- Kaplan–Meier: SVT log-rank p<0.001
- Kaplan–Meier: AF log-rank p=0.008
- Complete-case model n=707

CTI was associated with lower AF recurrence after adjustment.

B MI addition in index non-PAF procedures



Sensitivity analyses

- Propensity-stratified: HR 1.55, p=0.056
- Matched 142 pairs: HR 1.88, p=0.017

Key facts

- Comparison: PVI+PWI n=213 vs PVI+PWI+MI n=284
- Index non-paroxysmal AF procedures

MI addition did not reduce AF recurrence and showed a consistent higher-SVT-recurrence signal.

Key message: In this registry, CTI showed a favorable association, whereas empirical MI addition showed no clear benefit and a signal toward higher SVT recurrence.

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Limitations

- ✓ Single-center and non-randomized study. Not standardized procedures.
- ✓ In the index cases, the complete CTI/MI block was not confirmed.
- ✓ The number of the applications per specific line was not counted.
- ✓ Follow up intervals were not uniformed.

Summary

~Farapulse: non-PV ablation strategy~

- ✓ PFA with adjunctive lesions was feasible with a low rate of serious complications in this single-center registry.
- ✓ CTI ablation was associated with improved outcomes.
- ✓ Empirical MI addition was not associated with improved rhythm outcome and was linked to more SVT recurrence.

Nothing ventured, nothing gained..

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Sinus Conversion during Procedure may Predict Better Prognosis

Outcome after blanking	SR without CV	SR with CV	P value
N	222	179	—
Any SVT recurrence	28.8%	36.3%	0.132
AF recurrence	**14.9%**	**26.3%**	**0.0056**
AT recurrence	10.4%	8.9%	0.735
AFL recurrence	3.6%	2.2%	0.560
Redo ablation	17.6%	16.2%	0.789
1-year SVT-free survival	67.6%	61.9%	0.240

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What we did in the Redo procedures?

Redo finding	Result	Interpretation
Repeat ablation after index PFA	128/780 (16.4%)	Clinically relevant redo burden
Median time to redo	358 [142–582] days	Mostly late recurrence
CTI performed at redo	**62/128 (48.4%)**	**CTI often retargeted**
MI performed at redo	**61/128 (47.7%)**	**MI often retargeted**
Both CTI and MI at redo	32/128 (25.0%)	Substantial linear-lesion overlap
Index CTI group: AFL recurrence	**3/386 (0.8%)**	**Low AFL recurrence after CTI**
Index MI group: AFL recurrence	**9/394 (2.3%)**	**Higher organized recurrence signal**
Index MI + AFL redo: MI repeated	**7/7 (100%)**	**Strong MI retargeting signal**
Index MI group: AT recurrence	46/394 (11.7%)	AT recurrence relatively frequent
Index MI + AT redo: MI repeated	16/26 (61.5%)	Supports MI durability/proarrhythmia concern

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Clinical Effect of MI and CTI Ablation

Subanalysis	Main result	Interpretation
CTI at index procedure	**SVT log-rank p<0.001; AF log-rank p=0.008**	**CTI was associated with better recurrence-free survival**
CTI and adjusted AF recurrence	**HR 0.68, 95% CI 0.48–0.98; p=0.038**	**CTI remained associated with lower AF recurrence after adjustment**
MI comparison in index non-PAF	PVI+PWI n=213 vs PVI+PWI+MI n=284	Main MI comparison
MI and AF recurrence, full follow-up	**HR 1.49, 95% CI 1.01–2.21; p=0.047**	**No evidence of benefit; possible harm**
MI and AF recurrence, 90-day landmark	HR 1.39, 95% CI 0.88–2.20; p=0.157	Not significant after blanking
MI and SVT recurrence, full follow-up	**HR 1.63, 95% CI 1.18–2.24; p=0.0029**	**Higher SVT recurrence**
MI and SVT recurrence, 90-day landmark	HR 1.70, 95% CI 1.17–2.46; p=0.0053	Consistent adverse SVT signal
PS stratification	HR 1.55; p=0.056	Directionally concordant
PS matching	142 pairs; HR 1.88; p=0.017	Supports same direction