PFA: What's Next?

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Disclosures

- **Dhanunjaya (DJ) Lakkireddy, MD, MBA, FHRS, FACC** has nothing to disclose
- **Devi Nair, MD, FACC, FHRS:** Consultant – Abbott, Biosense Webster Medtronic
- **David B. De Lurgio, MD, FACC, FHRS:** Consultant – Abbott Medical, Atricure, Boston Scientific, Haemonetics, Medtronic; speaker's bureau – Abbott Medical, Atricure, Boston Scientific, Haemonetics, Medtronic
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Learning Objectives

- Evaluate current evidence on pulsed field ablation (PFA) durability and identify best-practice strategies for managing recurrent atrial fibrillation (AF) after PFA therapy
- Assess the clinical rationale and outcomes associated with concomitant AF ablation and left atrial appendage management (LAAM) to optimize patient selection and procedural approach
- Compare occlusion vs exclusion techniques for left atrial appendage (LAA) management and apply decision-making criteria to improve safety and efficacy in patients with AF undergoing rhythm-control interventions

Durability of PFA and Management of Patients with Recurrent Arrhythmia: Time for a Different Approach!

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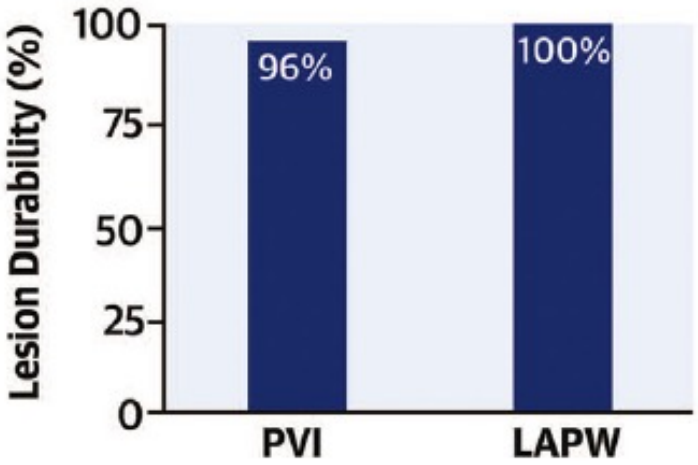
Pulsed Field Ablation in Patients with Persistent AF

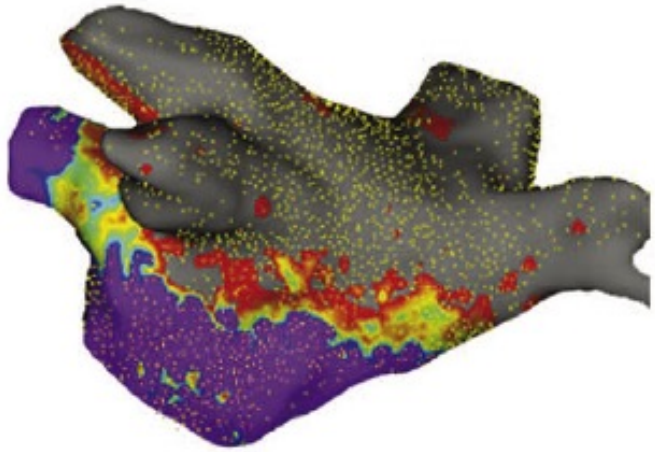
Pulsed Field Ablation for Persistent AF: PersAFOne

25 patients with PVI and LAPWI

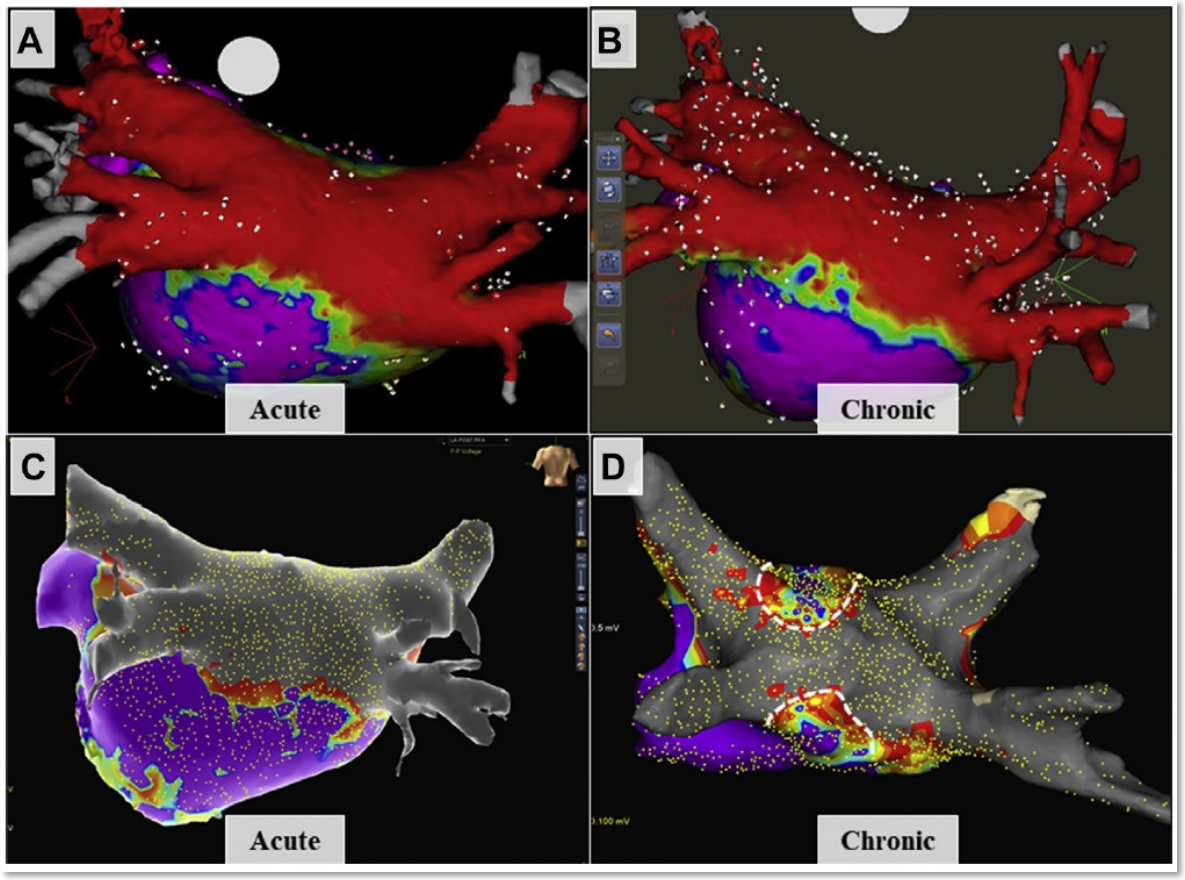
Outcomes Upon Invasive Remapping



Electroanatomical Mapping



PVI = pulmonary vein isolation; LAPW = left atrial posterior wall.
Reddy VY, et al. *J Am Coll Cardiol*. 2020;76(9):1068-1080.

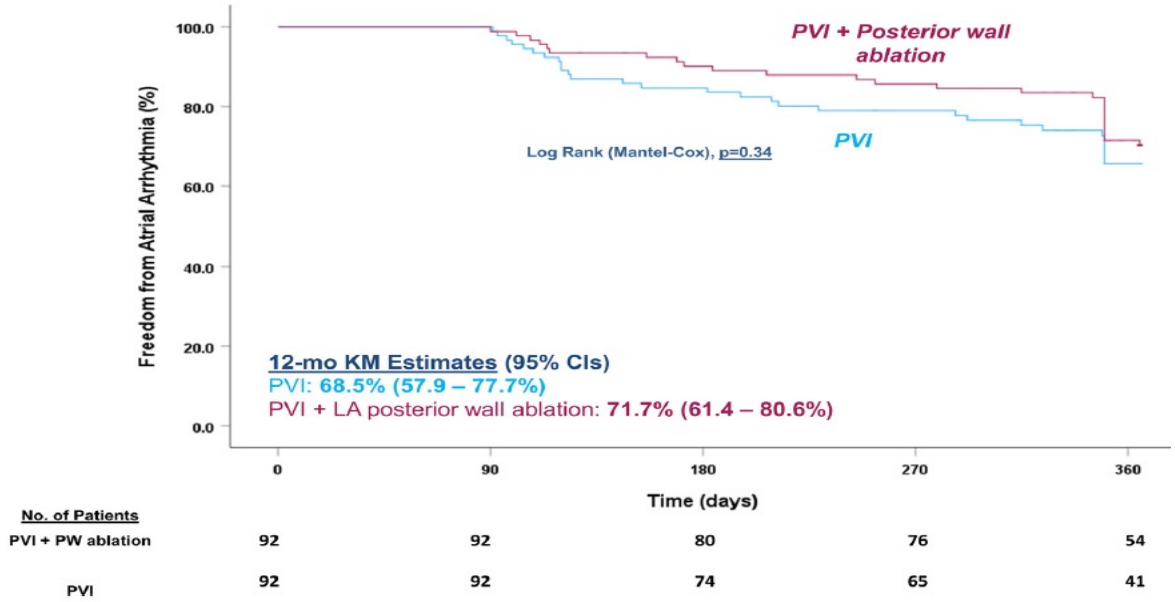


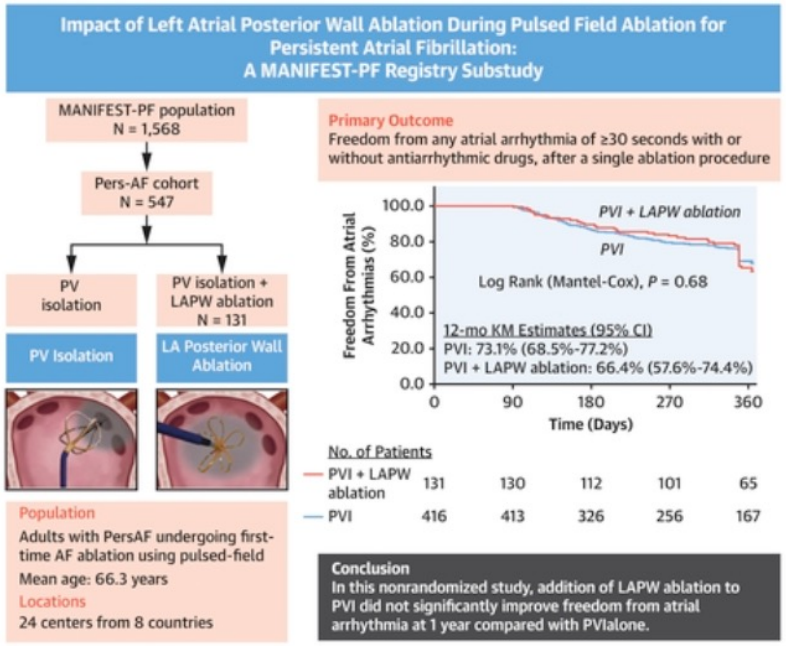
- Lesion regression is noted in some patients
- Epicardium not sampled in this study

Reddy VY, et al. *J Am Coll Cardiol*. 2020;76(9):1068-1080.

Impact of Left Atrial Posterior Wall Ablation during Pulsed-Field Ablation for Persistent AF

- Retrospective analysis of Manifest-PF

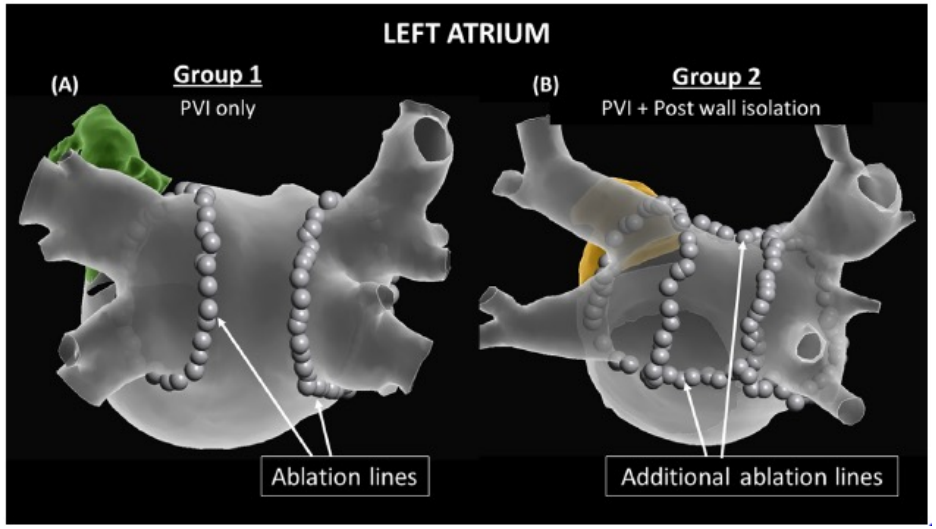


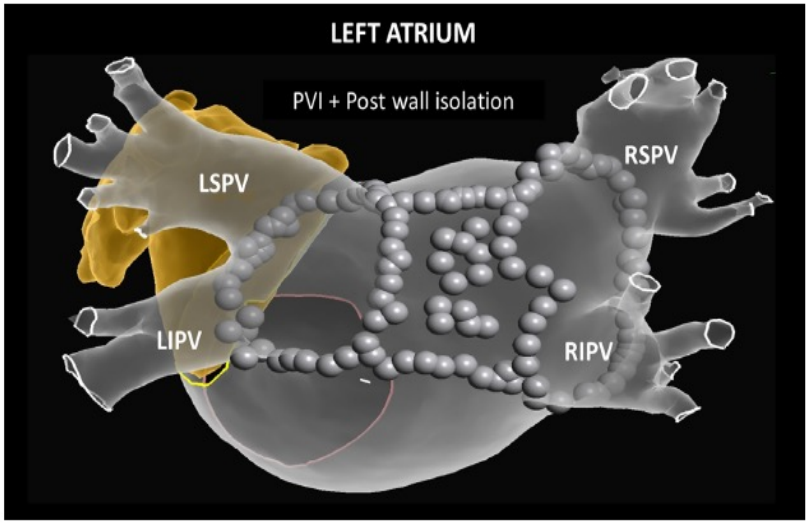


Turagam MK, et al. *JACC Clin Electrophysiol*. 2024;10(5):900-912.

Effect of Catheter Ablation Using Pulmonary Vein Isolation with vs without Posterior Left Atrial Wall Isolation on Atrial Arrhythmia Recurrence in Patients with Persistent Atrial Fibrillation: The CAPLA Randomized Clinical Trial

- RCT 338 patients
- Endocardial radiofrequency ablation
- PVI vs PVI + LAPW isolation
- Followed for 12 months
- No difference in AF recurrence
  - 53.3% vs 54.1% AF free

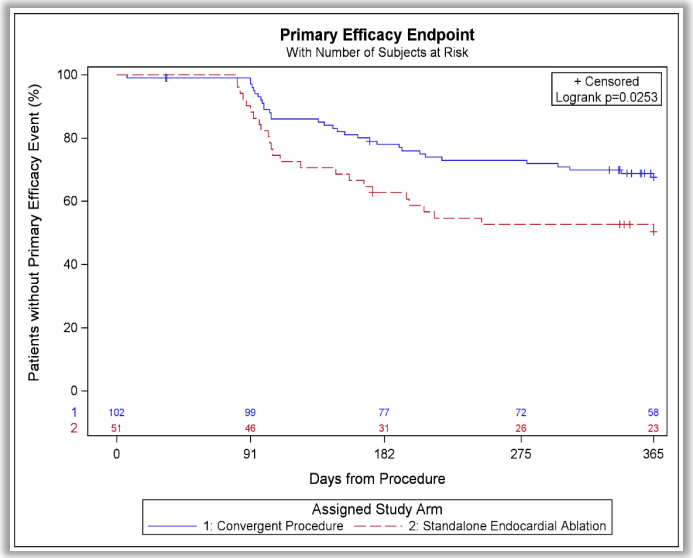




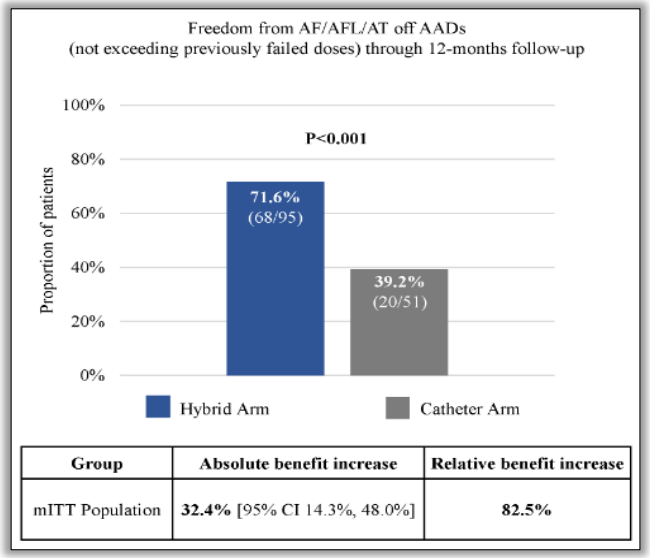
LIPV = left inferior pulmonary vein; LSPV = left superior pulmonary vein; RIPV = right inferior pulmonary vein; RSPV = right superior pulmonary vein.
Kistler PM, et al. *JAMA*. 2023;329(2):127-135.

Randomized Trials Support Hybrid AF Therapy

CONVERGE Trial

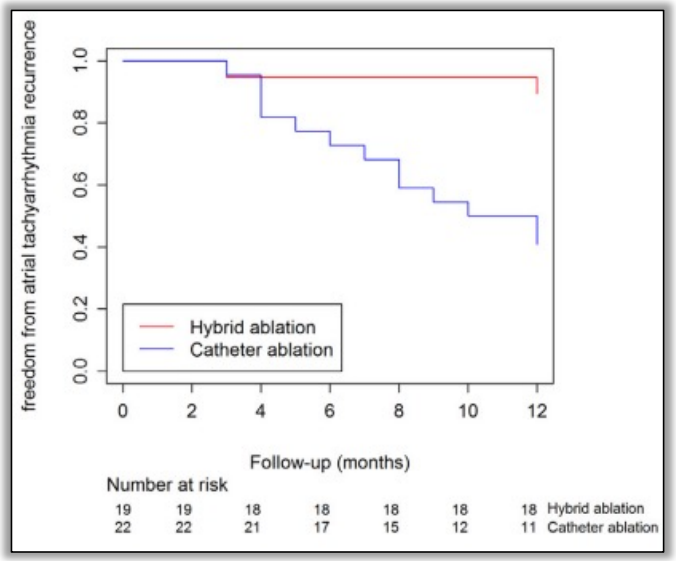


CEASE AF



Group	Absolute benefit increase	Relative benefit increase
mITT Population	**32.4%** [95% CI 14.3%, 48.0%]	**82.5%**

HARTCAP-AF



- Hybrid epicardial/endocardial AF ablation is the only strategy that has consistently treated advanced forms of AF
- Endocardial catheter ablation achieved ~40% success
  - With the addition of epicardial ablation, effectiveness increased to ~70% or higher

mITT = modified intention-to-treat; AAD = anti-arrhythmic drugl AFL = atrial flutter; AT = atrial tachycardia.

DeLurgio DB, et al. *Circ Arrhythm Electrophysiol.* 2020;13(12):e009288. Doll N, et al. *EClinicalMedicine*. 2023;61:102052. van der Heijden CAJ, et al. *JACC Clin Electrophysiol*. 2023;9(7 Pt 2):1013-1023.

Outcomes of Concomitant LAA Exclusion during Hybrid Convergent Ablation

- Single-center registry study
- 139 patients
- 45% long-standing persistent AF
- *De novo* ablation
- 52% underwent LAA exclusion
- At >3-mo TEE assessment, 98% had < 1 cm residual LAA stump
  - 2% (1 pt) had missed lobe
- No stroke, TIA, MI, phrenic nerve injury, AEF, or deaths occurred
  - 1 major bleeding,1 pericardial effusion, and 3 pericarditis in HA+LAAE group; 1 major bleeding in HA group

	Hybrid + LAAE	Hybrid	*P*-value
12-month freedom from atrial arrhythmias off AADs	77%	58%	0.04
12-month freedom from atrial arrhythmias on or off AADs	88%	76%	0.15
Repeat catheter ablation at 12 months	0%	10%	<0.05
Freedom from oral anticoagulation therapy	25%	7%	NS

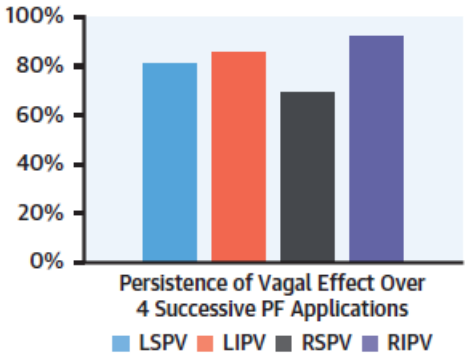
Patients with longstanding/persistent AF who underwent hybrid ablation with clip had improved freedom from atrial arrhythmias off AADs without any increased risk of stroke at 1 year

TEE = transesophageal echocardiogram; TIA = transient ischemic attack; MI = myocardial infarction; AEF = atrioesophageal fistula.
Gegechkori N, et al. *J Atrial Fibrillation Electrophysiol.* 2022;15(4).

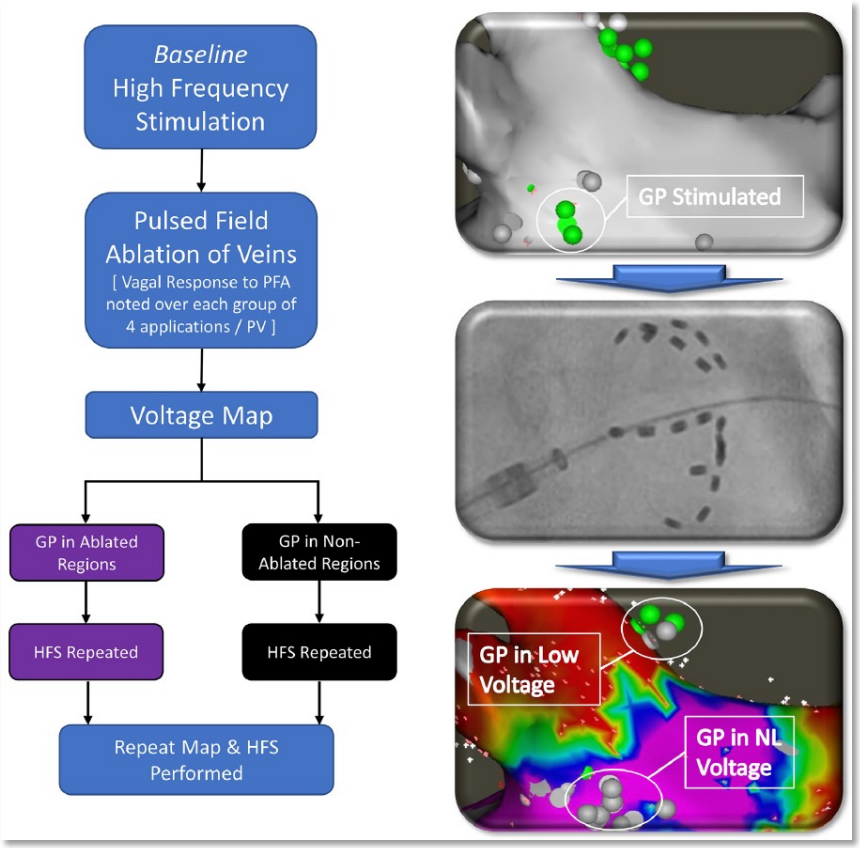
Possible Reasons LAPWI Did Not Improve Outcomes in Patients with PFA

- Patient selection (not sick enough/not enough abnormal substrate)
- Lack of autonomic effects (no ganglion ablation)
- Subacute LAPW reconnection
- ?other

PFA to Treat AF: Autonomic Nervous System Effects

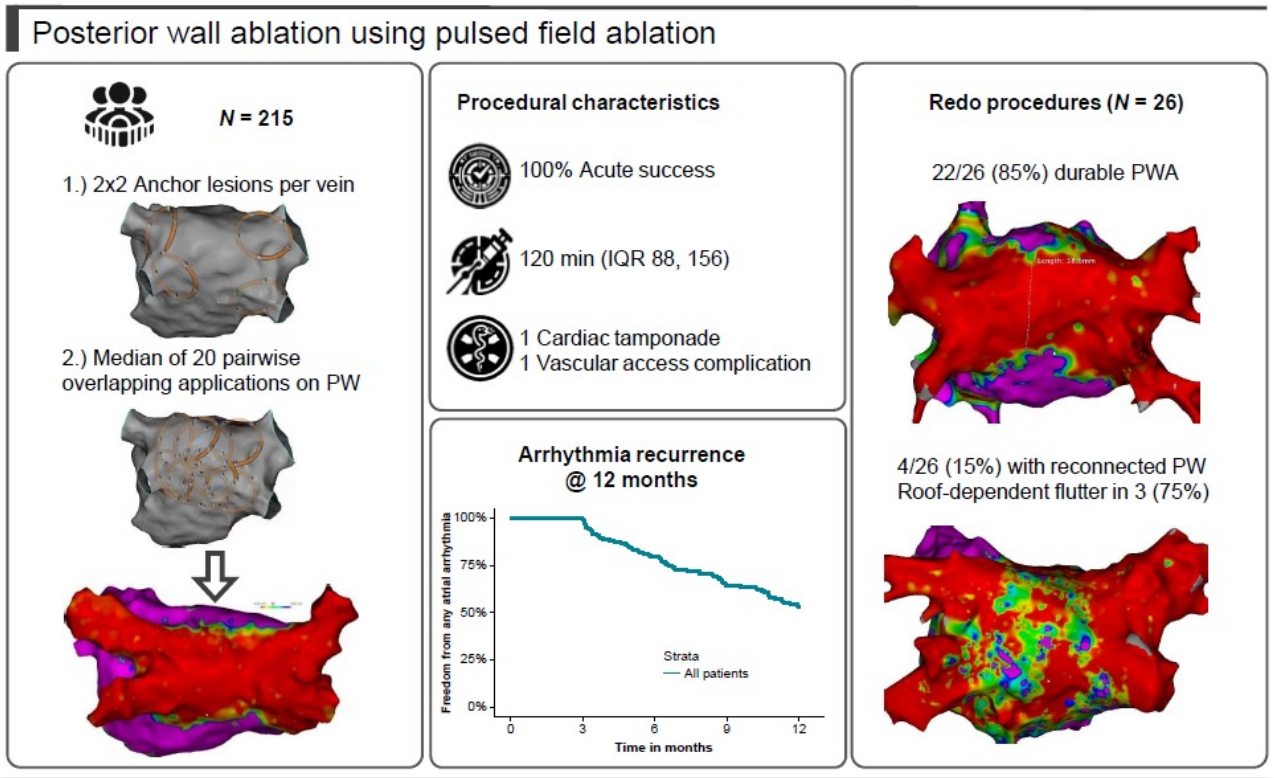


- Among GPs situated in post-PFA low voltage zones, 76% were not ablated
- A few "ablated" GP sites recovered functionality upon remapping
- Taken together, the estimated rate of intact GP functionality is 84%-95%



GP = ganglionated plexi.
Musikantow DR, et al. *JACC Clin Electrophysiol*. 2023;9(4):481-493.

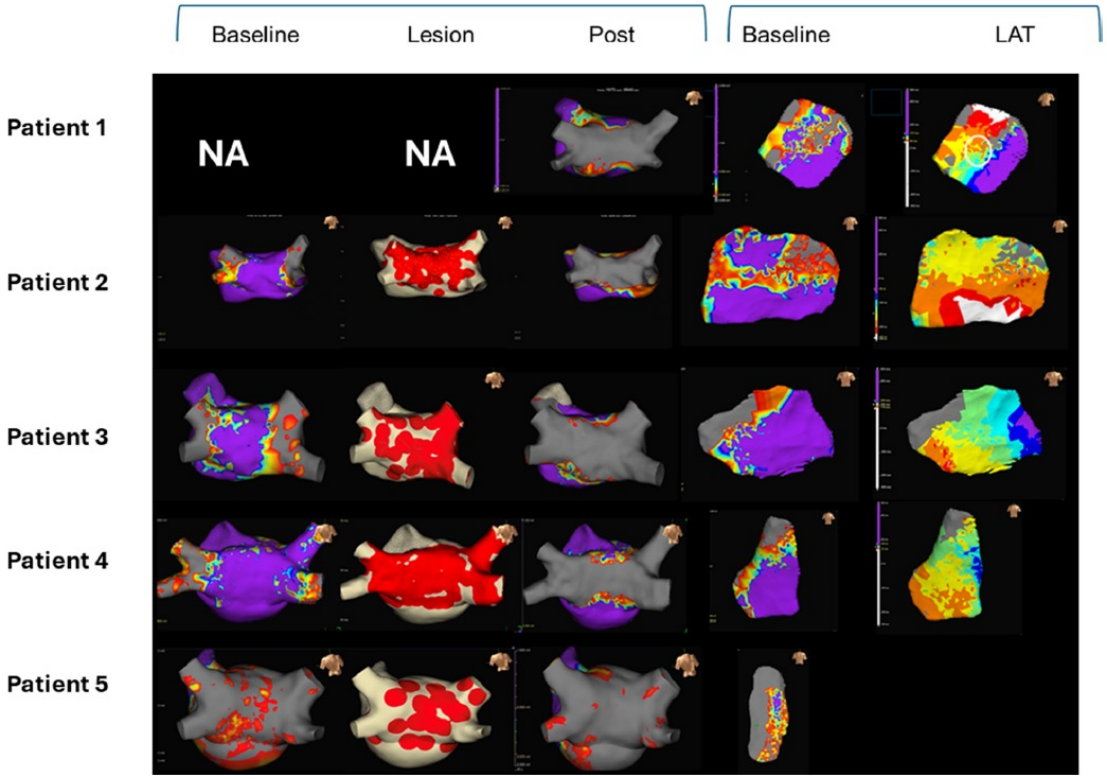
Posterior Wall Ablation by PFA: Procedural Safety, Efficacy, and Findings on Redo Procedures



Kueffer T, et al. *Europace*. 2023;26(1):euae006.

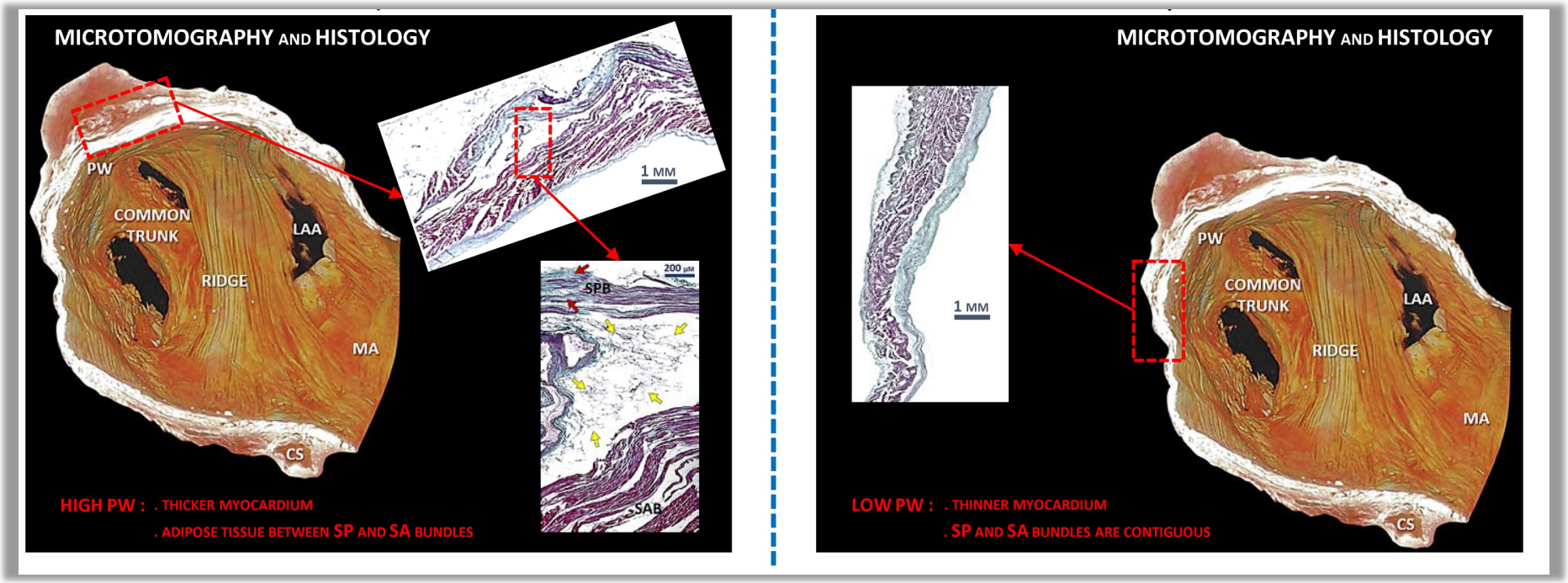
Failure of Transmural Posterior Wall Isolation by PFA Demonstrated with Epicardial Mapping

- 5/5 patients demonstrated epicardial activation



Sanborn L, et al. *JACC Clin Electrophysiol*. 2025;11(11):2519-2521.

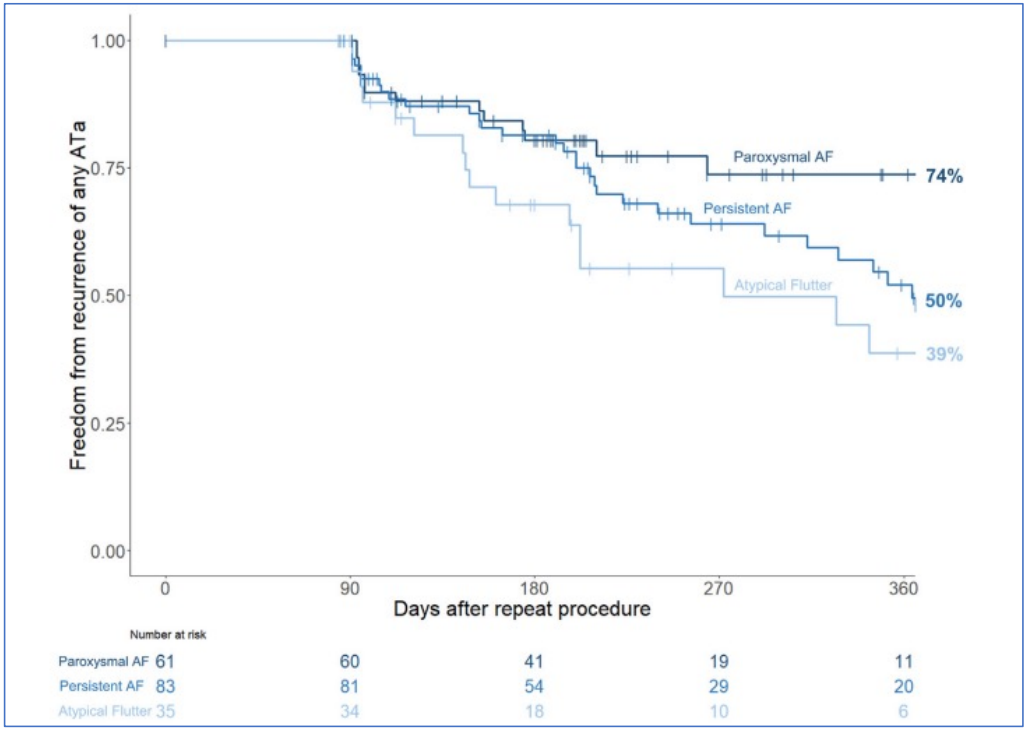
Complexity of the LAPW



Pambrun T, et al. *Heart Rhythm*. 2021;18(3):349-357.

PFA Outcomes after Prior Failed Ablation

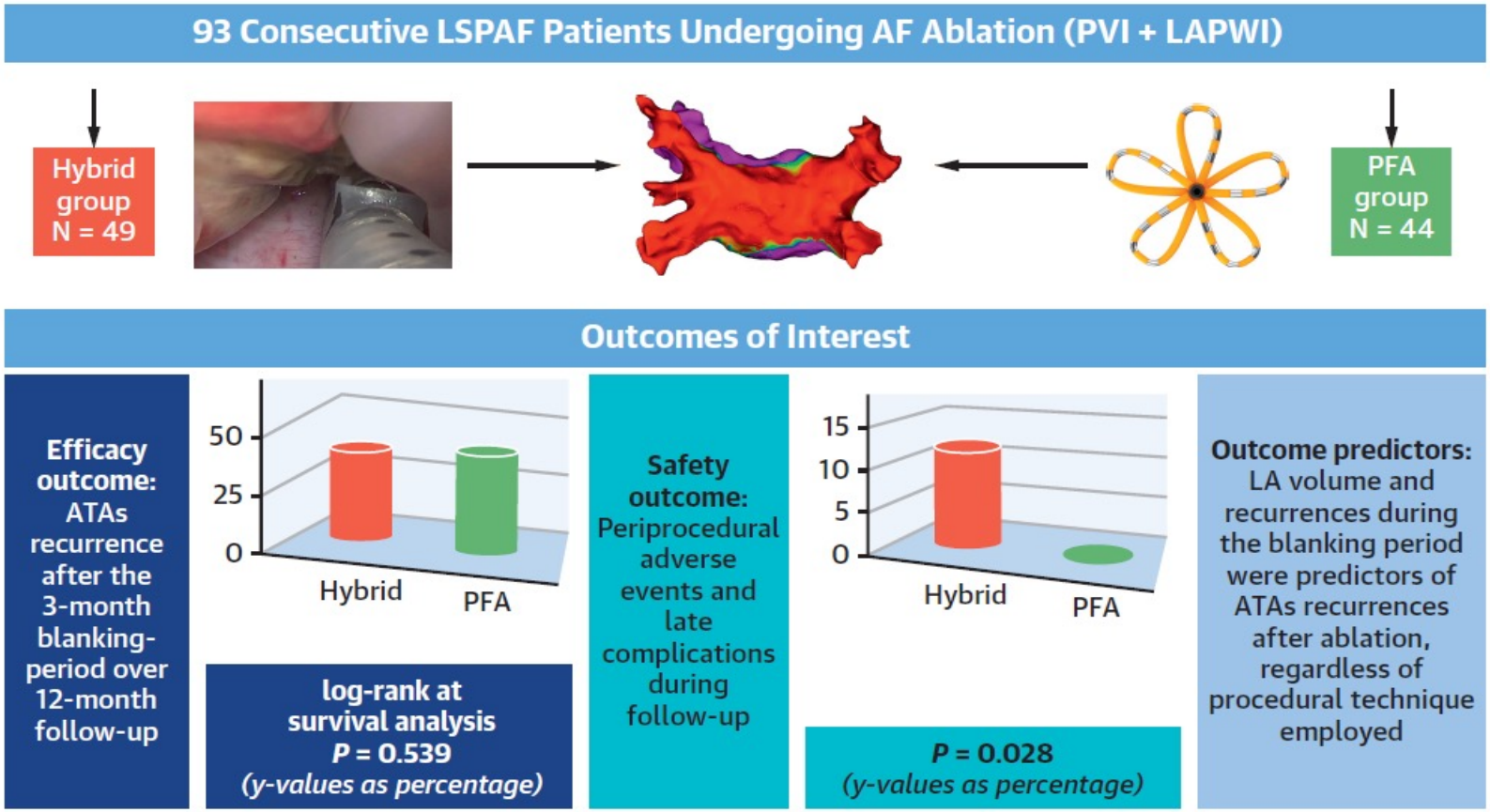
- Prospective, single-center study
- 186 pts underwent repeat ablation procedure with PFA of which 84 pts had persistent AF
- 50% of pts with pers AF who underwent a repeat ablation experienced atrial arrhythmia recurrence at 12 months
  - Recurrence rate was not statistically different between pts with pers AF who underwent LAPW ablation vs no LAPW ablation (37% vs 47%, *p*=0.44)



Kaplan-Meier curves of freedom from any atrial tachyarrhythmia (ATa) (AF, AFL, AT) after repeat AF ablation using PFA. Group comparison between types of ATa leading to repeat AF ablation

Maurhofer J, et al. *Heart Rhythm O2*. 2024;5(5):257-265.

Hybrid-Convergent Procedure or PFA in Longstanding Persistent AF

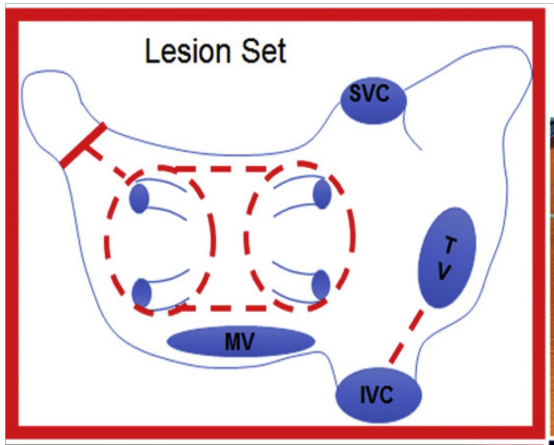


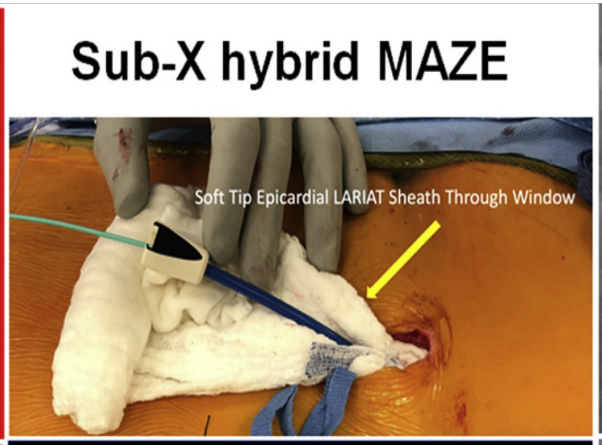
ATA = atrial tachyarrhythmias; LSPAF = long-standing persistent atrial fibrillation.
Bianchini L, et al. *JACC Clin Electrophysiol*. 2024;10(7 Pt 2):1700-1710.

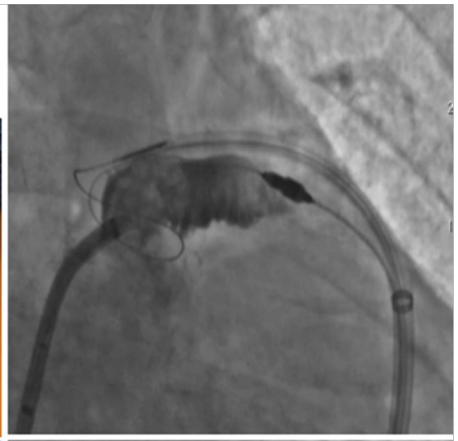
Options for Management of Patients with Advanced AF

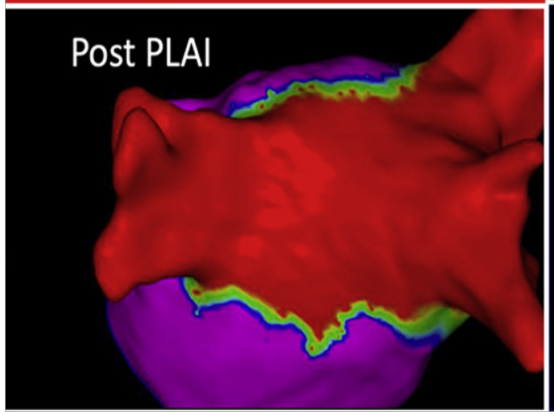
- Convergent/hybrid ablation as first-line therapy
- PFA as first-line therapy
- Convergent as second-line therapy in patients with recurrent arrhythmia

Sub-X Hybrid Maze: Lariat + Epicardial/Endocardial LA Ablation

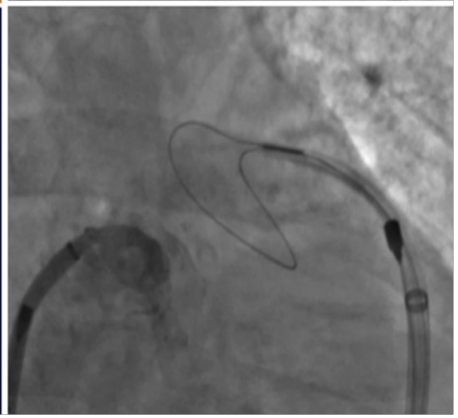








- 90% freedom from AT/AF at 12 months
- No acute peri-procedural complications (< 7 days)
- 30-day adverse events:
  - 2 pericardial effusions
  - 1 incisional hernia repair
- No long-term strokes or death



PLAI = posterior left atrial isolation.
Ellis CR, et al. *JACC Clin Electrophysiol*. 2020;6(13):1603-1615.

Key Learning Points

- PFA has become a very useful tool for management of atrial fibrillation, with data focused on peripheral artery disease (PAD) and early pers AF
- Recurrences of AF/AT after PFA for advanced AF have led to an appreciation of the limitations of current platforms
- Hybrid AF ablation has shown a consistently superior response in patients with advanced AF
- Modifications of hybrid therapies may add significant value for management of complex patients or patients failing initial endocardial ablation

Merits of Concomitant Treatment AF Ablation plus LAAM

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Chief of Cardiac Electrophysiology & Research

St. Bernard's Heart & Vascular Center

Arrhythmia Research Group

Jonesboro, AR

From Innovation to Integration

- Evidence for LAA exclusion has matured
  - Technologies are established
  - Reimbursement pathways evolving (DRG 317)
  - The question is no longer Can we?'
  - The question is 'How do we integrate into routine AF care?'

Patient 1 History

- 78-yo female with HTN, DM, CAD, persistent AF, s/p PVI in 2014 now with recurrence of AF and atypical atrial flutter and developed tachycardiac cardiomyopathy, on amiodarone, with recurrent GI bleed requiring transfusions

- Referred for concomitant procedure
  A. Endocardial LAAC / epicardial LAAE
  B. AF ablation and LAAC / LAAE

Patient 2 History

- 66-yo female with DM, HTN and CAD s/p PCI underwent a presumably successful ablation 15 month ago. She is on aspirin and warfarin. She is an avid mountain biker and has reported several falls and injuries. Wears a smartwatch 12-14 hrs a day

A. 2-week monitor and if no AF, then DC warfarin
B. Proceed with a LAAC + PV mapping +/- ablation

Patient 3 History

- 69-yo male with HTN, DM, CAD, persistent AF, tachycardiac cardiomyopathy, on amiodarone, with spontaneous IC bleed from AVMs

- Also develops multiple DVTs during that admission – gets IVC filter, taken off OAC; imaging shows occluded IVC with collaterals

AVM = arteriovenous malformation; IC = intracerebral; DVT = deep vein thrombosis.

What Do the Guidelines Say?

Circulation

CLINICAL PRACTICE GUIDELINES

2023 ACC/AHA/ACCP/HRS Guideline for the Diagnosis and Management of Atrial Fibrillation: A Report of the American College of Cardiology/ American Heart Association Joint Committee on Clinical Practice Guidelines

ACC = American College of Cardiology; AHA = American Heart Association; HRS = Heart Rhythm Society.
Joglar JA, et al. *Circulation*. 2024;149(1):e1-e156.

What Do the Guidelines Say?

Recommendations for Anticoagulation Therapy Before and After Catheter Ablation
Referenced studies that support the recommendations are summarized in the Online Data Supplement.

COR	LOE	Recommendations
1	B-NR	1. In patients on warfarin who are undergoing catheter ablation of AF, catheter ablation should be performed on uninterrupted therapeutic anticoagulation with a goal INR of 2.0 to 3.0.[1]
1	A	2. In patients on a DOAC who are undergoing catheter ablation of AF, catheter ablation should be performed with either continuous or minimally interrupted oral anticoagulation.[2–10]
1	B-NR	3. In patients who have undergone catheter ablation of AF, oral anticoagulation should be continued for at least 3 months after the procedure with a longer duration determined by underlying risk.[11]
1	B-NR	4. In patients who have undergone catheter ablation of AF, continuation of longer-term oral anticoagulation should be dictated according to the patients' stroke risk (eg, CHA^2DS^2-VASc score ≥2).[11–17]

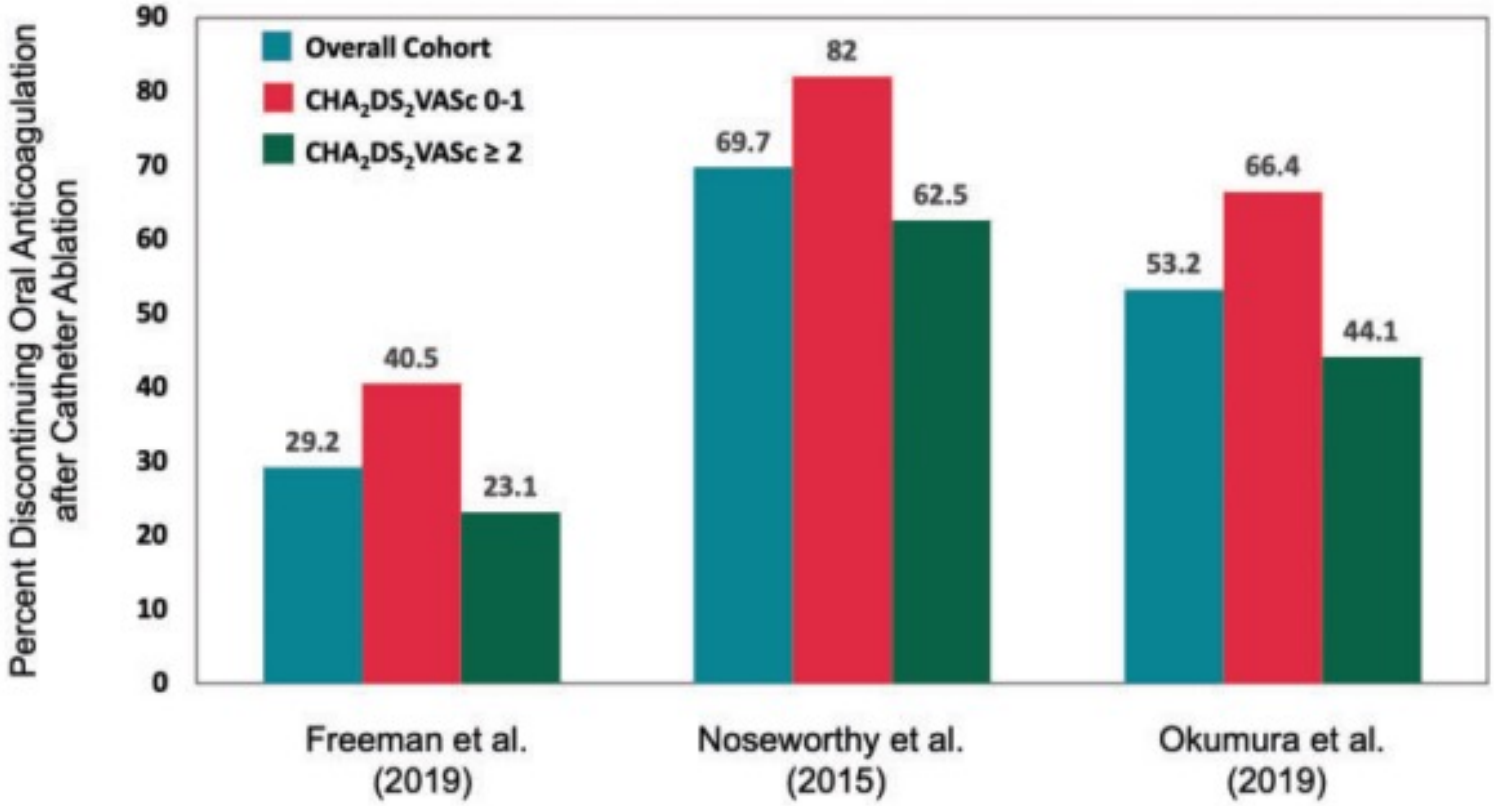
1	B-NR	3. In patients who have undergone catheter ablation of AF, oral anticoagulation should be continued for at least 3 months after the procedure with a longer duration determined by underlying risk.[11]
1	B-NR	4. In patients who have undergone catheter ablation of AF, continuation of longer-term oral anticoagulation should be dictated according to the patients' stroke risk (eg, CHA^2DS^2-VASc score ≥2).[11–17]

Joglar JA, et al. *Circulation*. 2024;149(1):e1-e156.

What Do the Guidelines Say?

Guideline/consensus document	Recommendation	Strength of recommendation
2020 ESC Guidelines for the diagnosis and management of atrial fibrillation developed in collaboration with the EACTS[38]	'Long-term continuation of systemic anticoagulation beyond 2 months post-ablation is based on the patient's stroke risk profile and not on the apparent success or failure of the ablation procedure'.	Class I Level C
2018 CHEST Guideline and Expert Panel Report[39]	'In patients in whom sinus rhythm has been restored, we suggest that long-term anticoagulation should be based on the patient's CHA_2DS_2-VASc thromboembolic risk profile, regardless of whether sinus rhythm has been restored via ablation, cardioversion (even spontaneous), or other means'.	Weak recommendation, low-quality evidence
2017 HRS/EHRA/ECAS/APHRS/SOLAECE expert consensus statement on catheter and surgical ablation of atrial fibrillation	'Decisions regarding continuation of systematic anti-coagulation more than 2 months post-ablation should be based on the patient's stroke risk profile and not on the perceived success or failure of the ablation procedure'.[40]	Class I Level C
2014 Focused Update of the CCS Guidelines for Management of Atrial Fibrillation[41]	'AF ablation should not be considered as an alternative to oral anticoagulation. If a patient has a high thromboembolic risk profile (e.g., $CHADS_2$ risk score of ≥ 2), then the patient should continue oral anticoagulation even after successful AF ablation'.	NA
2014 AHA/ACC/HRS Guideline for the Management of Patients with Atrial Fibrillation[42]	'AF catheter ablation to restore sinus rhythm should not be performed with the sole intent of obviating the need for anticoagulation'.	Class III (Harm) Level C

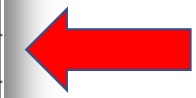
How Is Post-AF Ablation Anticoagulation Managed in the Real World?



How Is Post-AF Ablation Anticoagulation Managed in the Real World?

Outcomes and Anticoagulation Use After Catheter Ablation for Atrial Fibrillation

Among Those With Ablation	Overall, N=1101	Low CHADS-VASc, N=412	High CHADS-VASc, N=689	*P* Value
On OAC				<.0001
No	119 (10.81%)	66 (16.02%)	53 (7.69%)	
Yes	982 (89.19%)	346 (83.98%)	636 (92.31%)	
Among those on OAC				
Discontinued OAC				<.0001
Missing	6 (0.61%)	2 (0.58%)	4 (0.63%)	
No	689 (70.16%)	204 (58.96%)	485 (76.26%)	
Yes	287 (29.23%)	140 (40.46%)	147 (23.11%)	
Among those who discontinued OAC				
Months from ablation until discontinuation				0.0233
Median (Q1–Q3)	6.2 (3.2–9.6)	5.8 (3.1–8.4)	6.9 (3.4–10.5)	
Mean (SD)	7.16 (4.90)	6.31 (3.96)	7.98 (5.54)	

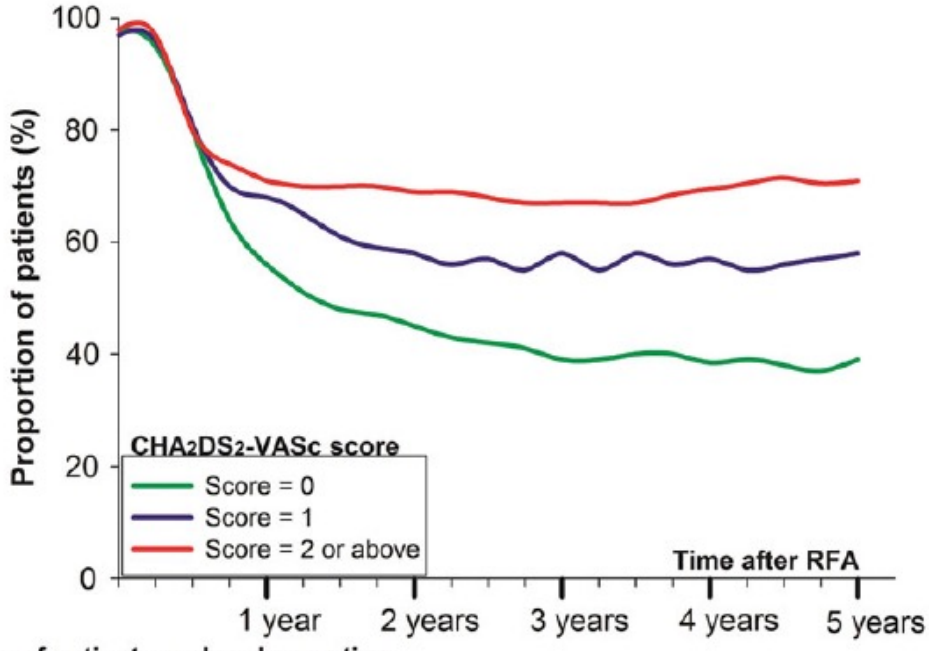


Freeman JV, et al. *Circ Arrhythm Electrophysiol*. 2019;12(12):e007612.

How Is Post-AF Ablation Anticoagulation Managed in the Real World?

Oral anticoagulation therapy after radiofrequency ablation of atrial fibrillation and the risk of thromboembolism and serious bleeding: long-term follow-up in nationwide cohort of Denmark

- National registry
- N= 4050

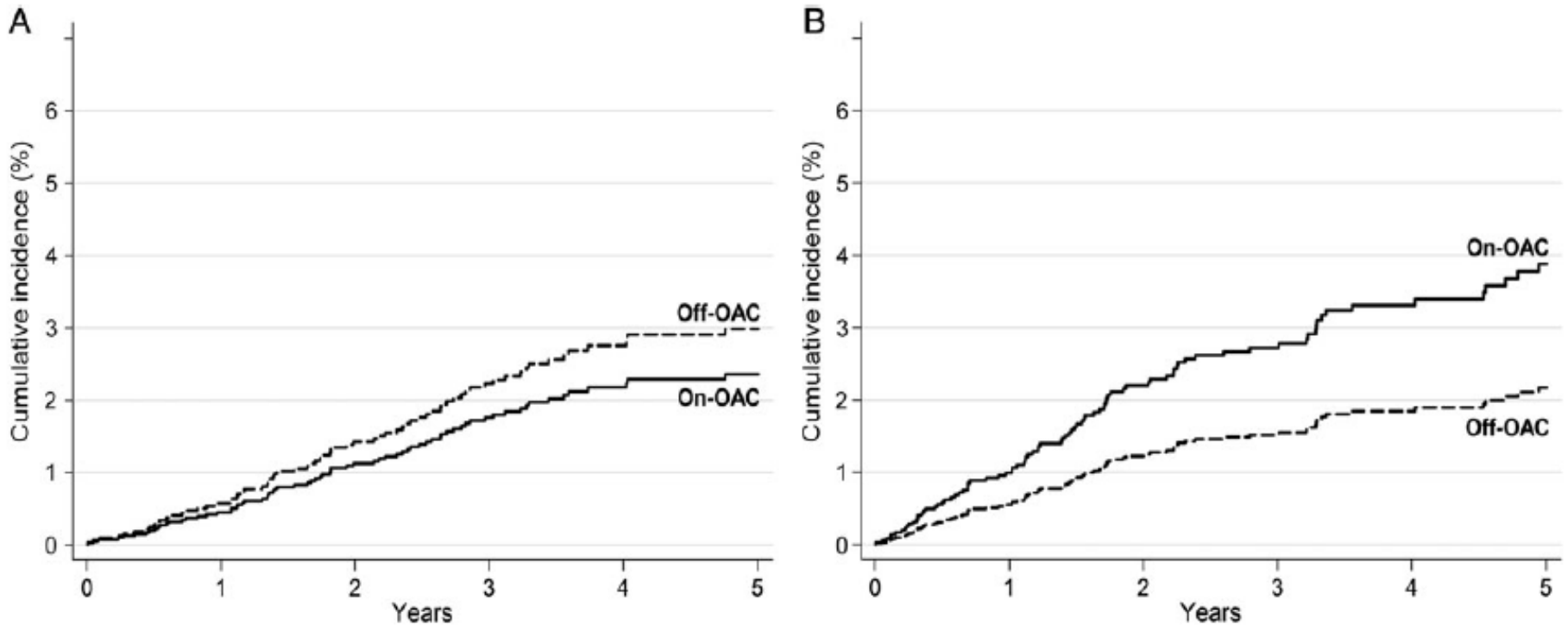


Number of patients under observation						
Score = 0	1275	644	484	386	335	281
Score = 1	1268	785	618	564	475	392
Score = 2 or above	1507	1047	944	846	744	655

RFA = radiofrequency ablation.
Karasoy D, et al. *Eur Heart J*. 2015;36(5):307-314a.

Thromboembolism

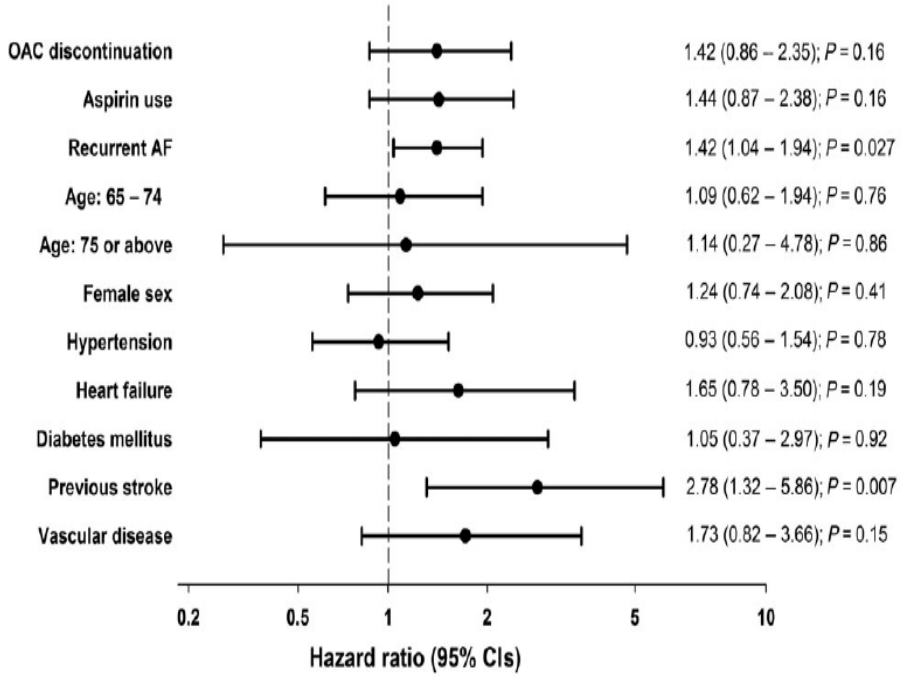
Major Bleeding



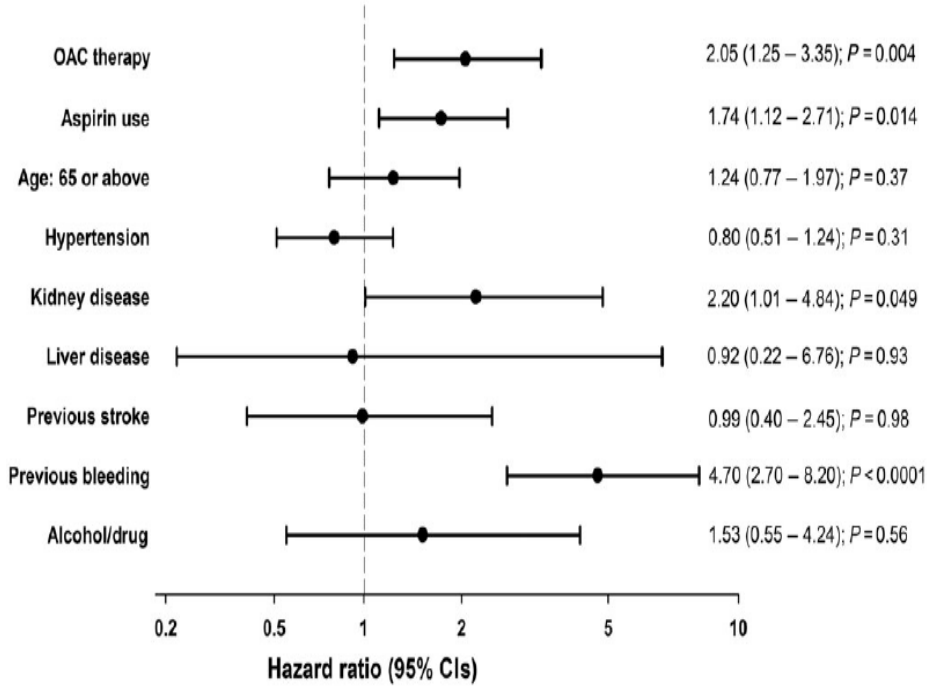
Karasoy D, et al. *Eur Heart J*. 2015;36(5):307-314a.

Hazard Ratios

Thromboembolism



Major Bleeding



Karasoy D, et al. *Eur Heart J*. 2015;36(5):307-314a.

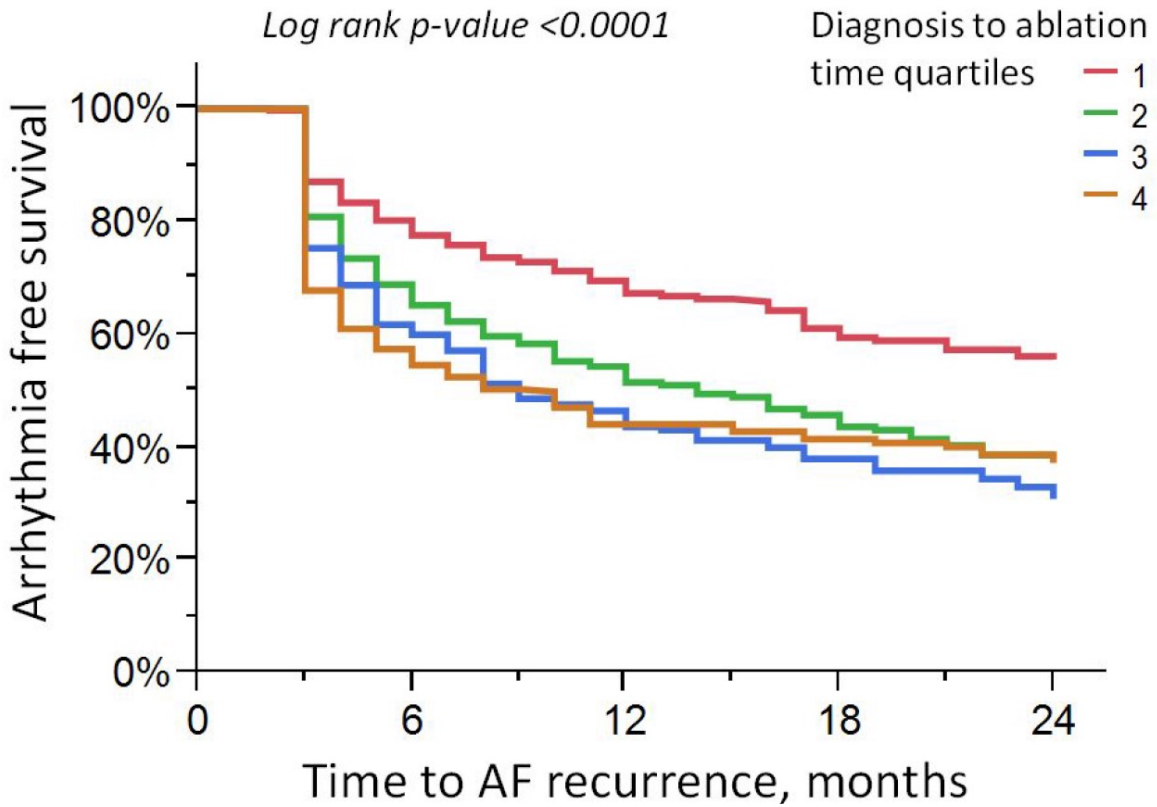
Is a successful ablation
SUFFICIENT
for stroke prevention?

Argument #1

Ablation is NOT enough for stroke prevention in high-risk patients

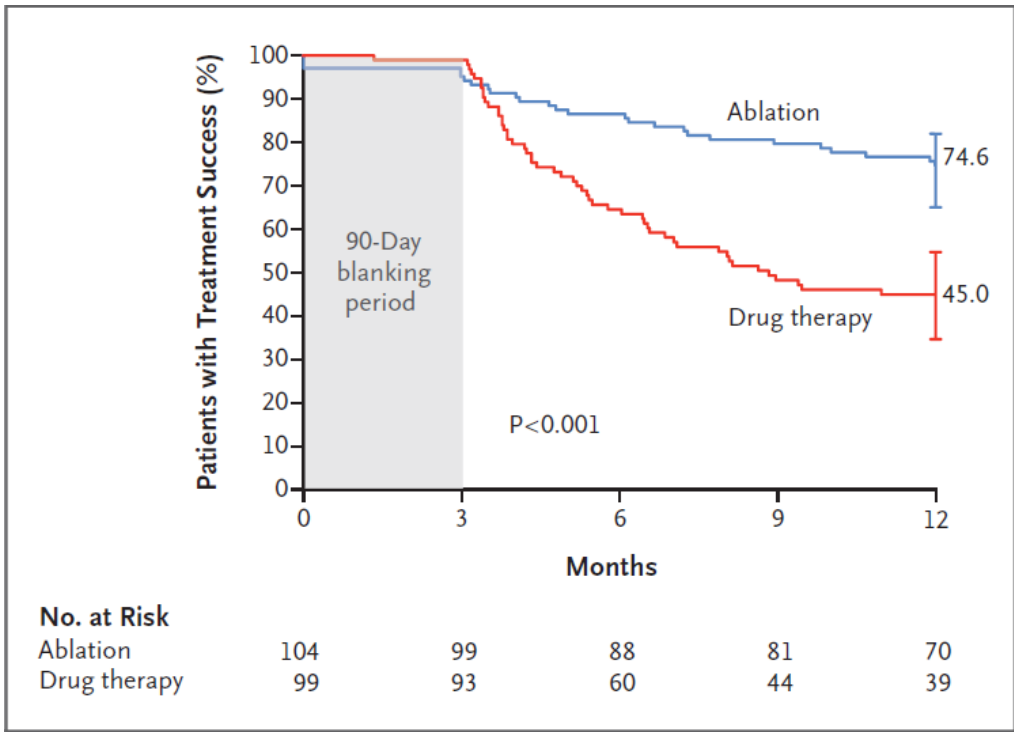
Ablation is NOT CURATIVE

Success Is Limited and Drops with Time



Hussein AA, et al. *Circ Arrhythm Electrophysiol*. 2016;9(1):e003669.

Paroxysmal AF Cryo Success Rate



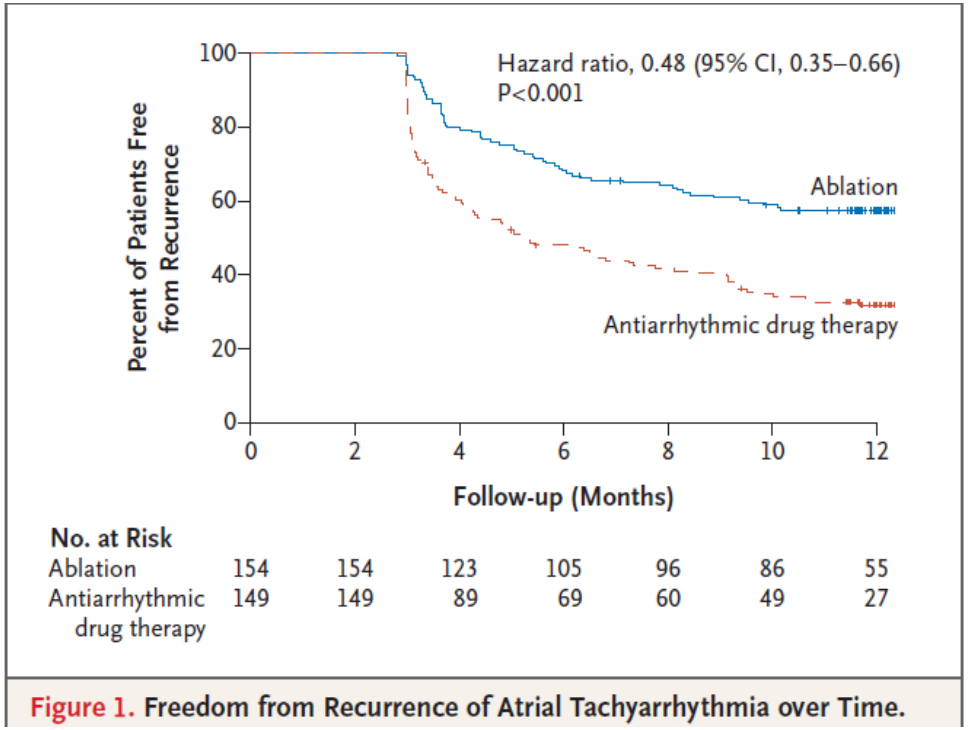


Figure 1. Freedom from Recurrence of Atrial Tachyarrhythmia over Time.

Wazni OM, et al. *N Engl J Med*. 2021;384(4):316-324. Andrade JG, et al. *Am Heart J*. 2018;206:94-104.

1-Year Outcomes from MANIFEST-PF and EU-PORIA Are Encouraging, but May Continue to Have AF

Results from different clinical investigations are not directly comparable. Information provided for educational purposes only.

MANIFEST-PF Registry[1]

24 EU centers

77 operators

1,568 patients

81.6%
Freedom from AF/AFL/AT ≥30 sec in paroxysmal AF patients

80%
Freedom from AF/AT in paroxysmal AF patients

71.5%
Freedom from AF/AFL/AT ≥30 sec in persistent AF patients

66%
Freedom from AF/AT in persistent AF patients

61 min
Median procedure time, IQR: 40-90

58 min
Median procedure time, IQR: 35-60

EU-PORIA Registry[2]

7 EU centers

42 operators

1,233 patients

[1]Turagam et al. Safety and effectiveness of PFA to treat atrial fibrillation: One-year outcomes from the MANIFEST-PF registry. *Circulation.* 2023;148:35-46. [2]Schmidt B., et al. European real-world outcomes with Pulsed field ablation in patients with symptomatic atRIAl fibrillation: lessons from the multi-centre EU-PORIA registry. *Europace*. 2023;25:1-11.

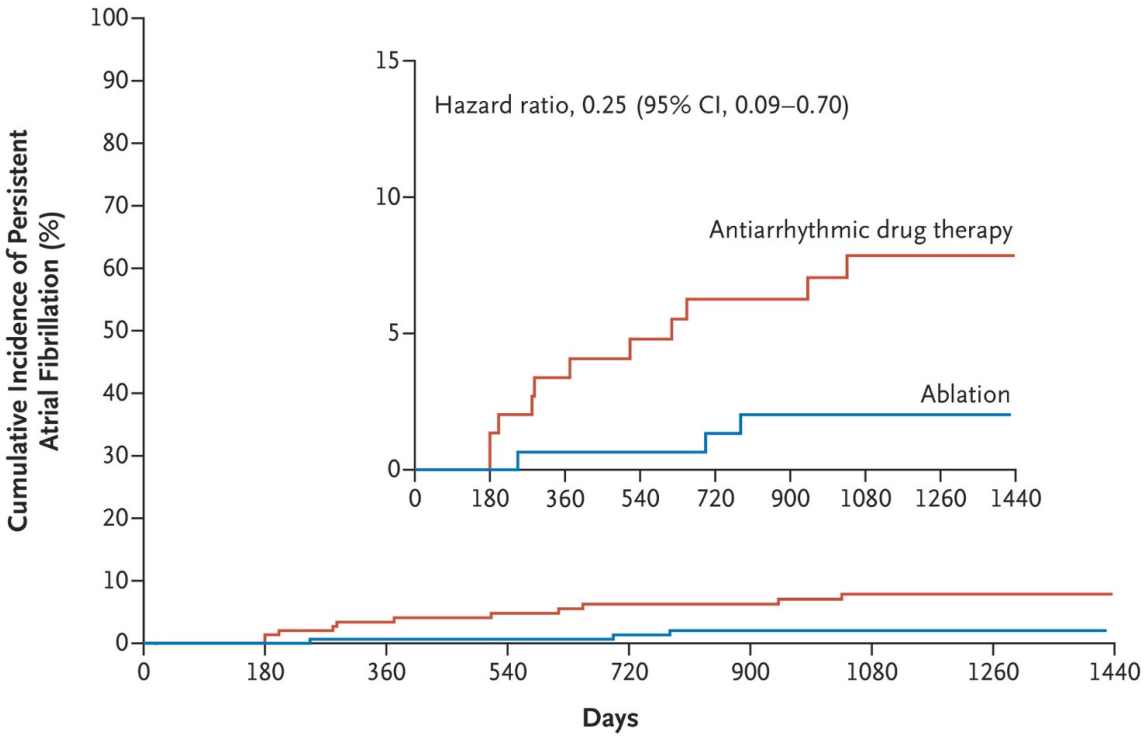
Schmidt B, et al. *Europace*. 2023;25(7):euad185. Ekanem E, et al. *Nat Med.* 2024;30:2020-2029.

Argument #2

Ablation is NOT enough for stroke prevention in high-risk patients

AF is progressive!

Progression of AF after CryoAblation or Drug Therapy



No. at Risk									
Antiarrhythmic drug therapy	149	148	142	133	129	123	104	43	0
Ablation	154	154	153	151	145	141	125	43	0

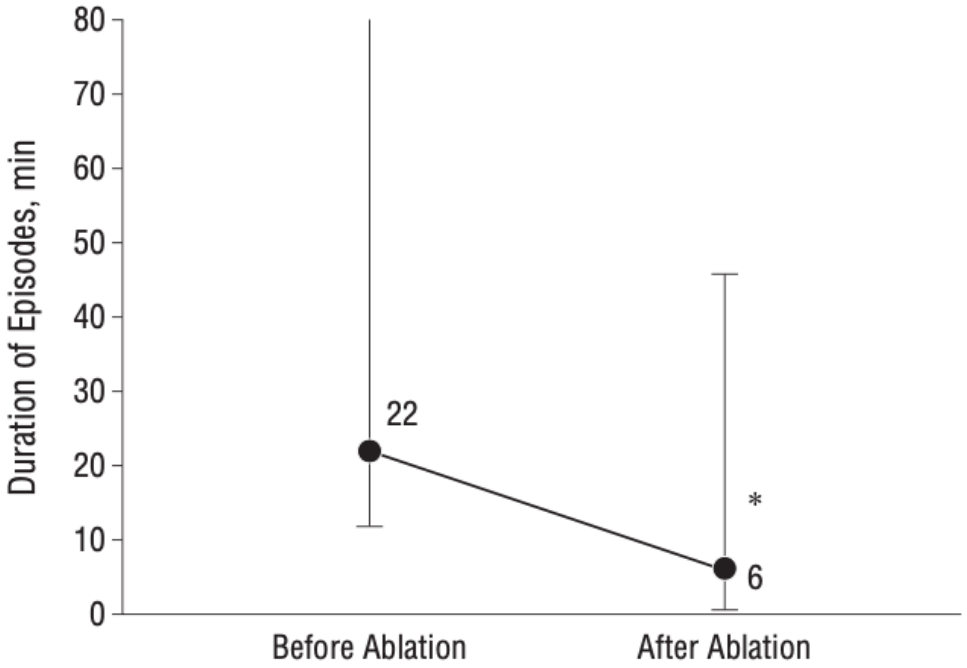
Andrade JG, et al. *N Engl J Med*. 2023;388(2):105-116

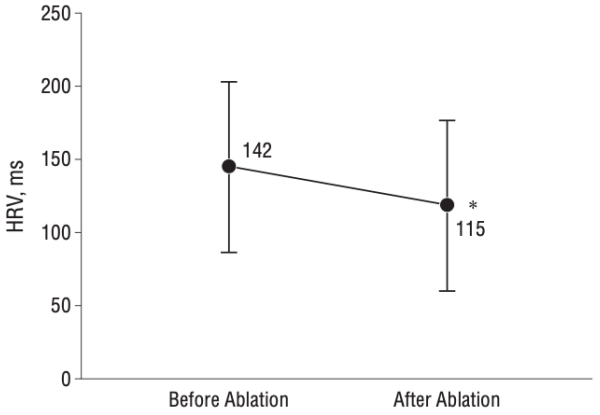
Argument #3

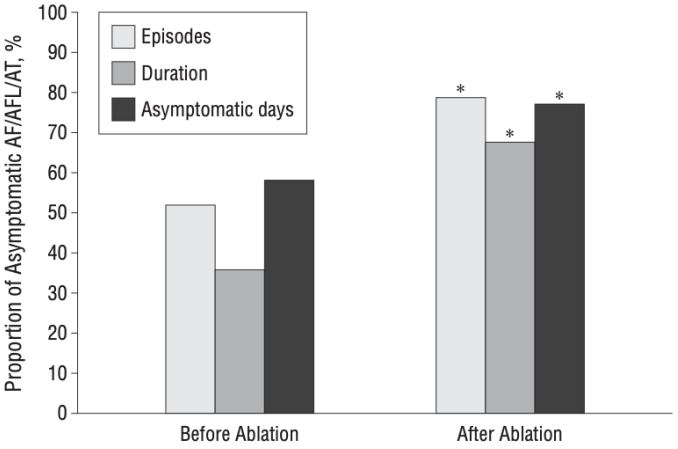
Ablation is NOT enough for stroke prevention in high-risk patients

AF can be asymptomatic after ablation

Post-AF Ablation: AF Episodes







Verma A, et al. *JAMA Intern Med*. 2013;173(2):149-156.

Argument #4

Ablation is NOT enough for stroke prevention in high-risk patients

AF recurrence will be missed even with the new electronic gadgets

Clinical Validation of 5 Direct-to-Consumer Wearable Smart Devices to Detect AF

Wearable Study

Manufacturer					
Version					
Sensitivity (95% CI)	85% (72-94%)	85% (72-94%)	58% (42-72%)	66% (51-79%)	79% (64-89%)
Specificity (95% CI)	75% (67-83%)	75% (66-82%)	75% (67-83%)	79% (70-86%)	69% (60-77%)
Inconclusive tracings	18%	17%	24%	21%	26%
Preferred Choice*a	39%	12%	24%	15%	5%
Limit of HR interpretation*b	50-150 bpm	50-120 bpm	No information	50-120 bpm	50-100 bpm
Battery capacity*c	18 h*d	45 h*d	720 h*d	144 h*d	90 h / 2 y*e
Price*d	449	265	303	244	147

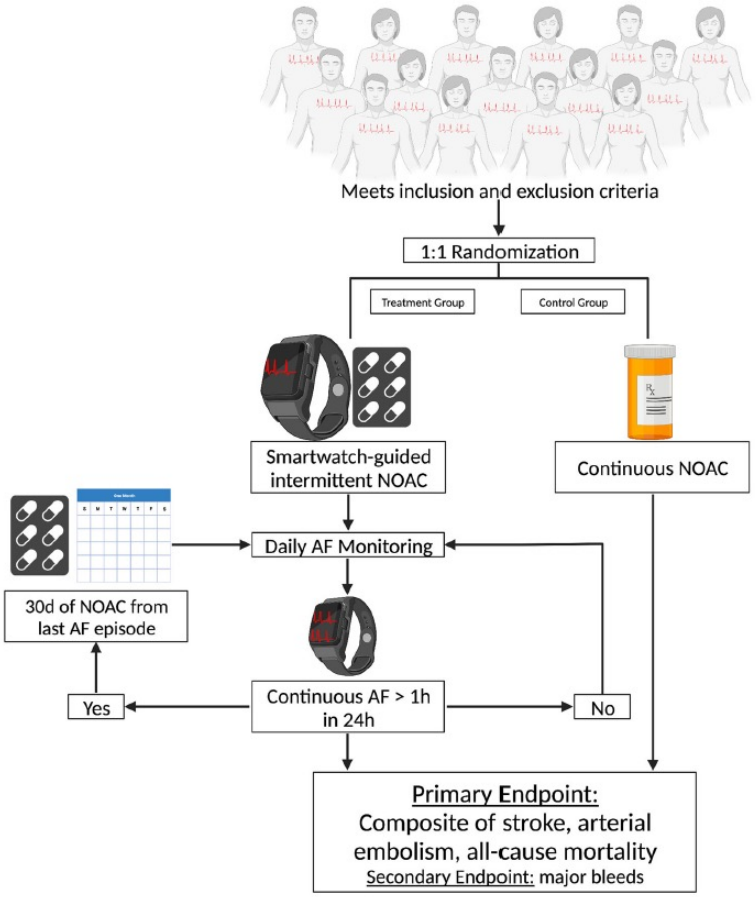
*a: Out of 165 analyzed patients, 10 patients were not able to decide between the available devices
*b: Information obtained from manufacturers website, 11/21
*c: Time with GPS disabled
*d: Information obtained on digitec.ch on 12.11.21, no discounts / special offers were included in the price, price includes tax / all prices in CHF
*e: 90 h net operating time, under regular use up to 2 years

Mannhart D, et al. *JACC Clin Electrophysiol*. 2023;9(2):232-242.

Pill-in-Pocket Anticoagulation: REACT-AF

Maximum Daily AF Duration	CHA_2DS_2-VASc Score 0 n=2922 (13.4%)	1 n=2151 (9.9%)	2 n=4554 (20.9%)	3-4 n=7164 (32.9%)	≥5 n=4977 (22.9%)
No AF n=16815 (77.2%)	0.33% 40 events	0.62% 46 events	0.70% 95 events	0.83% 139 events	1.79% 157 events
AF 6 min–23.5 h n=3381 (15.5%)	0.52% 11 events	0.32% 4 events	0.62% 17 events	1.28% 42 events	2.21% 36 events
AF >23.5h n=1572 (7.2%)	0.86% 4 events	0.50% 3 events	1.52% 19 events	1.77% 28 events	1.68% 13 events

- 5380 patients
- 100 US sites
- Currently enrolling



NOAC = non–vitamin K oral anticoagulants.
Peigh G, Passman RS. *J Cardiovasc Electrophysiol*. 2023;34(10):2152-2157.

Lack of Temporal Relationship between Stroke and Occurrence of AF

Subclinical device-detected atrial fibrillation and stroke risk: a systematic review and meta-analysis

Studies	Total strokes	AHRE absent during monitoring period	AHRE present during monitoring period			
		Strokes without AHRE	Total Strokes with AHRE	AHRE preceding stroke (%)	AHRE at time of stroke (%)	AHRE after stroke (%)
Ancillary MOSTT	10	2	8	—	7[a] (87)	1 (13)
TRENDS	40	14	26	14 (54)	6 (23)	6 (23)
ASSERT	51	25	26	17 (65)	1(4)	8 (31)
Home CARE and everesT trials	11	2	9	4 (45)	3 (33)	2(22)
IMPACT	69	40	29	20 (69)	0 (0)	9 (31)
Total	181	83	98	55 (55)	17 (17)	26 (27)

AHRE = atrial high-risk episode.
Mahajan R, et al. *Eur Heart J*. 2018;39(16):1407-1415.

Argument #5

Ablation is NOT enough for stroke prevention in high-risk patients

AF is a MARKER and not SOLE RISK for STROKE

Should AF Be in the CHADSVASc Score?

Variable	Stroke/TIA, OR (95%CI)	*P*
Smoking	3.45 (1.50-8.04)	.004
Exercise	0.39 (0.17-0.88)	.023
$CHADS_2 = 2^*$	1.36 (0.60-3.01)	.469
$CHADS_2 = 3^*$	2.91 (1.12-7.52)	.028
$CHADS_2 \geq 4^*$	9.40 (3.33-26.49)	< .001

Maximum Daily AF Duration	CHA_2DS_2-VASc Score 0 n=2922 (13.4%)	1 n=2151 (9.9%)	2 n=4554 (20.9%)	3-4 n=7164 (32.9%)	≥5 n=4977 (22.9%)
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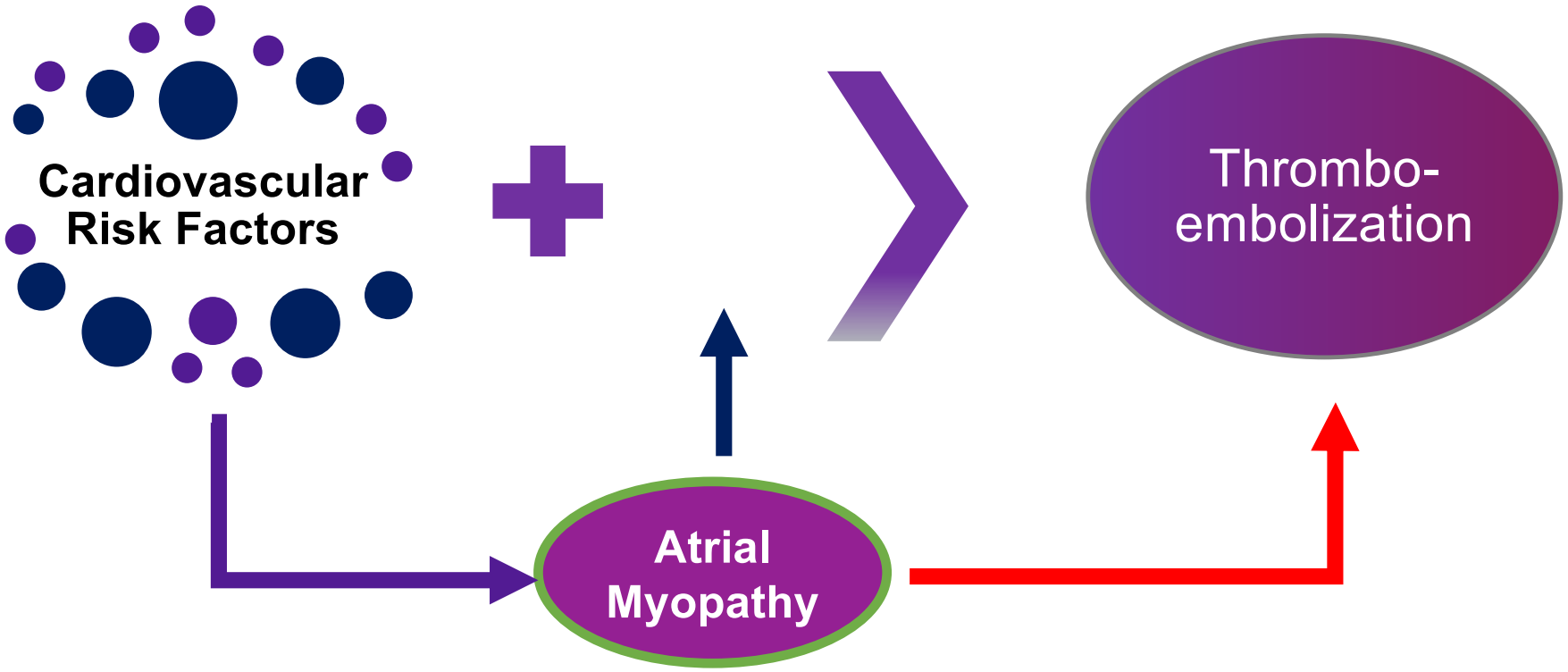
AF >23.5h n=1572 (7.2%)	0.86% 4 events	0.50% 3 events	1.52% 19 events	1.77% 28 events	1.68% 13 events

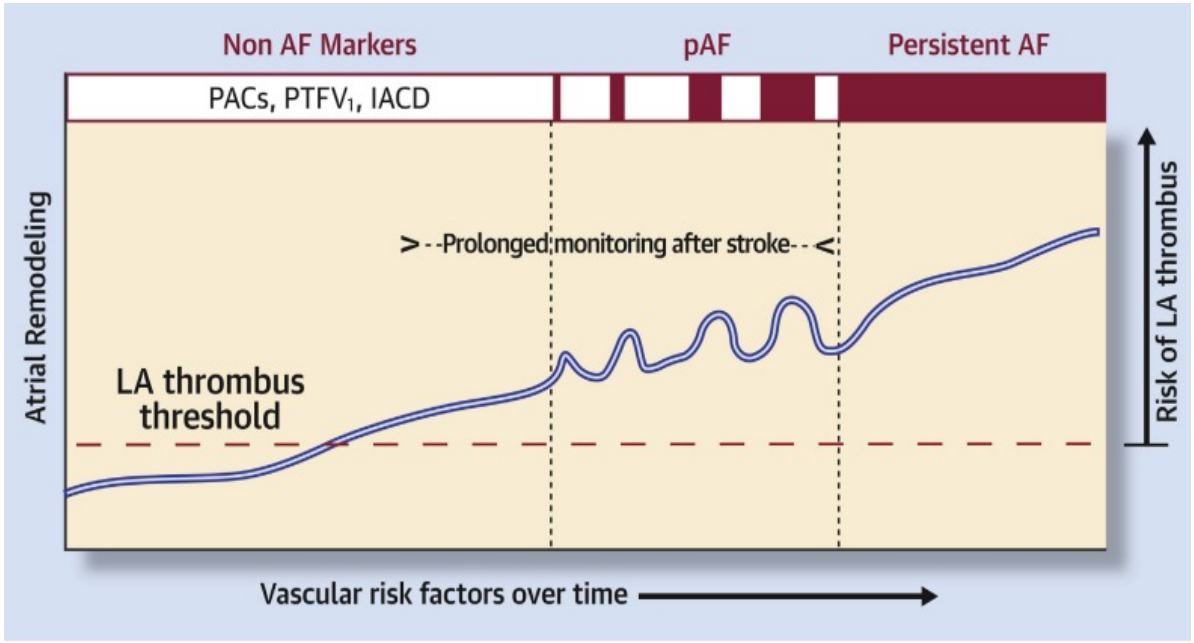
Morillas P, et al. *Rev Esp Cardiol* (Engl Ed). 2015;68(6):485-491. Kaplan RM, et al. *Circulation*. 2019;140(20):1639-1646.

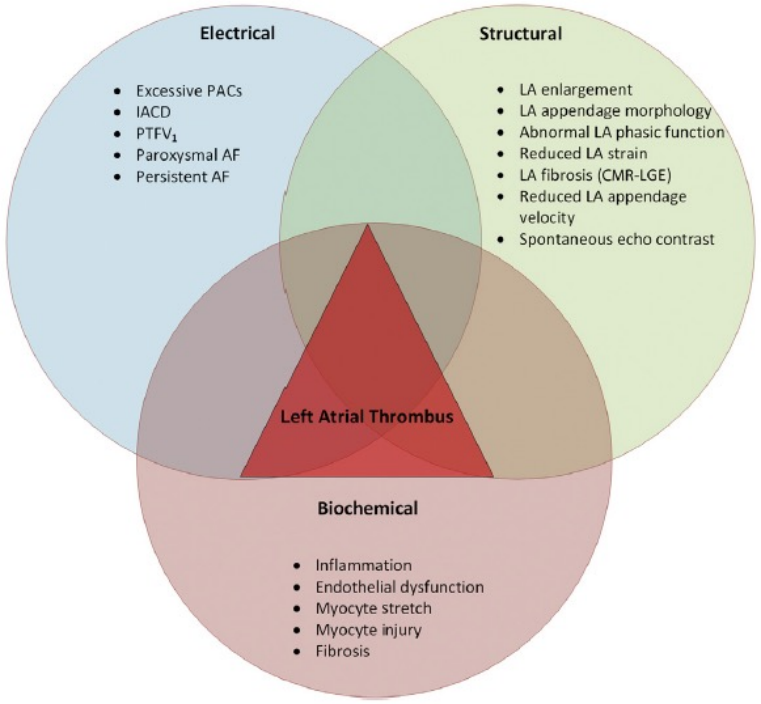
Atrial Myopathy: Link to Stroke



The Atrium and Embolic Stroke

Myopathy Not Atrial Fibrillation as the Requisite Determinant?





IACD = interatrial conduction delay; PTFV = P-wave terminal force in lead.
Sajeev JK, et al. *JACC Clin Electrophysiol*. 2020;6(3):251-261.

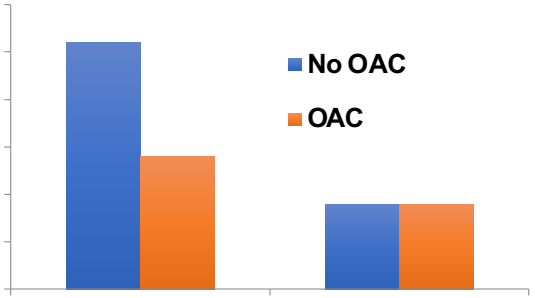
Argument #6

Ablation is NOT enough for stroke prevention in high-risk patients

Stroke prevention is still needed after ablation

Strokes after AF Ablation off OAC

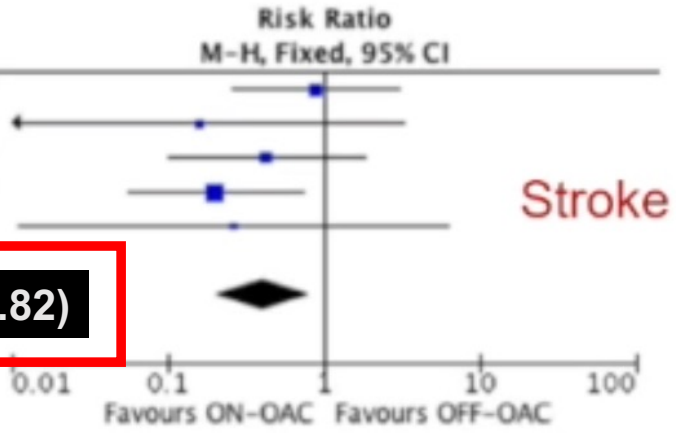
Oral anticoagulation after catheter ablation of atrial fibrillation and the associated risk of thromboembolic events and intracranial hemorrhage: A systematic review and meta-analysis



Study or Subgroup	ON-OAC Events	ON-OAC Total	OFF-OAC Events	OFF-OAC Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Gallo 2016	5	364	5	321	23.8%	0.88 [0.26, 3.02]
Hunter 2012	0	276	2	220	12.5%	0.16 [0.01, 3.31]
Liang 2018	4	121	3	39	20.4%	0.43 [0.10, 1.84]
Själander 2017	4	421	5	106	35.8%	0.20 [0.06, 0.74]
Winkle 2013	0	60	1	48	7.5%	0.27 [0.01, 6.43]
Total (95% CI)		**1242**		**734**	**100.0%**	**0.41 (0.21,0.82)**
Total events	13		16			

Heterogeneity: $Chi^2 = 3.09$, $df = 4$ ($P = 0.54$); $I^2 = 0\%$

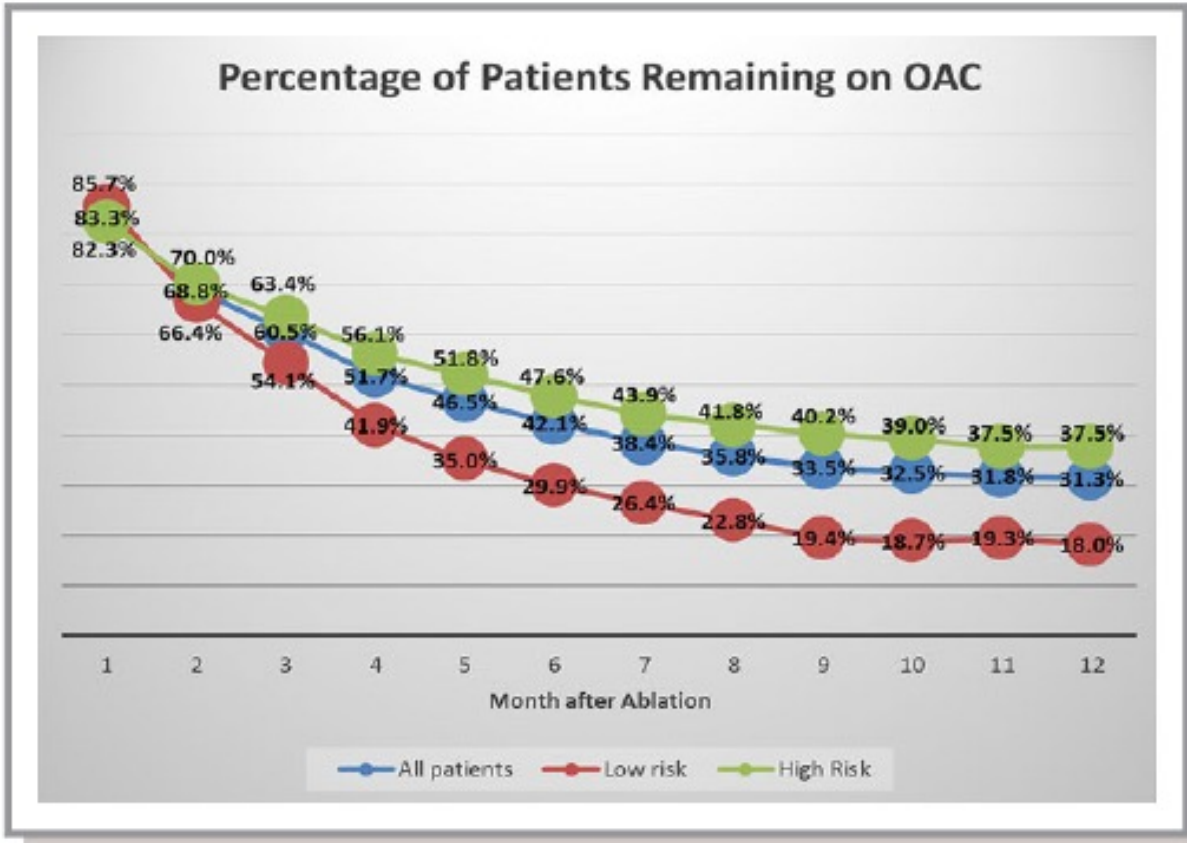
Test for overall effect: $Z = 2.53$ ($P = 0.01$)



Romero J, et al. *J Cardiovasc Electrophysiol*. 2019;30(8):1250-1257.

Strokes after AF Ablation

Patterns of Anticoagulation Use and Cardioembolic Risk after Catheter Ablation for Atrial Fibrillation



- National database
- N=6886

Noseworthy PA, et al. *J Am Heart Assoc*. 2015;4(11):e002597.

Strokes after AF Ablation off OAC

Risk Factor	HR (95% CI)
Time not on OAC	
0 to 3 months	Reference
3 to 6 months	1.69 (0.60–4.78)
6 months to 1 year	2.74* (1.12–6.74)
>1 year	3.98** (1.56–10.12)
CHA_2DS_2-VASc	
0 to 1	Reference
2	0.82 (0.16–4.14)
3	2.41 (0.62–9.37)
≥4	8.50** (2.30–31.36)
Index medication	
Warfarin	Reference
NOAC	0.83 (0.37–1.86)
Charlson comorbidity index	
0	Reference
1	1.71 (0.44–6.57)
≥2	2.85 (0.78–10.37)
Race	
White	Reference
Nonwhite	2.17** (1.21–3.91)

Risk Factor	HR (95% CI)
Anticoagulation use	
Low risk patients (CHA_2DS_2-VASc 0 or 1)	
Continuation	Reference
≥3 mo off OAC	0.34 (0.04–2.62)
High risk patients (CHA_2DS_2-VASc ≥2)	
Continuation	Reference
≥3 mo off OAC	2.48* (1.11–5.52)

Noseworthy PA, et al. *J Am Heart Assoc*. 2015;4(11):e002597.

Ablation is NOT enough for stroke prevention?

We have a solution:
Concomitant ablation + LAAC / LAAE

OPTION Trial

1710 patients assessed for eligibility

1600 eligible for 1:1 Randomization

110 patients were excluded

- **71** eligibility criteria not met
- **26** patients withdrew consent
- **7** investigator discretion
- **5** other reasons
- **1** lost to follow-up

Ablation + WATCHMAN FLX™
N=803 ITT
475 sequential
328 concomitant

Ablation + OAC
N=797 ITT
471 sequential
326 concomitant

~95% of patients were taking DOAC

753 received WATCHMAN FLX™

- 41 did not receive WATCHMAN FLX procedure
- 9 unsuccessful implantation

796 treated as assigned

- 1 treated with device in error

82 crossovers
66 1° endpoint event
16 no 1° endpoint event

28 withdrew consent
17 lost to follow-up
9 other
4 investigator discretion
2 died

43 withdrew consent
28 lost to follow-up
7 other
5 investigator discretion
1 died

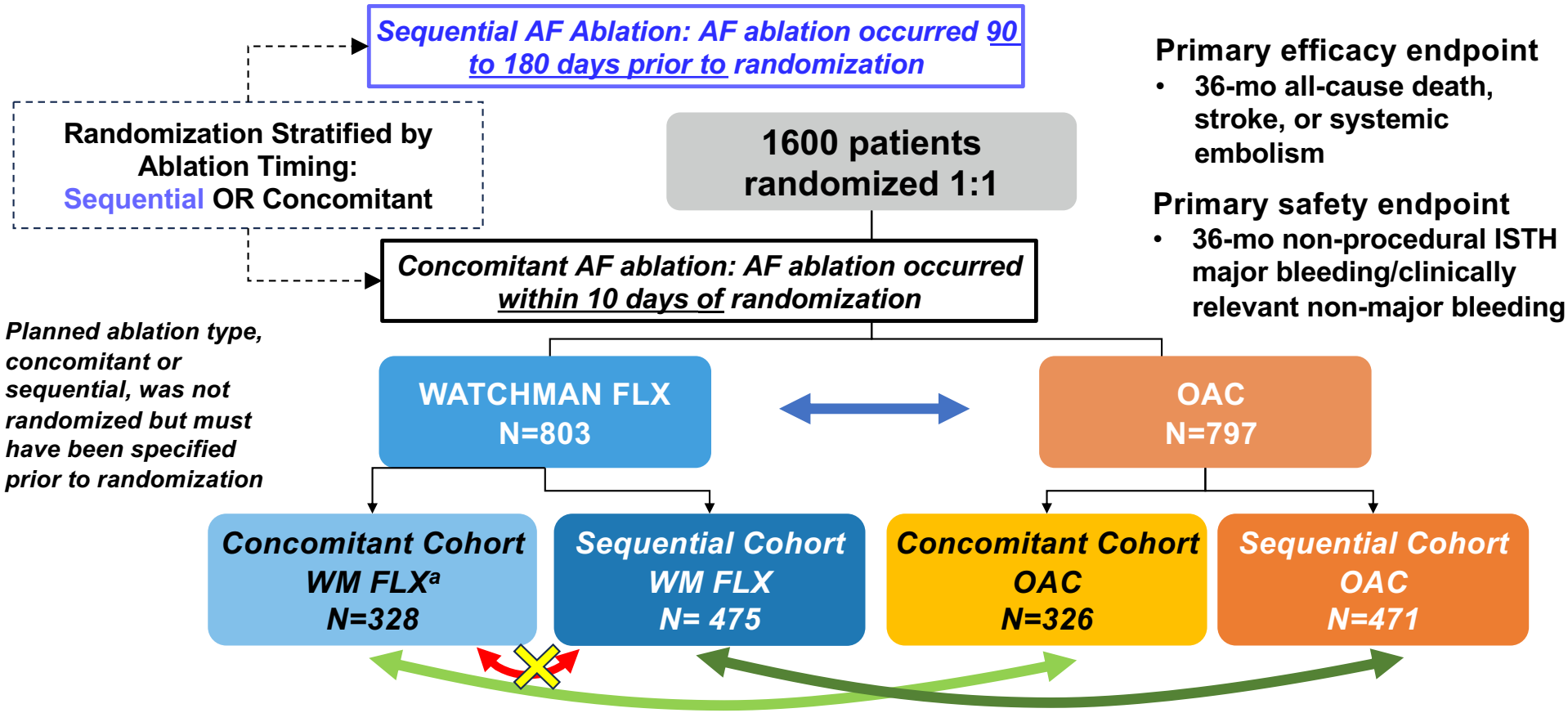
36-month follow-up
94.4% N=758 ITT

36-month follow-up
92.5% N=737 ITT

DOAC = direct oral anticoagulants.

Saliba W, Nair D, et al. *Heart Rhythm*. 2025;22(10):2585-2594.

OPTION Concomitant and Sequential Analyses: Study Design



Primary efficacy endpoint

- 36-mo all-cause death, stroke, or systemic embolism

Primary safety endpoint

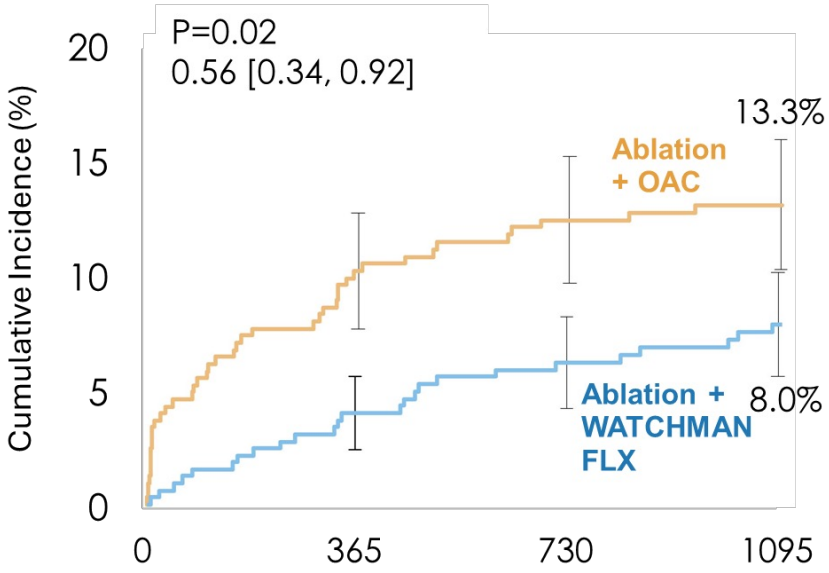
- 36-mo non-procedural ISTH major bleeding/clinically relevant non-major bleeding

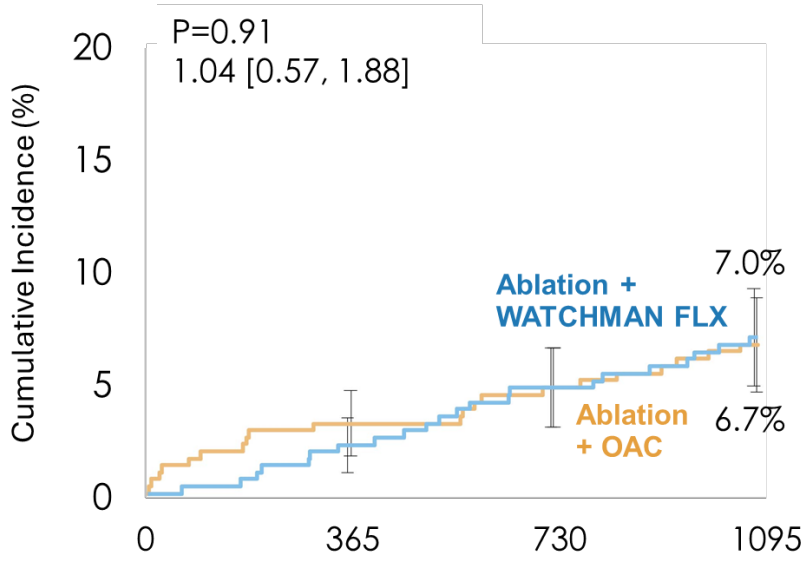
[a]99% (325/328) AF ablation and LAAC occurred on same day.
Saliba W, Nair D, et al. *Heart Rhythm*. 2025;22(10):2585-2594.

OPTION Concomitant and Sequential Analyses: Key Results

- Primary efficacy noninferiority and primary safety superiority endpoints maintained in both the concomitant and sequential subgroups

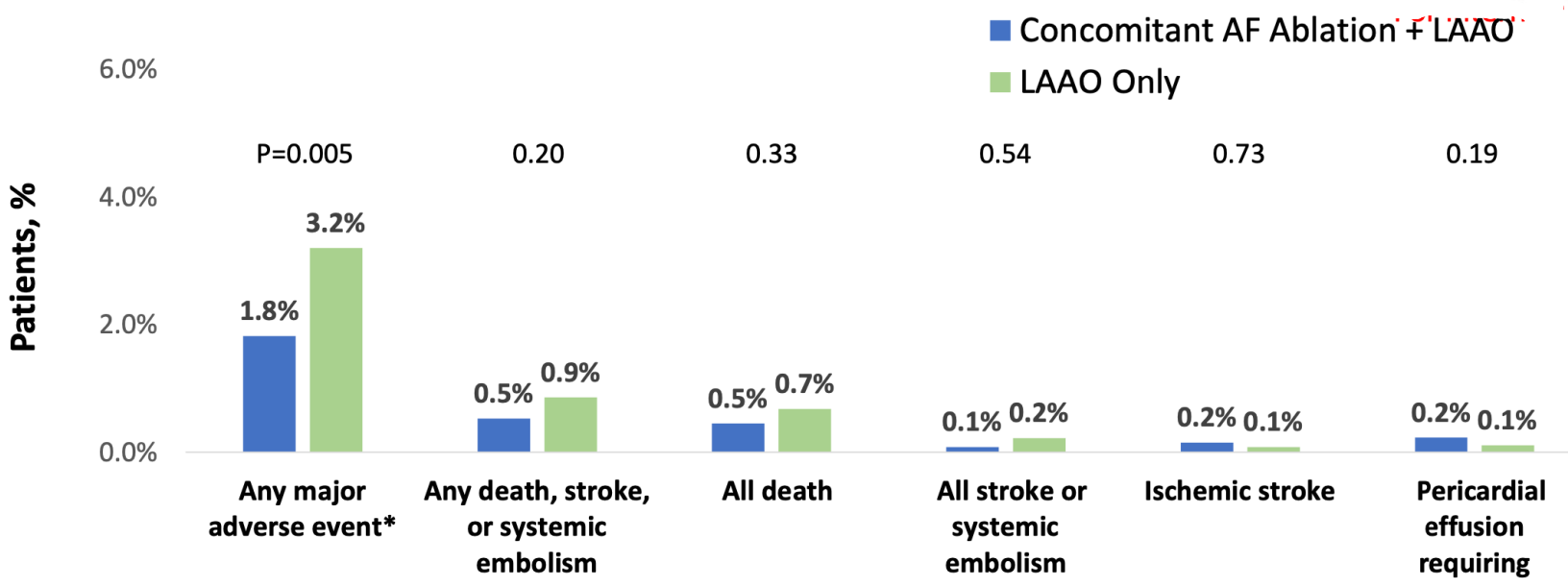
Concomitant





Saliba W, Nair D, et al. *Heart Rhythm*. 2025;22(10):2585-2594.

Complication Rate of Concomitant vs LAAO

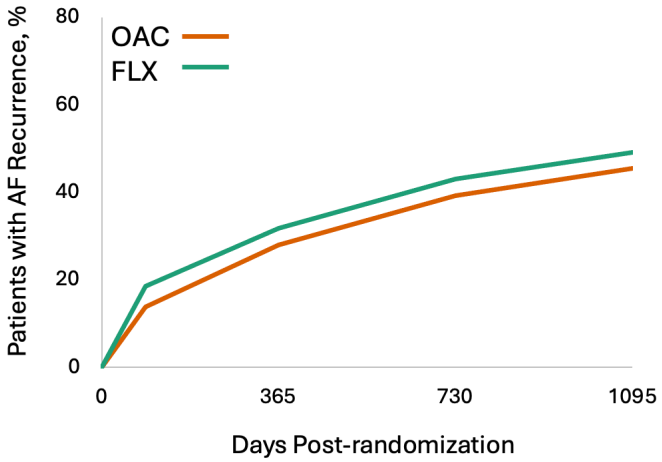


Patients undergoing concomitant catheter ablation + LAAO did not have higher rates of major adverse events at 45 days

Saliba W, Nair D, et al. *Heart Rhythm*. 2025;22(10):2585-2594.

Does LAAO Impact AF Ablation Outcomes?

Similar AF Recurrence Rates in OAC & WATCHMAN FLX



Group	OAC	WATCHMAN FLX
AF Recurrence Rate	45.5%	49.2%
Repeat AF Ablation	13.9%	15.2%
Cardioversions	41.9%	45.7%
Change in Medication	13.3%	16.2%

	Patients with AF Recurrence	
	OAC	WATCHMAN FLX
Age	69.5±7.9	70.0±7.2
Women	33.4%	35.9%
CHA_2DS_2-VASc Score	3.6±1.3	3.6±1.3
HAS-BLED Score	1.2±0.8	1.2±0.8
Paroxysmal AF	54.8%	52.6%
Persistent AF	45.2%	47.4%

Younis, et al. HRS, LBCT, 2025

Younis A, et al. *Heart Rhythm*. 2025;22(12):e1128-e1136.

A Medicare Analysis of AEs Occurring between Ablation and LAAC

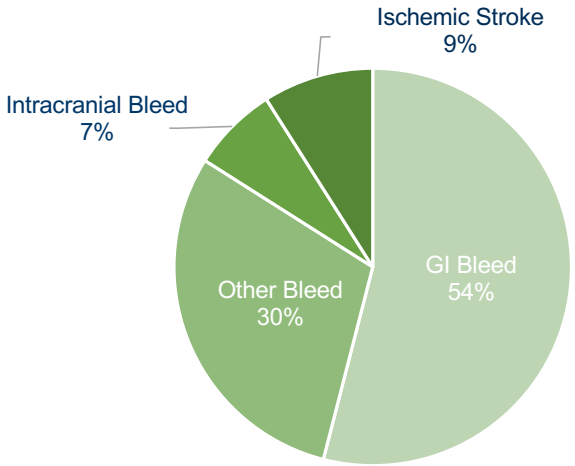
- Key results & conclusion

91 ± 48
Mean days between procedures

28%
of adverse events were associated with an in-hospital stay

12%
of adverse events were associated with an ED visit

Major Adverse Events Experienced Between Procedures



Patients experienced AEs while waiting for LAAC following ablation

Cumulative Costs between Procedures

	No AE (n=3,718)	1+ AEs (n=607)
CMS Payments		
Mean (SD)◊	$2,308 (6,385)	$11,308 (15,382)
Provider/Hospital Costs		
Mean (SD)◊	$2,032 (5,343)	$11,666 (15,446)
Beneficiary/Patient Responsibilities		
Mean (SD)◊	$99 (511)	$703 (1,279)

SD: standard deviation, ◊ All means were significantly different using a Student's t-test at alpha 0.05
Cost information gathered from Medicare Standard Analytical Files (SAF) from 2016-2022

1 in 7

14% of patients experienced ≥1 significant adverse event between staged cardiac ablation and LAAC procedures

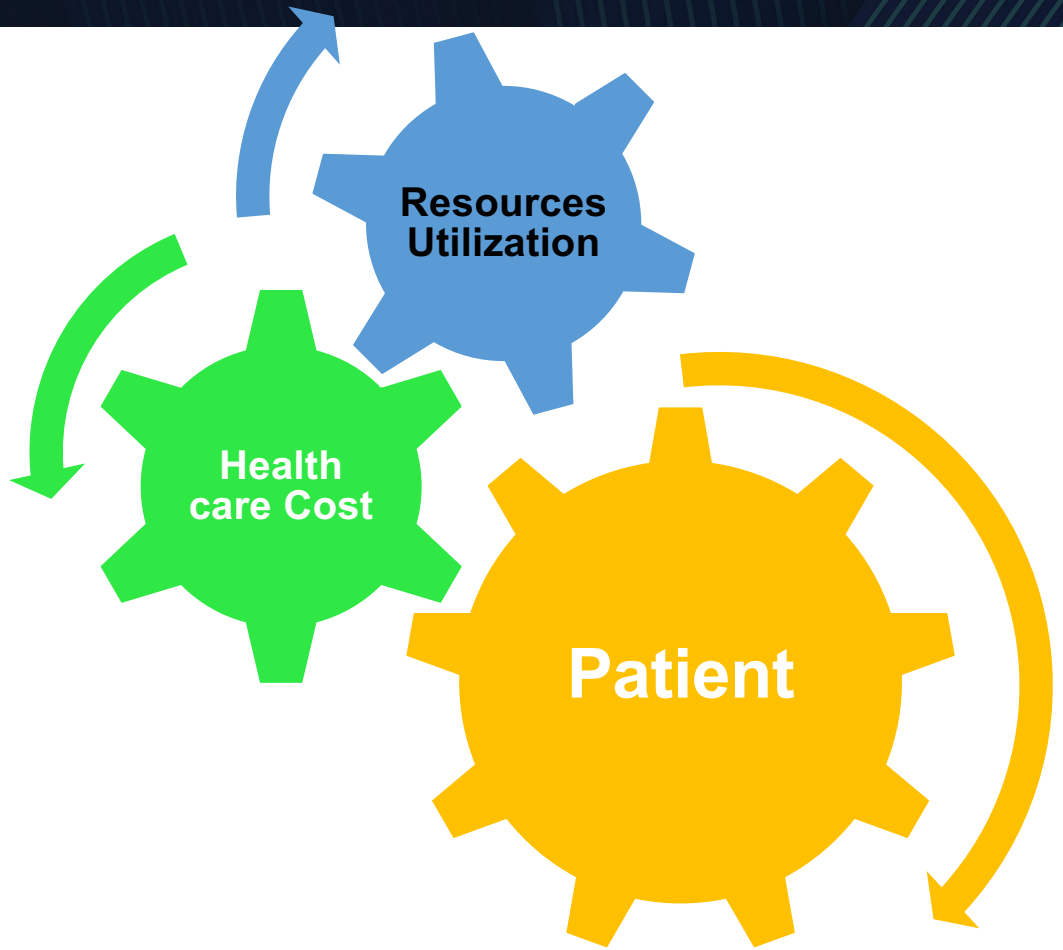
4,325 Medicare patients had a LAAC within 180 days of catheter ablation in the Medicare FFS data from 2016–2022.
Kayser S, et al. Presented at: International Society for Pharmacoeconomics and Outcomes Research (ISPOR) Conference 2024; May 5-8, 2024; Atlanta GA. PT39.

Who Is a CANDIDATE for Concomitant Procedure?

- Patients evaluated for PVI with rationale to stop OAC
  - Bleeding, higher risk of bleeding, lifestyle

- Most patients presenting for LAAC
  - PFA is safe and quick procedure
  - Benefit of AF ablation is present even in asymptomatic patients

Benefits



Where LAA Exclusion Fits in AF Care

- AF diagnosis → Stroke risk stratification
- CHA_2DS_2-VASc assessment

- Consideration during
  - Standalone ablation
  - Hybrid/convergent procedures
  - Concomitant cardiac surgery

Epicardial Exclusion: Two Pathways

- Percutaneous epicardial ligation (eg. LARIAT)
  - Pericardial + transseptal access
  - No intracardiac implant
  - Immediate mechanical closure

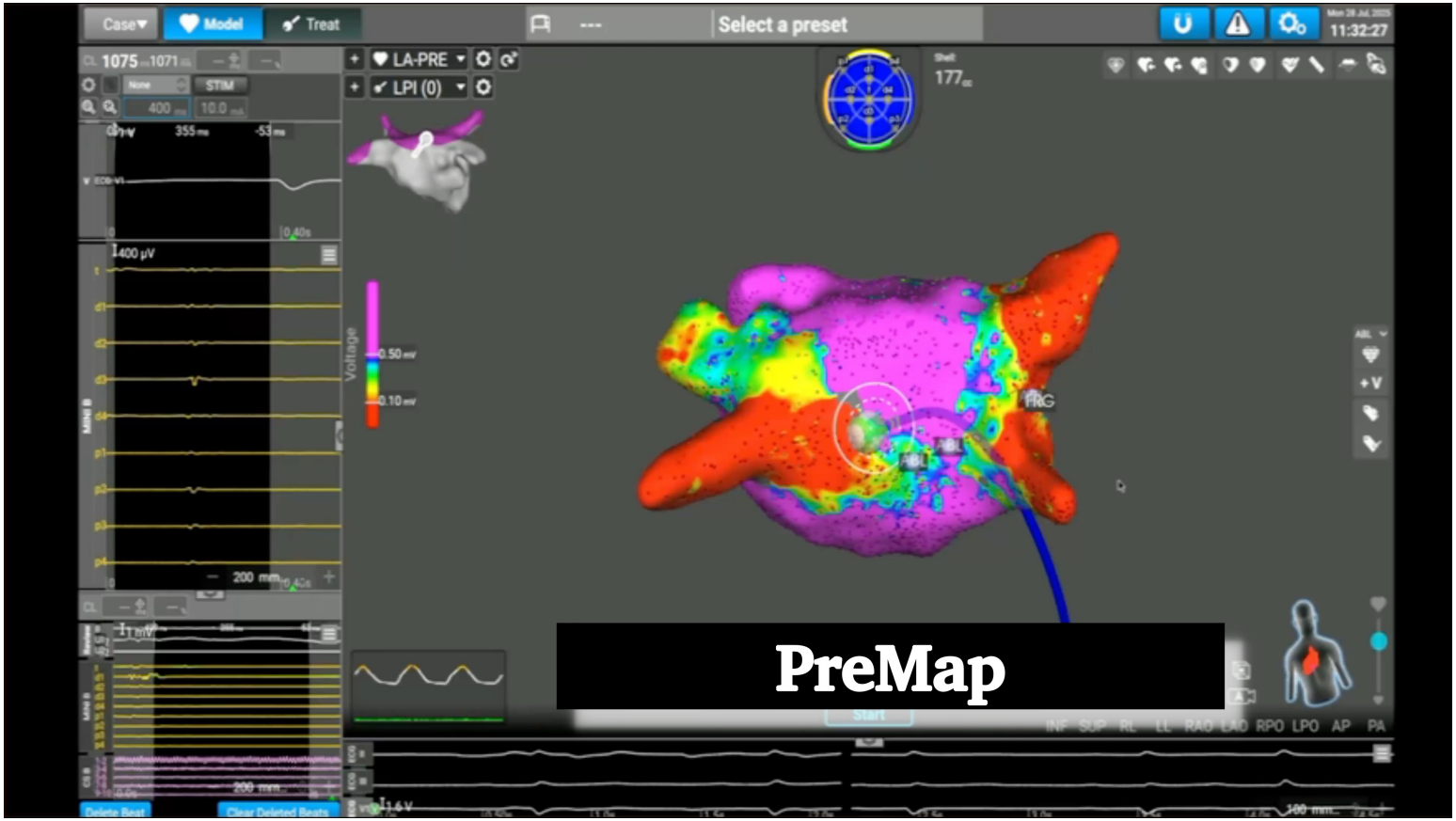
- Surgical epicardial clipping (eg. surgical ligation)
  - Thoracoscopic or open approach
  - Integrated into hybrid or concomitant surgery

Yarlagadda B, et al. *J Atr Fibrillation*. 2017;10(3):1725. Rosati F, et al. *J Cardiovasc Electrophysiol*. 2021;32(10):2865-2872.

Patient 1 History

- 78-yo female with HTN, DM, CAD, persistent AF, s/p PVI in 2014 now with recurrence of AF and atypical atrial flutter and developed tachycardiac cardiomyopathy, on amiodarone, with recurrent GI bleed requiring transfusions

- Referred for concomitant procedure
  A. Endocardial LAAC / epicardial LAAE
  B. AF ablation and LAAC / LAAE


Case
Model
Treat
Select a preset
11:32:27
LA-PRE
LPI (0)
Voltage
0.50 mV
0.10 mV
PreMap

Patient 3 History

- 69-yo male with HTN, DM, CAD, persistent AF, tachycardiac cardiomyopathy, on amiodarone, with spontaneous IC bleed from AVMs

- Also develops multiple DVTs during that admission – gets IVC filter, taken off OAC; imaging shows occluded IVC with collaterals

When Anatomy Sabotages You

- Planned transhepatic access
  - Get put back on OAC – hepatic AVM bleeds, requiring embolization. OAC stopped
- 3 months alter, recurrent afib, and stroke
- Concomitant PVI LAAC planned through IJ
- PFA-system PVI, PWI completed through right IJ


DA 15f/s
LAO 91 °
0 °
SID 120 cm
16 "
0 °
89 cm
43 cm
0 °
16%
L 31.2 min
0.0 mGy/min
1192.27 mGy
DA
F 78kV 152mA 10.4ms
R 88kV 428mA 10.0ms
H73 Table lat. sensor error. Auto operation disabled.

Key Learning Points

- Cessation of OAC in high-risk patients is not optimal, therefore guidelines recommend continuation

- Endocardial occlusion
  - Transseptal device-based therapy
  - Requires endothelialization and short-term OAC/DAPT

- Epicardial exclusion
  - No intracardiac implant
  - No device-related thrombus
  - May avoid long-term DAPT

DAPT = dual antiplatelet therapy.

LAA Management: Occlusion vs Exclusion Patient Selection

Rahul N. Doshi, MD, FACC, FHRS

Academic Chief Cardiology and Medicine, HonorHealth Professor of Medicine, John Shufeldt School of Medicine and Medical Engineering

Editor-in-Chief, Heart Rhythm Case Reports

For atrial fibrillation

Rate vs rhythm control
Ablation vs AAD

PVI vs PVI plus anatomic
vs electrical recurrence
vs burden occlude
vs exclude

It depends?

Goals of Therapy vs Risk/Benefit of LAA Interventions

- Stroke prevention
- Elimination of OAC
- Patient access/concomitant
- Rhythm control

- Safety
- Ease of use
- Resource utilization
- Hospitalization/LOS

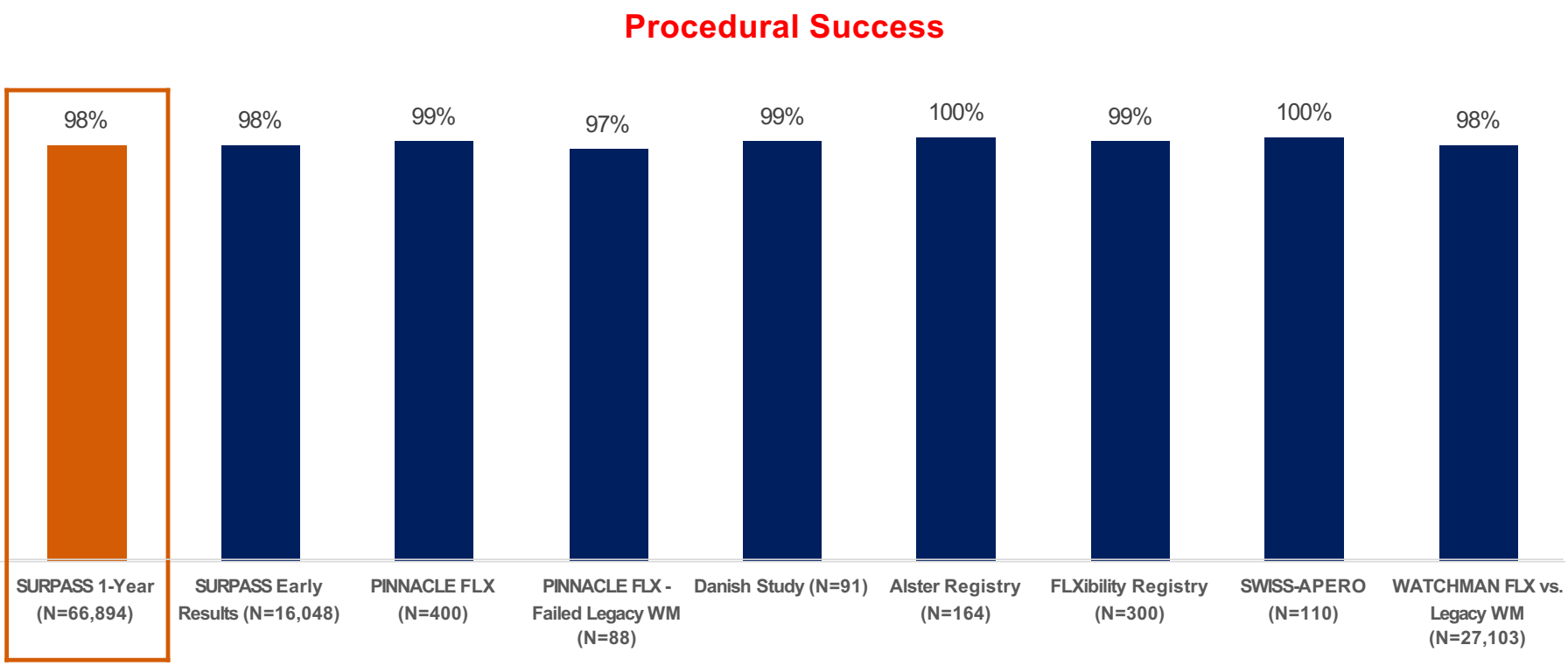
OAC = oral anticoagulation; LOS = length of stay.

Case 1

Clinical	Goal	Therapy
• 66-year-old woman with PAF – Burden 1.3%, longest episode 14 minutes, asymptomatic – HTN, DM, CAD/stent to OM1 – History of LGIB/diverticulosis – LVEF 62% – On metoprolol, clopidogrel, and apixaban	Stroke risk mitigation (CHA_2DS_2VASc 6) Elimination of OAC (need for clopidogrel, history of LGIB)	→ ***Occlusion***

HTN = hypertension; DM = diabetes mellitus; CAD = coronary artery disease; LVEF = left ventricular ejection fraction; LGIB = lower gastrointestinal bleeding.

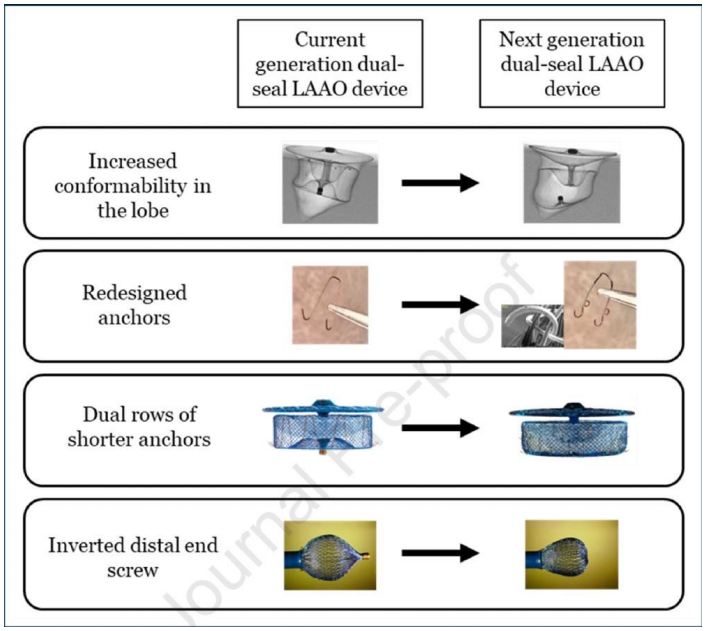
SURPASS: Confirmation of Procedural Success: 98% Procedural Success among 66,894



Kapadia S, et al. Presented at: Cardiovascular Research Technologies 2023; February 25-28, 2023; Washington, DC. Kar S, et al. *Circulation*. 2021;143(18):1754-1762. Ellis CR, et al. *Heart Rhythm*. 2021;18(7):1153-1161. Korsholm K, et al. *JACC Clin Electrophysiol*. 2020;6(13):1633-1642. Bergmann MW, et al. Presented at: EuroPCR 2021; May 18-20, 2021; Paris, FR. Betts T, et al. Presented at: European Heart Rhythm Association (EHRA) 2022. Galea R, et al. *Circulation*. 2022;145(10):724-738. Freeman J, et al. Presented at: Heart Rhythm 2022; April 29-May 1, 2022; San Francisco, CA.

Veritas

Early Outcomes with a Next-Generation Dual-Seal Left Atrial Appendage Occluder: Results from the VERITAS Study

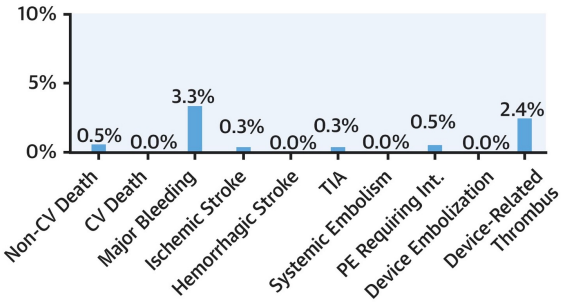


Early Outcomes of the VERITAS Study

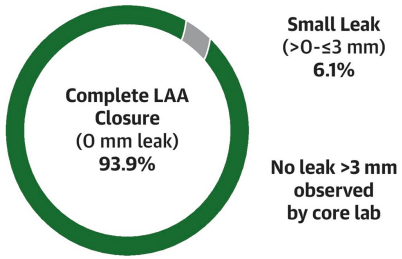
PRIMARY SAFETY
0%

PRIMARY EFFECTIVENESS
100%

Key Clinical Outcomes Through 45 Days



- Global, prospective, multicenter, pre-market study on the next-generation dual-seal LAAO device
- 400 patients underwent an implant attempt after baseline imaging review across 34 global sites



LAAO = left atrial appendage occlusion.
Nair D, et al. *JACC Clin Electrophysiol*. 2026:S2405-500X(26)00028-9. [Epub ahead of print.]

Case 2

Clinical

- 74-year-old male with PAF
  - Burden 28.5%, longest episode 13 hours, symptomatic
  - HTN, CAD/stent to LAD
  - LVEF 65%, mild LAE
  - On dronedarone, clopidogrel, and apixaban

Goal

Rhythm control (symptomatic AF despite AAD)

Stroke risk mitigation (CHA_2DS_2VASc 3)

Elimination of OAC (need for clopidogrel)

Patient convenience…

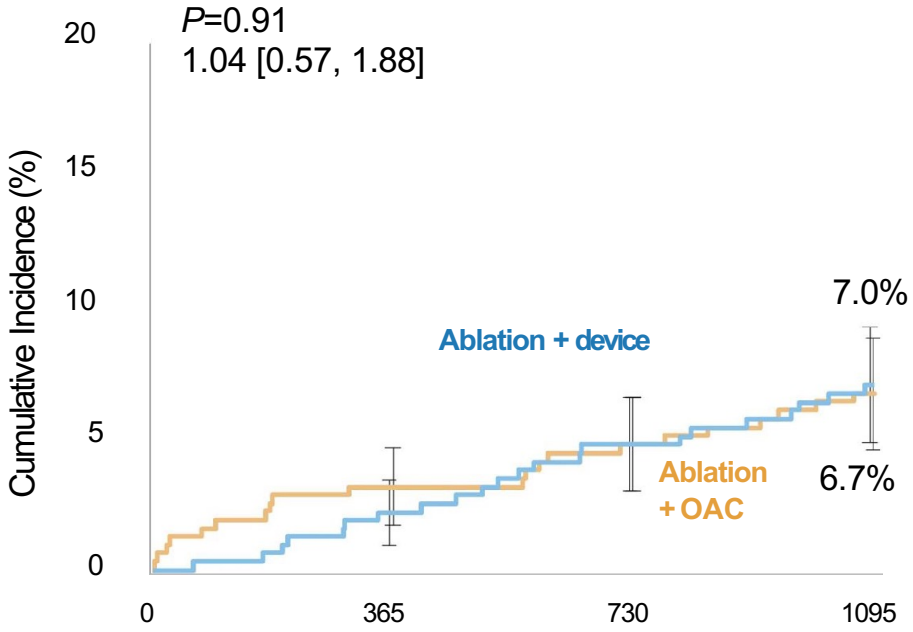
Therapy

Concomitant PVI with occlusion

LAD = left anterior descending; LAE = left atrial enlargement.

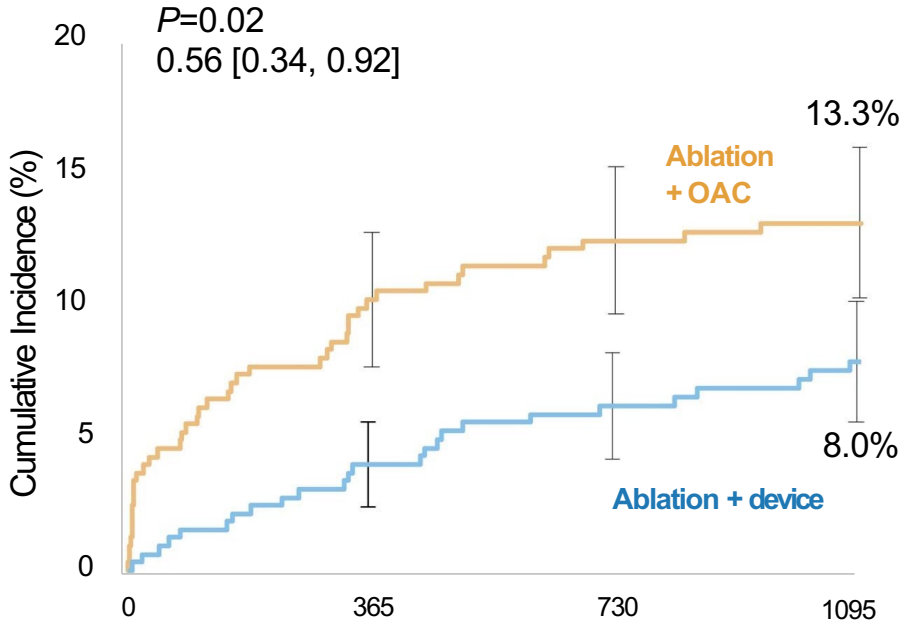
OPTION

Primary Efficacy Endpoint



No. at risk				
Ablation + device	328	319	310	288
Ablation + OAC	326	310	306	290

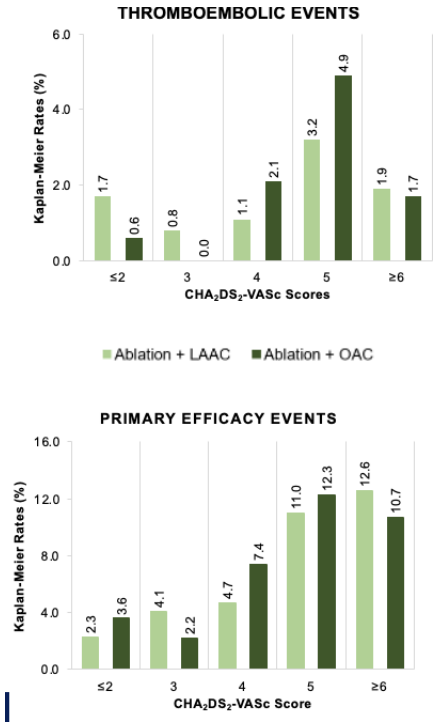
Primary Safety Endpoint

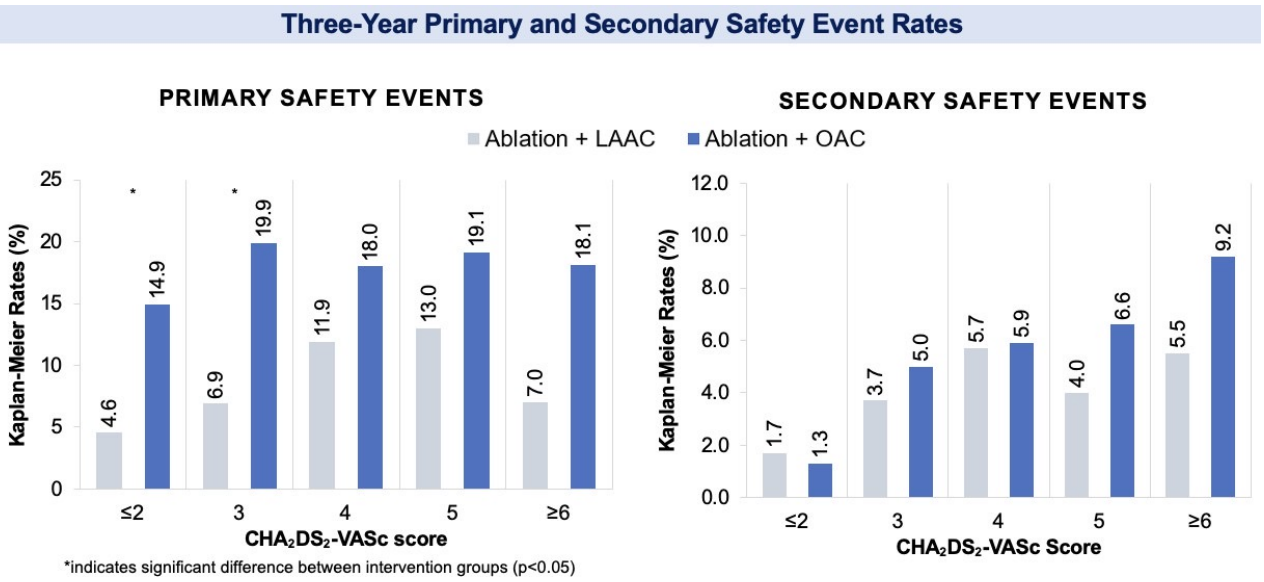


Ablation + device	328	311	297	275
Ablation + OAC	326	290	276	255

Saliba W, et al. Presented at: 30th Annual AF Symposium; January 16-18, 2025; Boston, MA.

OPTION Subgroup Analysis by Stroke Risk



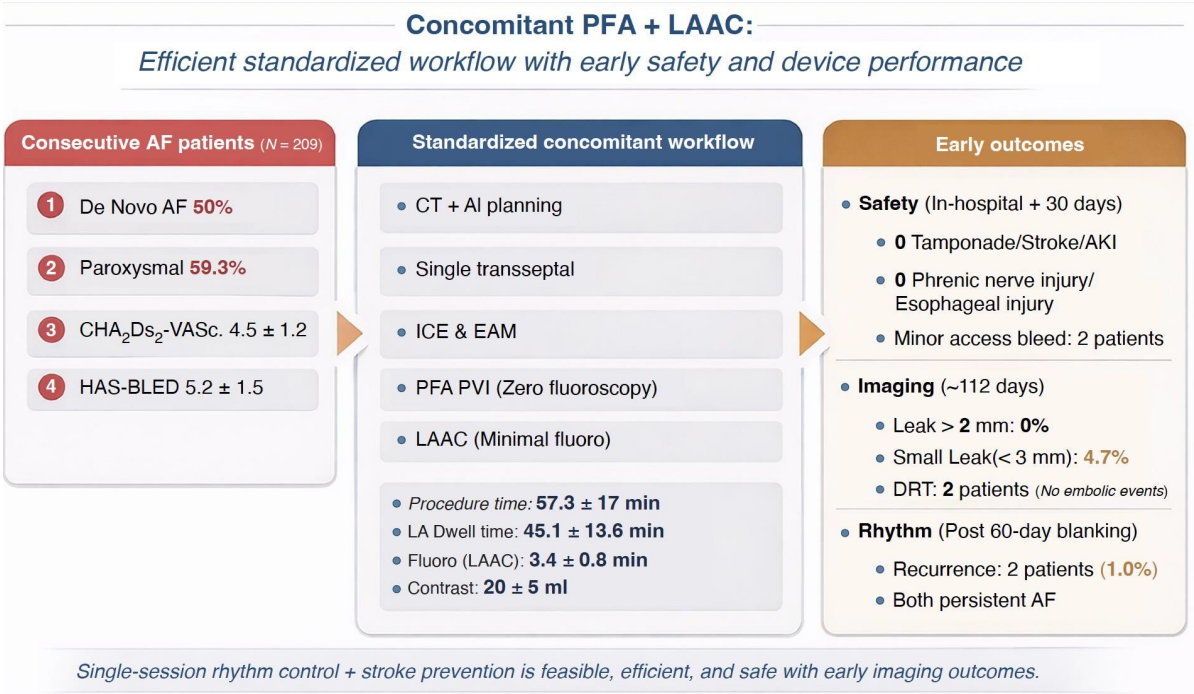


Doshi R, et al. *Heart Rhythm.* 22(4):S336-S337.

LAAO Leaks with Concomitant Procedures

- Signal for increased leaks with concomitant
- ? related to ridge ablation with left vein ablation
- ? differences in closure devices
- ? is ablation itself thrombogenic
- ? RF vs PFA

- Contemporary data supportive of concomitant!

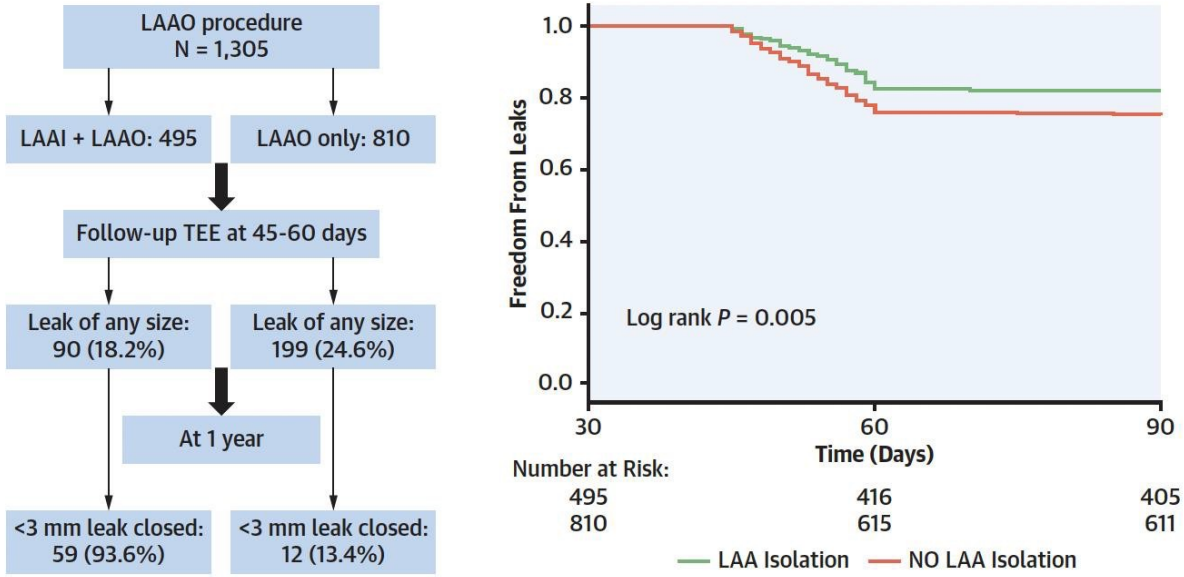


ICE = intracardiac echocardiography; EAM = electro-anatomical mapping.
Doty B, et al. *Europace*. 2026;28(2):euag017.

Concomitant and Leaks

Prevalence of Peridevice Leak in Patients With Left Atrial Appendage-Occlusion vs Without Electrically Isolated Left Atrial Appendage

CENTRAL ILLUSTRATION **Flowchart and the Kaplan-Meier Curve Demonstrating the Main Findings**



Mohanty S, et al. JACC Clin Electrophysiol. 2026;12(1):108-115.

The flowchart shows the trajectory of leak in post-Watchman patients with vs without left atrial appendage (LAA) isolation (LAAI). Kaplan-Meir curve shows the leak rate in both groups. At the first follow-up transesophageal echocardiogram (TEE) at 45 to 60 days, leaks of any size were noted in 90 (18.2%) patients in Group 1 and 199 (24.6%) patients in Group 2 (log-rank test, $P = 0.005$). LAAO = left atrial appendage occlusion.

Case 3

Clinical

- 78-year-old male with PersAF
  - HTN, OSA, HF
  - LVEF 48%, moderate to severe LAE, mild MR
  - On amiodarone, carvedilol, and rivaroxaban

Goal

Rhythm control (HF with decreased LVEF) and need for more than PVI

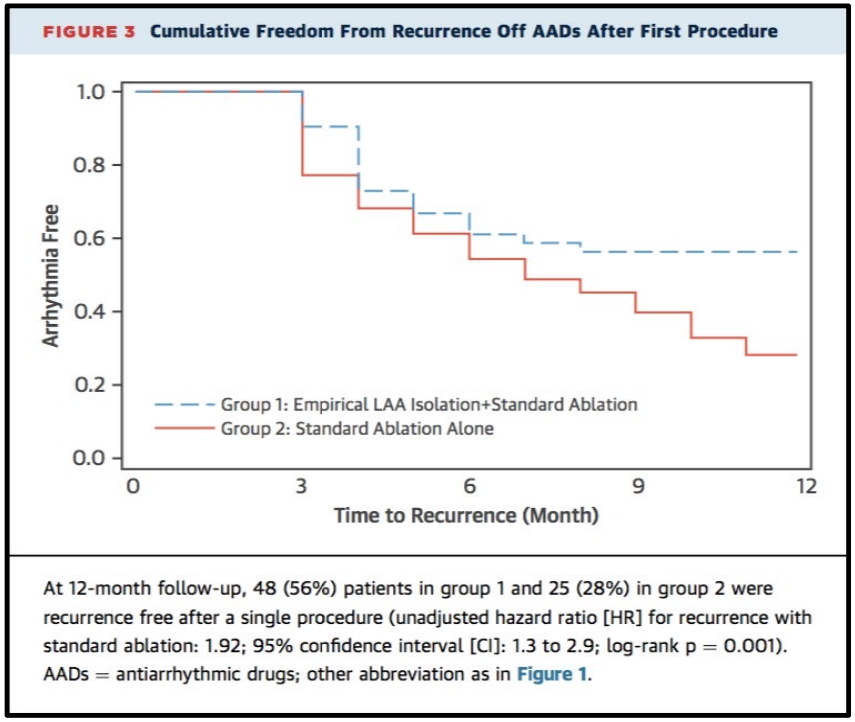
Stroke risk mitigation (CHA_2DS_2VASc 4)

Therapy

Occlusion with exclusion

Importance of the LAAEI for AF: Do You BELIEVE?

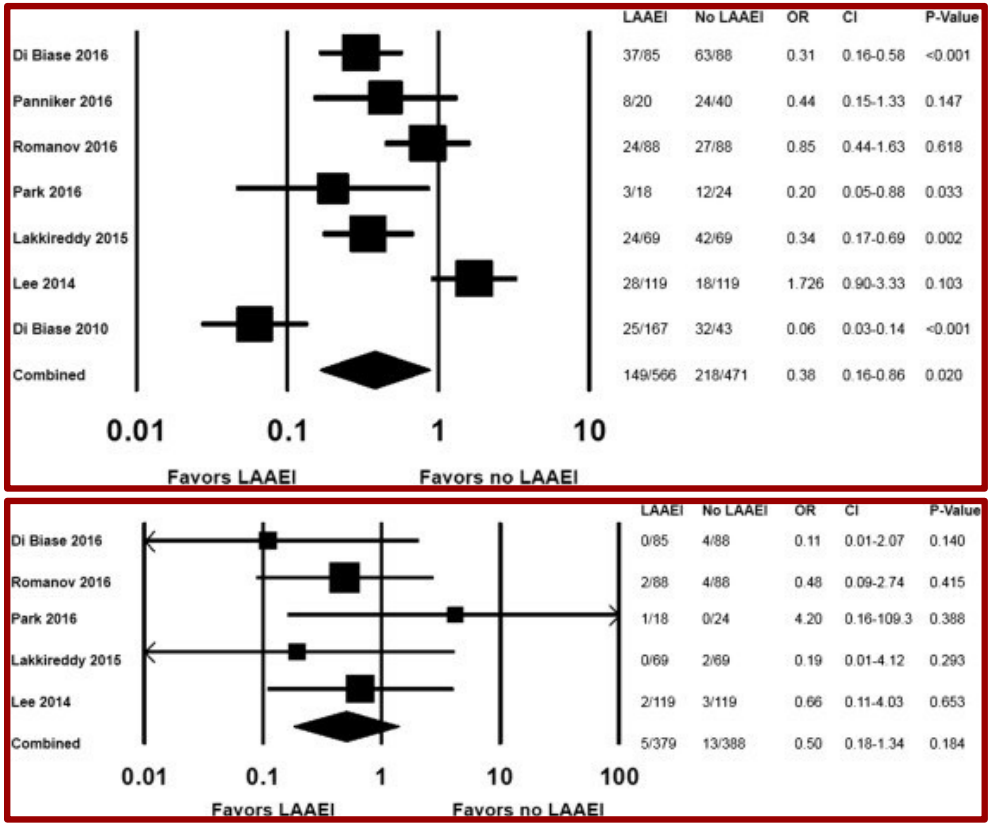
- AF ablation closely mirrors surgical MAZE except…
  - LAA ligation alone shown to decrease AF burden
  - Triggers present in LAA 30% of the time in persistent AF
  - BELIEVE trial: 76% success at 24 months with LPAF with LAA isolation vs 56% without
  - AMAZE trial vs CONVERGE
  - Potential for increased risk of thrombus (20%) after LAA isolation despite OAC



Afzal MR, et al. *Heart Rhythm.* 2015;12:52-59. Di Biase L, et al. *Circulation*. 2010;122:109-126. DiBiase L, et al. *J Am Coll Cardiol.* 2016;68:1929-1940. Lee RJ, et al. *Am Heart J.* 2015;170:1184-1194. Rillig A, et al. *Circ Arrhythm Electrophysiol*. 2016;9:e003461.

Data Supporting LAAEI for PS/PLAF

- LAA electrical isolation meta-analysis
  - 7 studies, 1037 patients, 566 patients with electrical isolation
  - Lower rate AT/AF $p<0.02$
  - No increased risk of thromboembolism though incorporated LAA occlusion



LAAEI = left atrial appendage electrical isolation.
Friedman DJ, et al. *JACC Clin Electrophysiol.* 2018;4(1):112-120.

LAAEI and Occlusion

Safety and feasibility of combined atrial fibrillation ablation and left atrial appendage occlusion after left atrial appendage electrical isolation

Kenneth Kita[1] · Steven Carlson[1] · Mary Huntsinger[1] · Han Tun[1] · Jina Sohn[1] · Rahul N. Doshi[1]

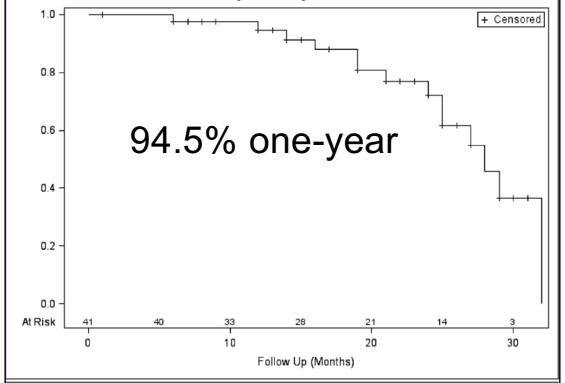
Table 2 Device-related results

	All ($n=42$)	De novo ablation ($n=20$)	Re-do ablation ($n=22$)	P value
Average follow-up, months	18.6 ± 8.6	17.0 ± 9.9	20.1 ± 7.1	0.24
Average WATCHMAN™ size, mm	27.1 ± 3.5	27.6 ± 4.0	26.6 ± 3.1	0.36
Acute significant leak	0/42	0/20	0/22	
Significant leak at 3 months	1/41	1/19	0/22	0.48
Significant leak at 6 months	0/41	1/19	0/22	0.48
Device-related thrombus at 3 or 6 months	3/41	1/19 (5.0%)	2/22 (9.1%)	1.0
Device migration	3/42	0/19	3/22	0.54
Cerebrovascular accident/transient ischemic attack	0/42	0/20	0/22	

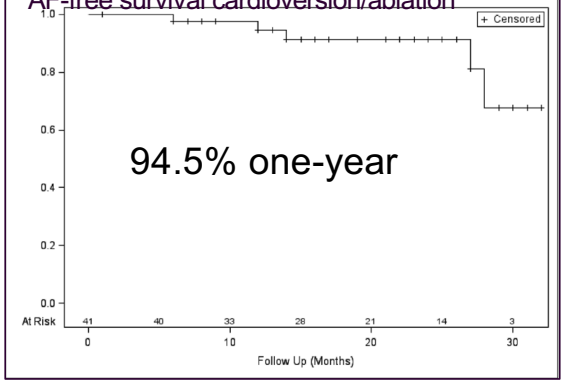
Table 4 Atrial fibrillation ablation results

	All ($n=42$)	De novo ($n=20$)	Re-do ($n=22$)
Average follow-up (months)	18.6 ± 8.6	16.5 ± 22.0	19.0 ± 7.1
Recurrence > 30 s	14 (33.3%)	6 (30.0%)	8 (36.4%)
Cardioverted or re-ablated	5 (11.9%)	4 (20.0%)	1 (4.5%)
Maintenance of sinus rhythm	42 (100%)	20 (100%)	22 (100%)

AF-free survival any arrhythmia > 30 seconds



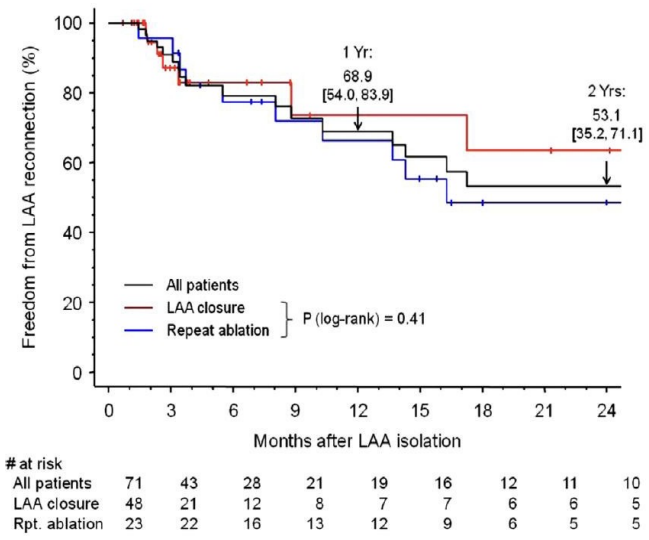
AF-free survival cardioversion/ablation

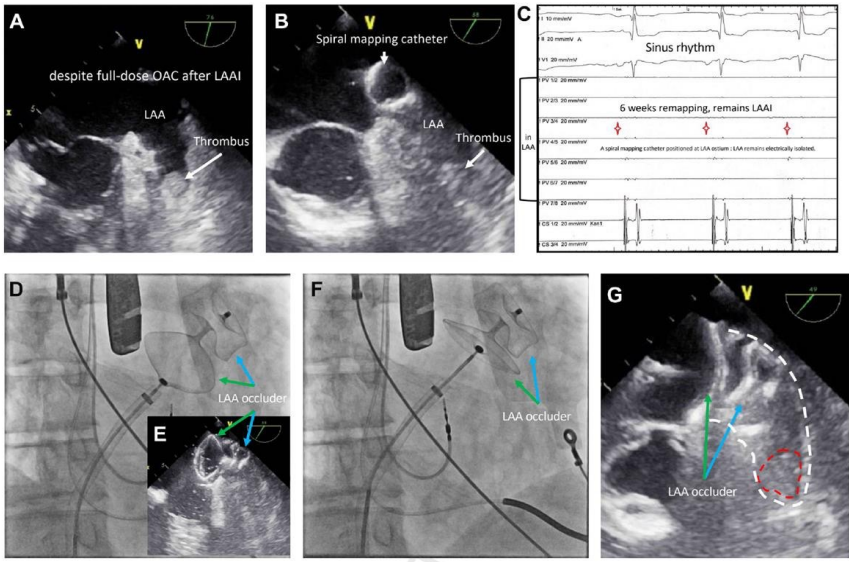


Kita K, et al. *J Interv Card Electrophysiol*. 2020;57(1):43-55.

Durability of LAAEI via Ablation Needs Improvement

- Durability with RF
  - Varies, ~70%
- Other energy sources
  - Cryoballoon
    - 81% durable at 6 weeks
  - PFA
- Regardless, still requires occlusion





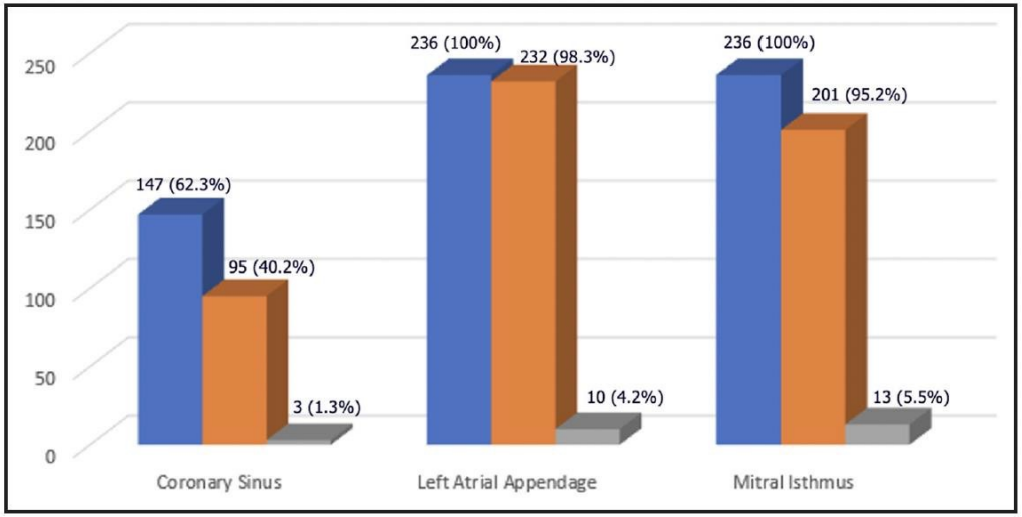
Reissmann B, et al. *Heart Rhythm*. 2017;14(3):314-319. Efe TH, et al. *Heart Rhythm*. 2025:S1547-5271(25)03137-6. [Epub ahead of print.]

Feasibility and Safety of Pulsed Field Ablation for Coronary Sinus and Left Atrial Appendage Isolation and Mitral Isthmus Ablation: Acute and Chronic Findings

Vincenzo Mirco La Fazia, MD; Sanghamitra Mohanty, MD; Carola Gianni, MD; Elio Zito, MD; Nicola Pierucci, MD; Giuseppe Stifano, MD; Preem Geeta Torlapati, MD; Domenico G. Della Rocca, MD; Weeranun Dechyapirom Bode, MD; J. David Burkhardt, MD; Rodney Horton, MD; Amin Al-Ahmad, MD; Luigi Di Biase, MD; Andrea Natale, MD

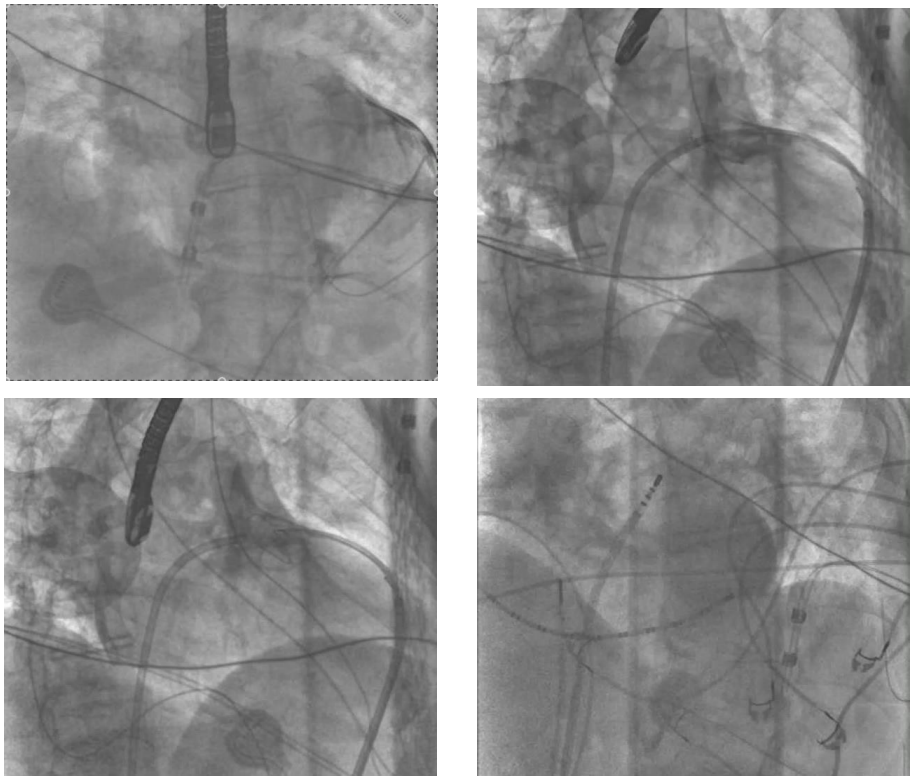
Table 3. Redo Findings

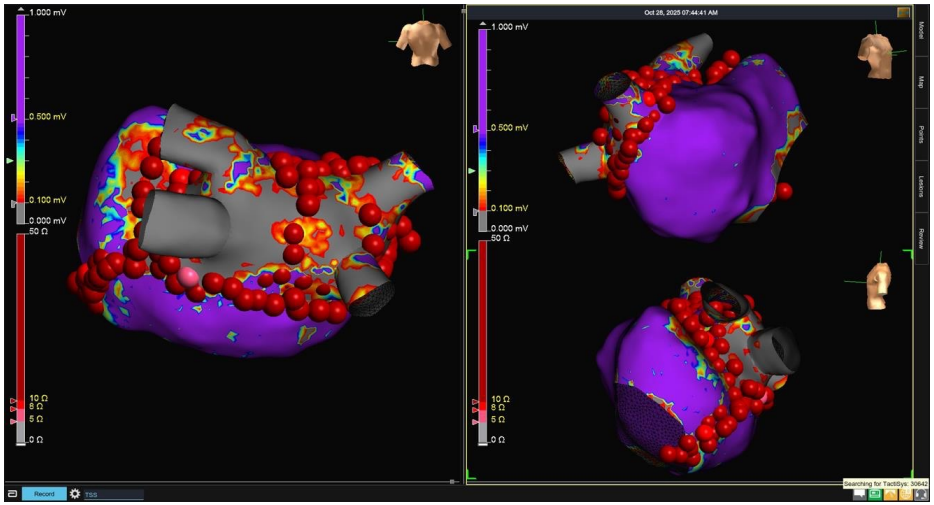
N=236		
Time to redo procedure, mean±SD	97.1±25.4	
Coronary sinus	Reconnection, n (%)	215 (98.6%)
	Radiofrequency time to isolation, mean ± SD	4±2
Left atrial appendage	Reconnection, n (%)	208 (95.4%)
	Radiofrequency time to isolation, mean±SD	3±1
Mitral isthmus	Reconnection, n (%)	191 (97.6%)
	Radiofrequency time to isolation, mean±SD	4±1



La Fazia VM, et al. *Circ Arrhythm Electrophysiol*. 2025;18(9):e014026.

Multiple Ways to Manage AF *and* LAA





LAALA-AF

Left Atrial Appendage Ligation and Ablation for Persistent Atrial Fibrillation

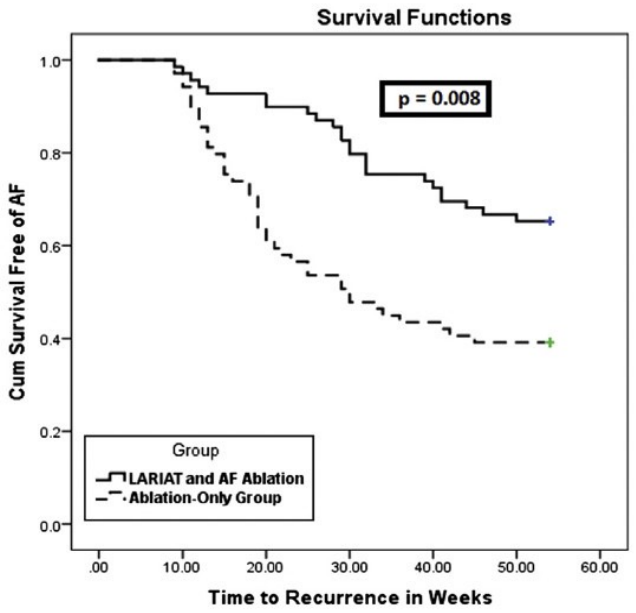
The LAALA-AF Registry

TABLE 2 Procedural Characteristics and Outcomes

	LARIAT Group (n = 69)	Ablation-Only Group (n = 69)	Total (N = 138)	p Value
AF ablation procedure time, min	238 ± 30	218 ± 57	228 ± 47	0.011
Fluoroscopy time, min	42 ± 9	50 ± 18	48 ± 15	<0.001
Ablation time, min	49 ± 28	52 ± 16	51 ± 21	0.440
Moderate-to-severe LA scar	51 (74)	52 (75)	103 (75)	0.841
Extra-pulmonary vein ablation	31 (45)	36 (52)	66 (48)	0.394
Freedom from AF/AT at 12 months off AADs after 1 ablation procedure	45 (65)	27 (39)	72 (52)	0.002
Median time to recurrence, weeks	27 (12-37)	19 (11-25)	21 (11-28)	0.030
Repeat ablation in 12 months	11 (16)	23 (33)	34 (25)	0.018
Patients on AADs at 12-month follow-up	9 (13)	15 (22)	24 (17)	0.177
Freedom from AF/AT at 12 months off AADs after >1 ablation procedure	53 (77)	40 (58)	93 (67)	0.018

Values are mean ± SD, n (%), or median (interquartile range).
AF = atrial fibrillation; AT = atrial tachycardia; other abbreviations as in Table 1.

FIGURE 3 Survival Analysis Using a Kaplan-Meier Curve of the Primary Outcome in Both Groups



AF = atrial fibrillation; Cum = cumulative.

Lakkireddy DR, et al. *JACC Clin Electrophysiol*. 2015;1(3):153-160.

AMAZE

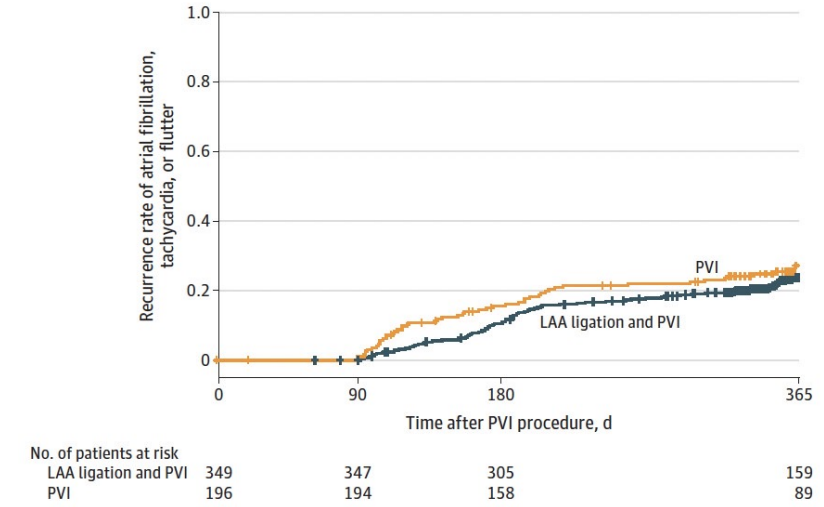
JAMA | Original Investigation

Pulmonary Vein Isolation With or Without Left Atrial Appendage Ligation in Atrial Fibrillation
The aMAZE Randomized Clinical Trial

Table 2. Primary Outcomes[a]

Outcome	LAA ligation plus PVI (n = 378)[b]	PVI (n = 198)[b]	Difference (bayesian 95% credible interval)	Posterior probability
Bayesian-estimated primary effectiveness through 365 d, %[c]	64.3	59.9	4.3 (−4.2 to 13.2)	0.835
Primary effectiveness rate, No./total No. (%)	211/331 (63.7)	108/182 (59.3)		
Bayesian-estimated primary safety at 30 d, %[d]	3.4		(2.0 to 5.0)	1
Primary safety, No./total No. (%)[e]	12/372 (3.2)			
Bleeding	8 (2.2)			
Serious injury to cardiac/related structure requiring surgical intervention	3 (0.8)			
Vascular injury requiring surgical treatment, hospital admission, or PRBC transfusion	1 (0.3)			

Figure 2. Freedom From Recurrent Atrial Arrhythmias by Treatment Group After Ablation

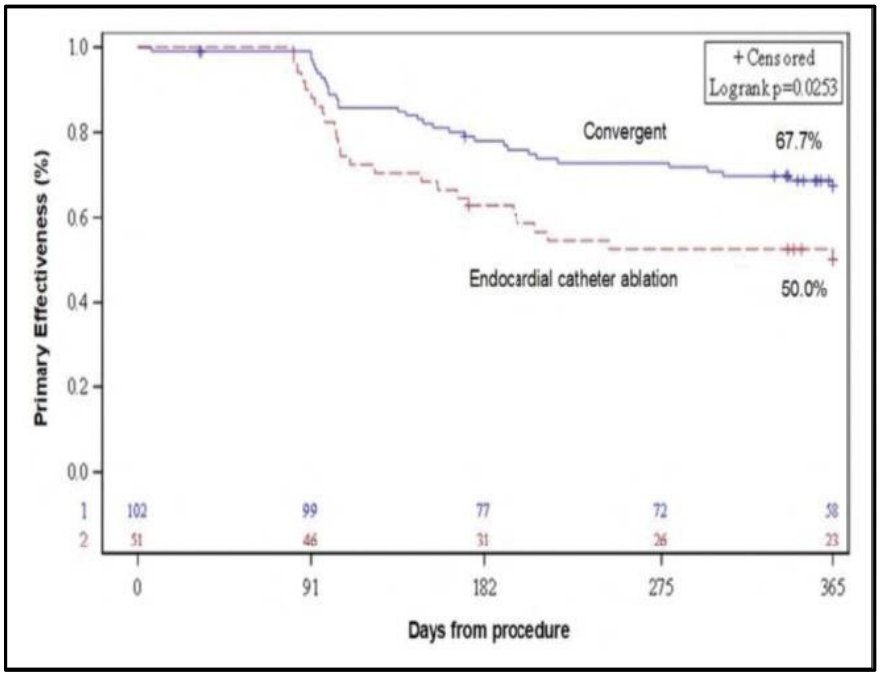


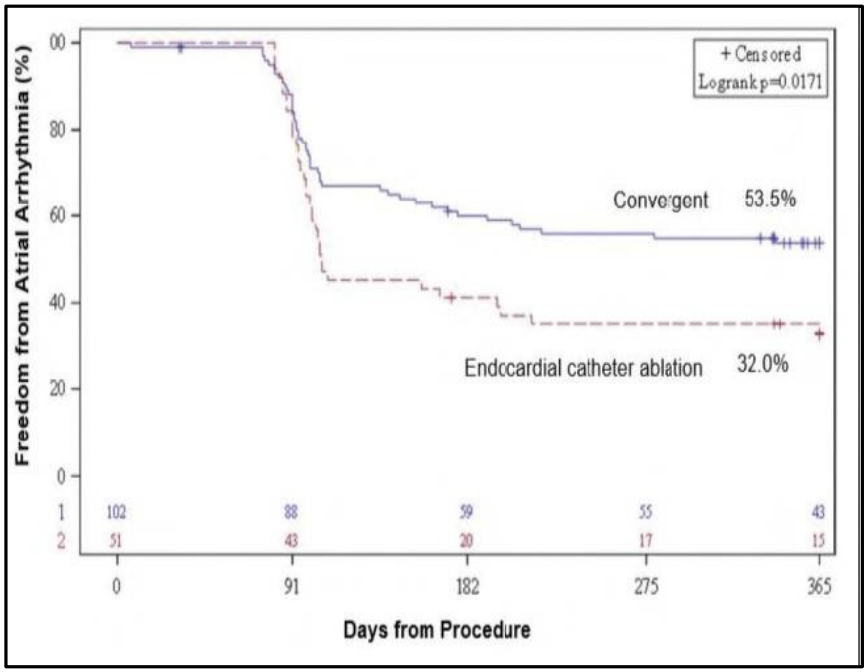
Lakkireddy DR, et al. *JAMA*. 2024;331(13):1099-1108.

CONVERGE

Hybrid Convergent Procedure for the Treatment of Persistent and Long-Standing Persistent Atrial Fibrillation

Results of CONVERGE Clinical Trial





DeLurgio DB, et al. *Circ Arrhythm Electrophysiol*. 2020;13(12):e009288.

Pulse Field Ablation for Persistent Atrial Fibrillation

Does Posterior Wall Isolation Improve Outcomes?

TABLE 1 Summary of Randomized Studies Evaluating Efficacy of PVI+PW in PerAF

Study/First Author, Year	Study Design	Patient Population	Ablation Type	Efficacy Endpoint	Efficacy
ADVANTAGE-AF, 2025[1]	Single-arm, multicenter trial	Persistent AF	PFA	Acute success and postblanking 1-y freedom from atrial tachyarrhythmia recurrence, redo ablation, cardioversion, or antiarrhythmic drug escalation	63.5%
Anter et al,[12] 2024	Randomized clinical trial	Persistent AF	Dual PFA/RFA	Freedom from acute procedural failure and repeat ablation at any time, plus arrhythmia recurrence, drug initiation or escalation, or cardioversion after a 3-mo blanking period	73.8%
Schiavone et al,[13] 2024	Prospective registry	Persistent AF	PFA	Freedom from arrhythmic recurrence after the 90-d blanking period (mean time to recurrence of 223 ± 100 d)	83.5%
Kordic et al,[14] 2024	Retrospective observational study	Persistent and long-standing persistent AF	PFA	Freedom from long-term AF/AFL/AT recurrence assessment based on an analysis of medical history; 24-h Holter ECGs at 3, 6, and 12 mo postablation; and 12-lead ECGs recorded during symptomatic episodes or visits	45.7%
CAPLA, 2023[4]		Persistent AF	RFA	Freedom from any documented atrial arrhythmia longer than 30 s without antiarrhythmic medications as assessed by frequent cardiac monitoring or from the downloaded data of recorded arrhythmia episodes from implanted cardiac rhythm devices	52.4%
CONVERGE, 2020[15]	Randomized clinical trial	Persistent and long-standing persistent AF	Hybrid surgical	12-mo freedom from atrial arrhythmia irrespective of antiarrhythmic drugs	76.8%
PRECEPT, 2020[16]	Prospective, nonrandomized trial	Persistent AF	RFA	Freedom from documented recurrence of AF/AFL/AT episodes of 30 s or longer duration	61.7%
Maclean et al,[17] 2020	Propensity-score matching	Long-standing persistent AF	Hybrid surgical	AF free at 12 mo on antiarrhythmic drugs	60.5%
Kress et al,[18] 2017	Propensity-score matching	Persistent and long-standing persistent AF	Hybrid surgical	16-mo AF-free survival	72%

ADVANTAGE-AF = A Prospective Single Arm Open Label Study of the FARAPULSE Pulsed Field Ablation System in Subjects with Persistent Atrial Fibrillation; AF = atrial fibrillation; AFL = atrial flutter; AT = atrial tachycardia; CAPLA = Effect of Catheter Ablation Using Pulmonary Vein Isolation With vs Without Posterior Left Atrial Wall Isolation on Atrial Arrhythmia Recurrence in Patients With Persistent Atrial Fibrillation: The CAPLA randomized clinical trial; CONVERGE = Convergence of Epicardial and Endocardial Ablation for the Treatment of Symptomatic Persistent AF; ECG = electrocardiogram; PFA = pulse field ablation; PRECEPT = Prospective Review of the Safety and Effectiveness of the THERMOCOOL SMARTTOUCH SF Catheter Evaluated for Treating Symptomatic PersistenT AF; RFA = radiofrequency ablation.

Ahmad A, Doshi RN. *J Am Coll Cardiol.* 2025;85(17):1679-1681.

ROK-AF

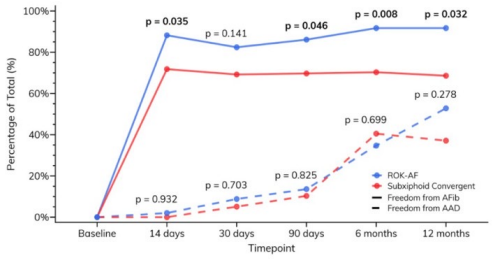
RESULTS: ROK Hybrid Ablation

ROK-AF

Outcome Metric	ROK-AF Group	Subxiphoid Group	Key Difference / Note
Freedom from AF at 12 months	91.7%	68.6%	Significant improvement (p=0.032)
Median Hospital Stay	2 days	3 days	Shorter stay (p<0.001)
% Discharged within 24h	48%	13%	270% improvement
Hospital LOS >2 days	30%	63%	53% reduction
Hospital LOS >3 days	13%	51%	75% reduction
Major Adverse Events	18.8%	18.8%	Equal
Freedom from AAD at 12 months	76.5%	60.0%	ROK-AF advantage
Hospital Mortality	0%	2.5%	Lower in ROK-AF
Left Atrial Appendage Occlusion Rate	100%	95%	Both groups high
Cardiovascular Hospitalization	9.5%	20%	Significantly reduced in ROK-AF

Khalpey Z., Kumar, U., Phillips, T., Adam, U., Krauthammer, Y., Stevens, K., Siefert, M., Patibandla, S., Kamik, A., Sadhu, A., Sheikh, I., Beshai, J., Riggio, D., Mattioni, T., Bhutta, J., Sidiqi, I., Hasan, M., Mann, R., Rizk, D., Patel, T., Burke, R., Kleinhans, A., Doshi, R. (2025). The ROK Procedure: Superior Outcomes with the Convergent Plus Lesion Set and a Platform for Future IDE Evaluation. European Journal of Cardio-Thoracic Surgery. [Accepted for publication].

Figure 1 – Freedom from atrial fibrillation and from antiarrhythmic drugs.



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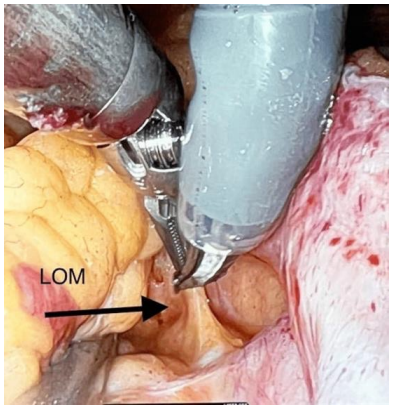

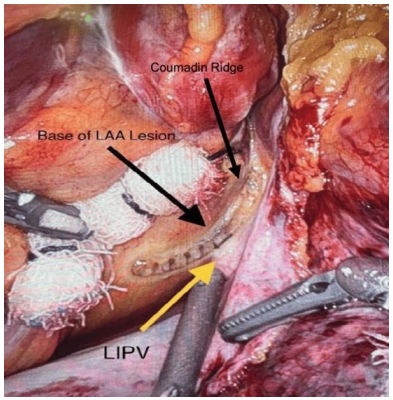

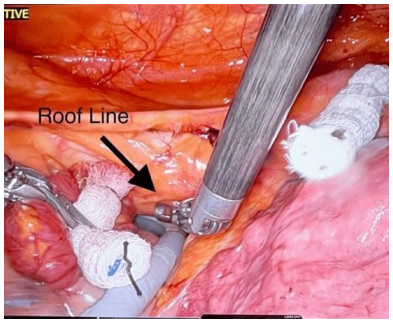

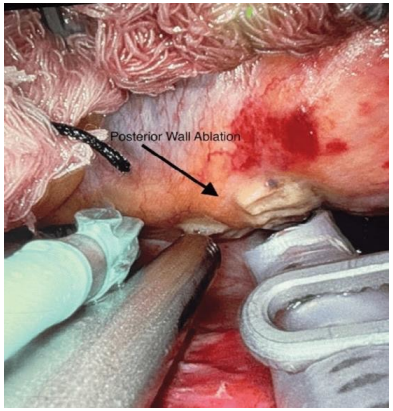

Key Learning Points

- "Occlusion" vs "exclusion": Depends on goal of therapy and overall risk/benefit
- Robust data supporting occlusion for improving risk of bleeding for stroke mitigation
- Robust data with concomitant procedure
- More data needed for catheter-based exclusion and concomitant
- The "convergent" procedure is a concomitant procedure!

Thank you

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