Concomitant Ablation of Atrial Fibrillation and Left Atrial Appendage Closure

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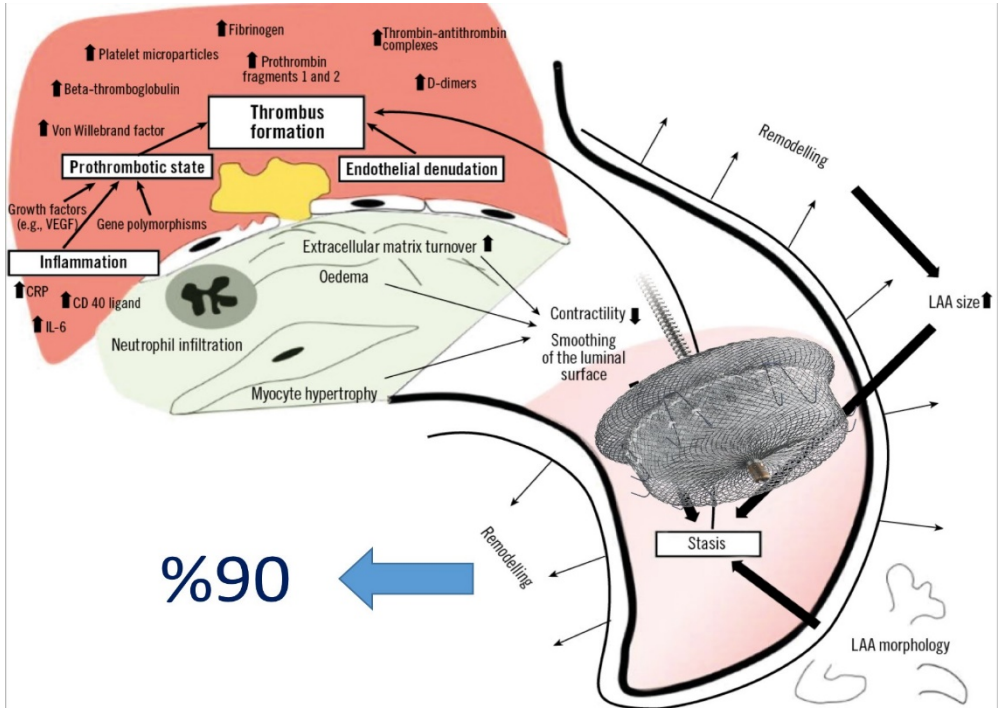
Disclosures

- *Recipient lectures' fee from Abbott Medical, Boston Scientific, Haemonetics*
- *Recipient tutoring, proctoring fees from Abbott Medical, Medtronic Inc, Biosense&Webster, Boston Scientific*
- *Member of Advisory Board of Abbott Medical, Medtronic, Boston Scientific*

LAA Occlusion: Why?

***Embolisation** of thrombotic material from the LAA has been witnessed and is the likely underlying mechanism for many (but not all) strokes. **Stasis, changes in the atrial geometry, and specific LAA morphologies**, including the inner surface on a macroscopic and microscopic level, and an unfavourable haemostatic milieu potentially caused by inflammation, growth factors, diminution of nitric oxide, or activation of the renin-angiotensin-aldosterone system are all likely to contribute to thrombus formation and thereby stroke risk*

Unfavorable Anatomy



***Glikson M, et al.** ESC Scientific Document Group. EHRA/EAPCI expert consensus statement on catheter-based left atrial appendage occlusion - an update. Europace. 2020 Feb 1;22(2):184.*

Clinical Evidence

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Left Atrial Appendage Closure or Medical Therapy in Atrial Fibrillation

U. Landmesser,[1-3] C. Skurk,[1,2] P. Kirchhof,[4-6] T. Lewalter,[7] J. Hartung,[1,2] A. Rroku,[1] B. Pieske,[8] J. Brachmann,[9] I. Akin,[10] C. Jacobshagen,[11] B. Meder,[12,13] A. Zeiher,[14,15] S.D. Anker,[2,16] H. Thiele,[17] S. Blankenberg,[4,5] S. Massberg,[18,19] H. Schunkert,[19,20] N. Frey,[12,13] A. Joost,[5,21] M. Bergmann,[22] R.S. von Bardeleben,[23] T. Friede,[24,25] M. Placzek,[24,25] A. Suling,[26] K.G. Haeusler,[27] M. Endres,[2,28] K. Wegscheider,[5,26] L.-H. Boldt,[2,29] and I. Eitel,[5,21] for the CLOSURE-AF Trial Investigators*

ABSTRACT

Among patients with atrial fibrillation at high risk for stroke and bleeding, ***left atrial appendage closure was not noninferior to physician-directed best medical care with regard to a composite end point of stroke, systemic embolism, major bleeding, or cardiovascular or unexplained death.***

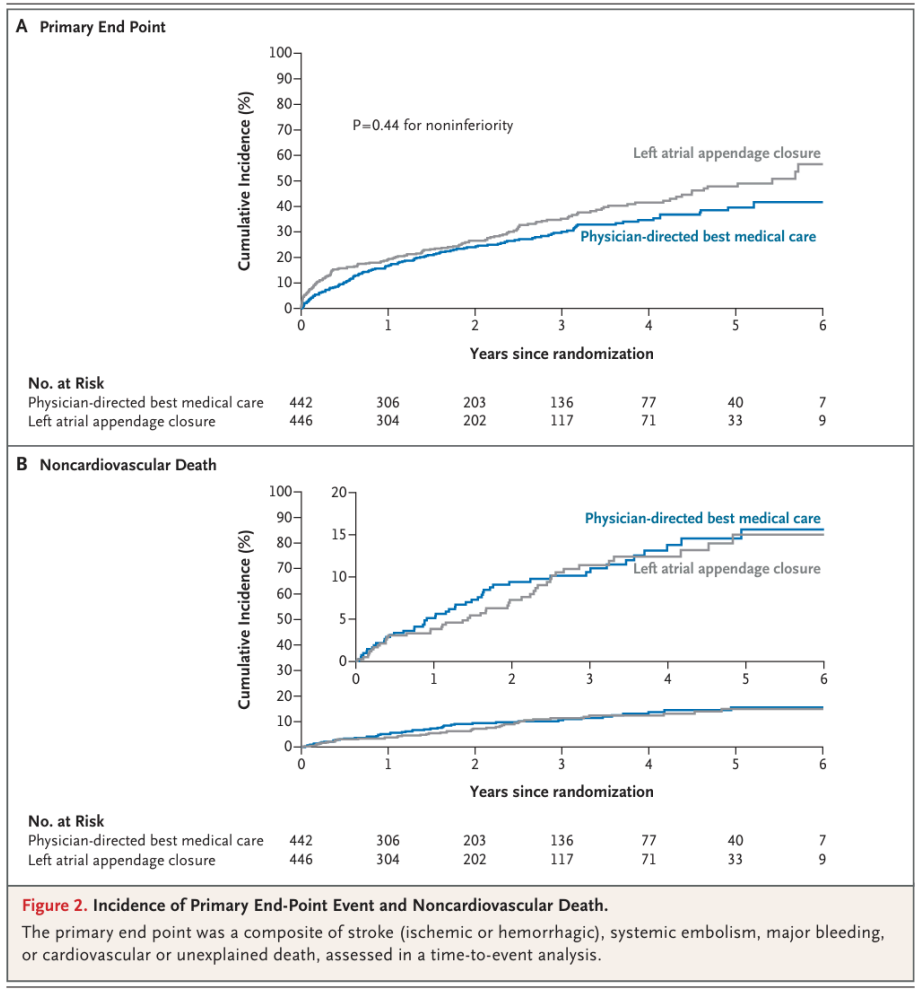


Figure 2. Incidence of Primary End-Point Event and Noncardiovascular Death.
The primary end point was a composite of stroke (ischemic or hemorrhagic), systemic embolism, major bleeding, or cardiovascular or unexplained death, assessed in a time-to-event analysis.

Clinical Evidence

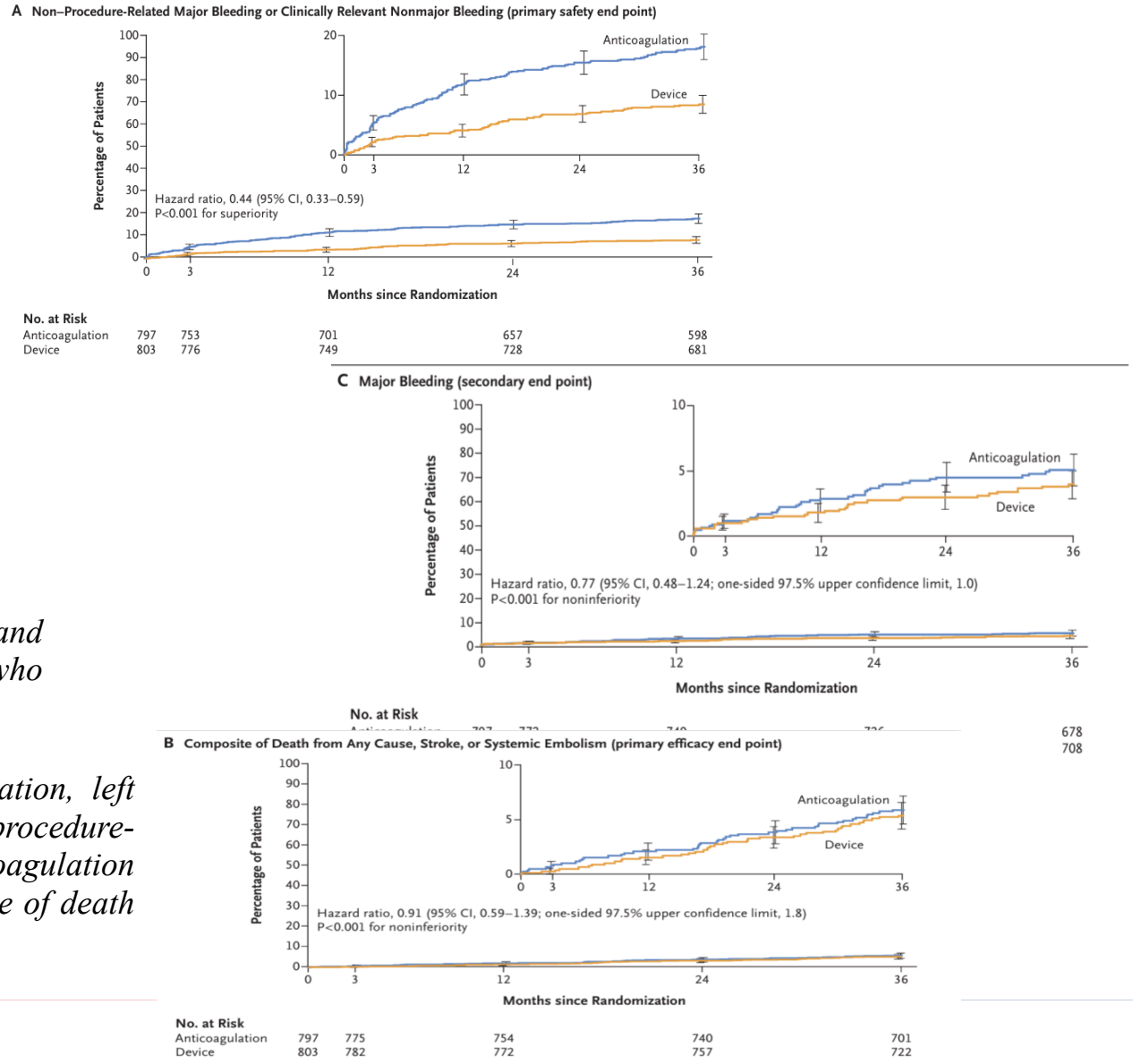
ORIGINAL ARTICLE

Left Atrial Appendage Closure after Ablation for Atrial Fibrillation

O.M. Wazni,[1] W.I. Saliba,[1] D.G. Nair,[2] E. Marijon,[3] B. Schmidt,[4] T. Hounshell,[5] H. Ebelt,[6] C. Skurk,[7] S. Oza,[8] C. Patel,[9] A. Kanagasundram,[10] A. Sadhu,[11] S. Sundaram,[12] J. Osorio,[13] G. Mark,[14] M. Gupta,[15] D.B. DeLurgio,[16] J. Olson,[17] J.E. Nielsen-Kudsk,[18] L.V.A. Boersma,[19,20] J.S. Healey,[21] K.P. Phillips,[22] F.M. Asch,[23] K. Wolski,[1] K. Roy,[24] T. Christen,[24] B.S. Sutton,[24] K.M. Stein,[24] and V.Y. Reddy,[25] for the OPTION Trial Investigators*

➢ *International randomized trial involving **1600 patients with AF** and elevated CHA2 DS2-VASc score (≥2 in men and ≥3 in women) and who underwent catheter ablation.*

*Among patients who underwent catheter-based atrial fibrillation ablation, left atrial appendage closure was associated with **a lower risk** of non–procedure-related major or clinically relevant nonmajor bleeding than oral anticoagulation and was **noninferior** to oral anticoagulation with respect to a composite of death from any cause, stroke, or systemic embolism at 36 months.*



Clinical Rationale

Why Concomitant LAAC plus AF catheter ablation?

Combining CA and LAAO in a "one-step" approach is safe and brings additional patients benefits in relieving symptoms.

Observational studies and meta-analysis found no significant difference in MACE and all-cause 30-day readmission rates among LAAO + CA patients compared with matched LAAO-only or CA-only patients.

ESC European Society of Cardiology

Europace (2023) **25**, 390–399
https://doi.org/10.1093/europace/euac181

CLINICAL RESEARCH

Combined atrial fibrillation ablation and left atrial appendage occlusion procedure in the United States: a propensity score matched analysis from 2016–2019 national readmission database

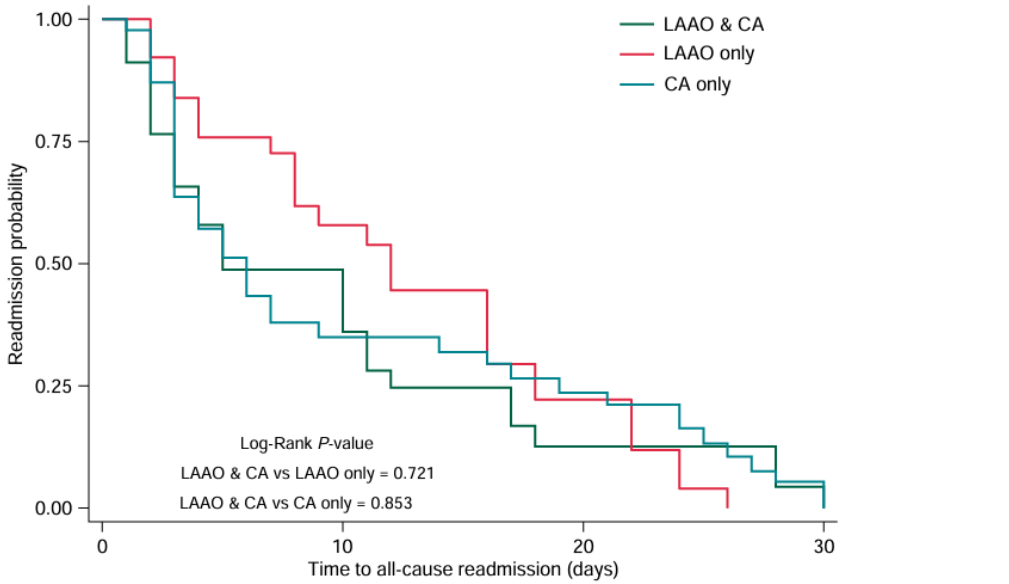
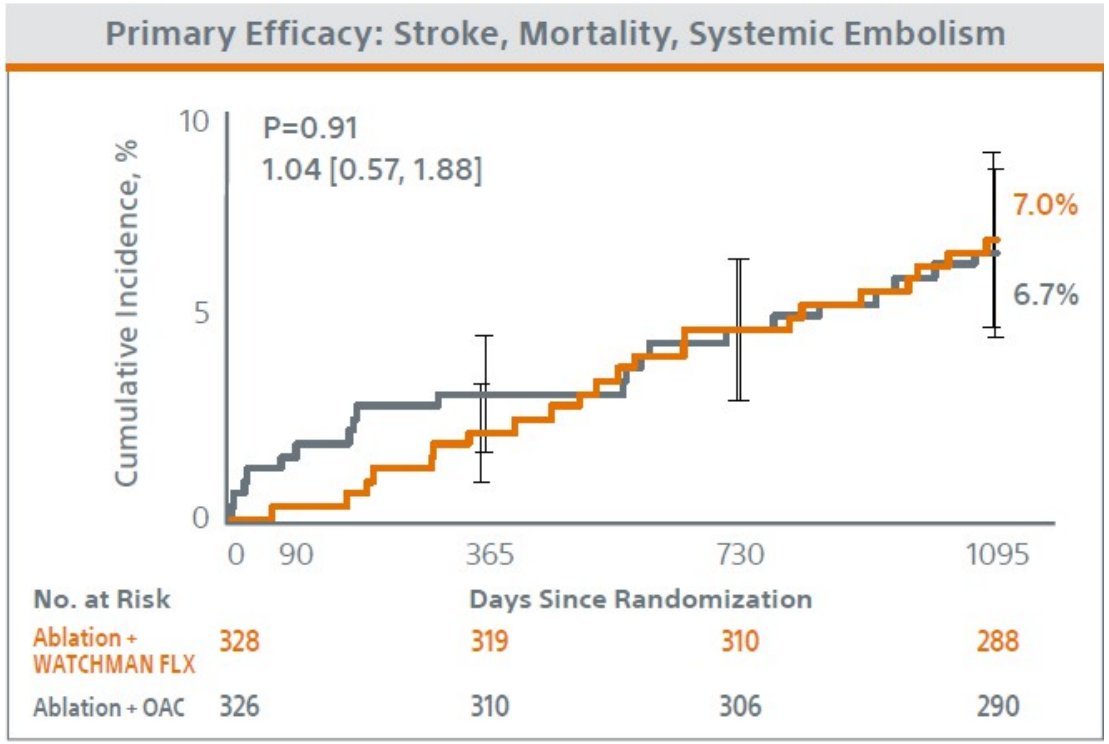
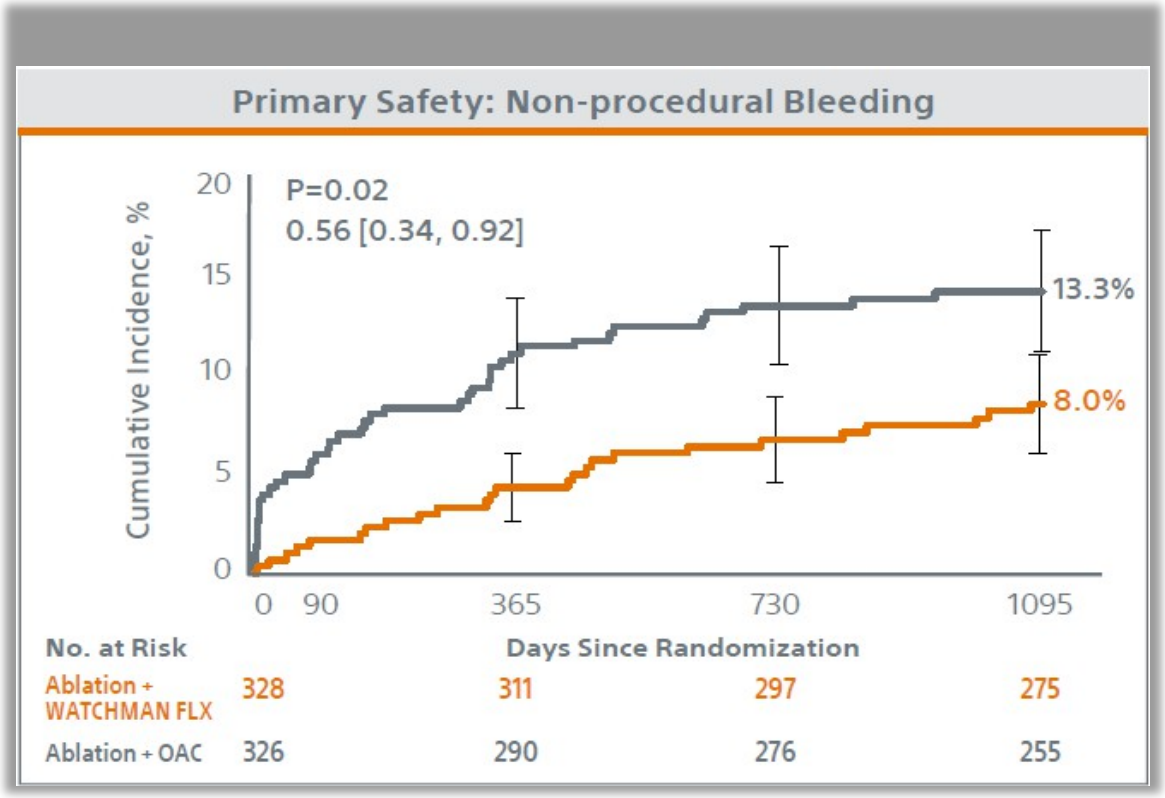


Figure 2 Kaplan-Meier curve for all-cause 30-day readmission risk stratified by study cohorts.

Concomitant or Sequential Subgroups Primary End-Points

Same outcomes regardless the approach



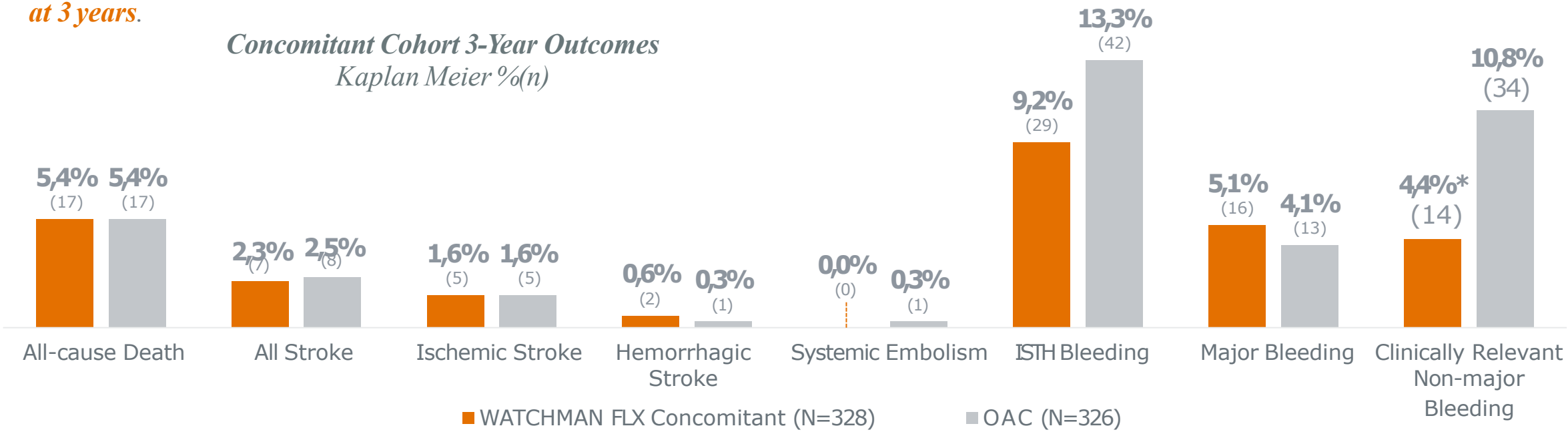


Saliba W, et al. Comparison of Left Atrial Appendage Closure and Oral Anticoagulation after Catheter Ablation for Atrial Fibrillation: Concomitant and Sequential Cohorts of the OPTION Randomized Controlled Trial. Late Breaking Clinical Trial, AF Symposium 2025

Concomitant & Sequential Cohort Subanalysis

Concomitant cohort

*Concomitant LAAC with WATCHMAN FLX demonstrated similar long-term stroke protection to anticoagulation, including a **1.6% ischemic stroke rate at 3 years**.*



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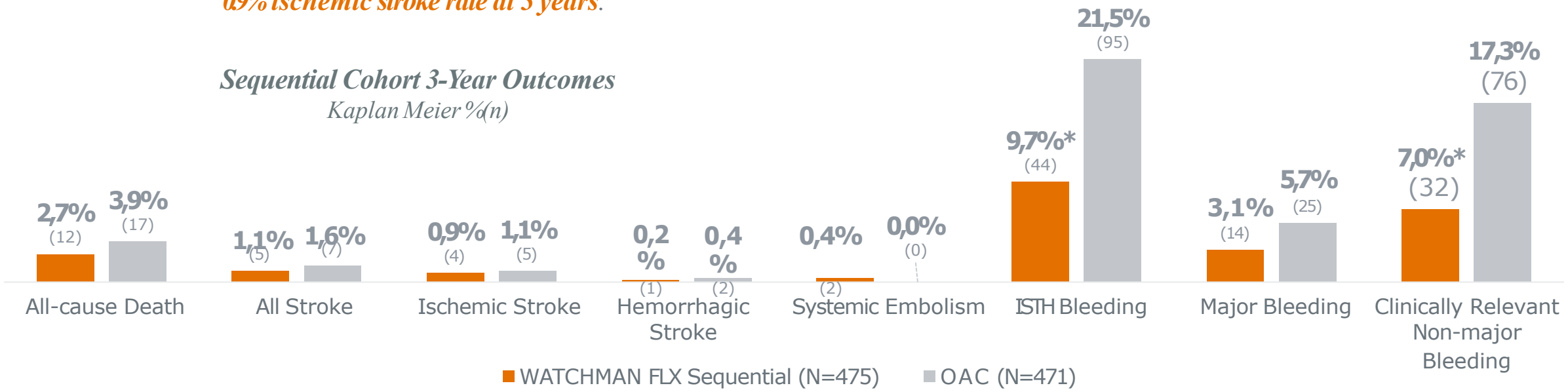
Concomitant & Sequential Cohort Sub-analysis

Sequential cohort

Sequential LAAC with WATCHMAN FLX demonstrated similar long-term stroke protection to anticoagulation, including a ***0.9% ischemic stroke rate at 3 years****.*

Sequential Cohort 3-Year Outcomes

Kaplan Meier %(n)

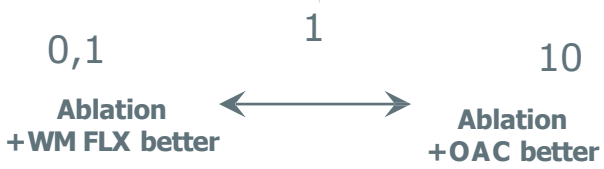


Saliba W, et al. Comparison of Left Atrial Appendage Closure and Oral Anticoagulation after Catheter Ablation for Atrial Fibrillation: Concomitant and Sequential Cohorts of the OPTION Randomized Controlled Trial. Late Breaking Clinical Trial, AF Symposium 2025.

OPTION AF Type Sub-analysis
Primary Endpoints by AF Type

Similar efficacy and superior safety outcomes demonstrated by WATCHMAN FLX at 36 months in the ***primary OPTION trial results are consistent within AF type subgroups***.

	Control	Device	Hazard Ratio [95% CI]	P value	Interaction P value
Primary Efficacy					0.98
Paroxysmal	**4.0% (19)**	**3.5% (16)**		0.69	
Persistent	**9.1% (25)**	**8.0% (25)**		0.65	
Primary Safety					0.45
Paroxysmal	**18.8% (90)**	**8.1% (37)**		<0.0001	
Persistent	**16.9% (47)**	**8.9% (28)**		0.0038	



Pattern of primary endpoint results seen for overall OPTION population were consistent by AF type

OPTION AF Type Sub-analysis
Conclusions & Key Takeaways

01 The OPTION AF type sub-analysis reaffirms the primary efficacy and safety outcomes within paroxysmal and persistent subgroups. Irrespective of paroxysmal or persistent AF, the WATCHMAN FLX Device demonstrated similar thromboembolic protection, with significantly reduced bleeding events at 36 months vs. OAC.

02 WATCHMAN FLX demonstrated low ischemic stroke rates in both paroxysmal and persistent AF patients (1.3% and 1.0%, respectively), despite fewer patients in sinus rhythm at baseline in persistent AF patients compared to OAC (52.8% vs. 66.3%; $p<0.05$).

03 AF type was not randomized, and therefore subgroup characteristics are not matched or directly comparable.

Why concomitant LAAC plus catheter ablation?

Current Clinical Evidence

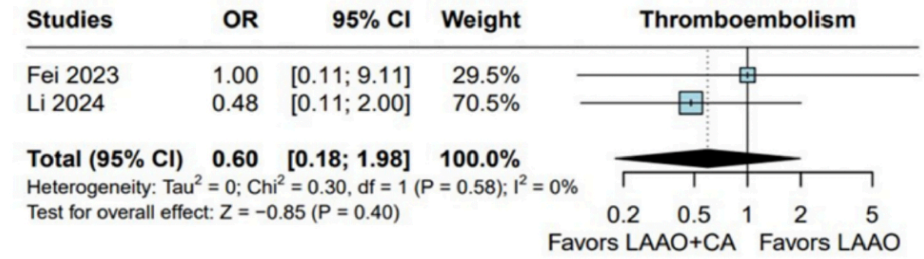
Combined left atrial appendage occlusion and catheter ablation for atrial fibrillation versus isolated left atrial appendage occlusion: A systematic review and meta-analysis

Mariana R.C. Clemente [a,*], Denilsa D.P. Navalha [b], Vinicius Bittar [c], Thomaz Alexandre Costa [d], Gabriel Prusch Fernandes [e], Livia Teixeira Martins Silva [f]

*MA published in **Feb 2025**: Eight studies comprising 51,802 patients, of whom 1375 (2.6 %) underwent combined LAAO and CA.*

*In this meta-analysis of observational studies, **combined LAAO and CA for AF was similar to isolated LAAO** in terms of efficacy and safety.*

A.



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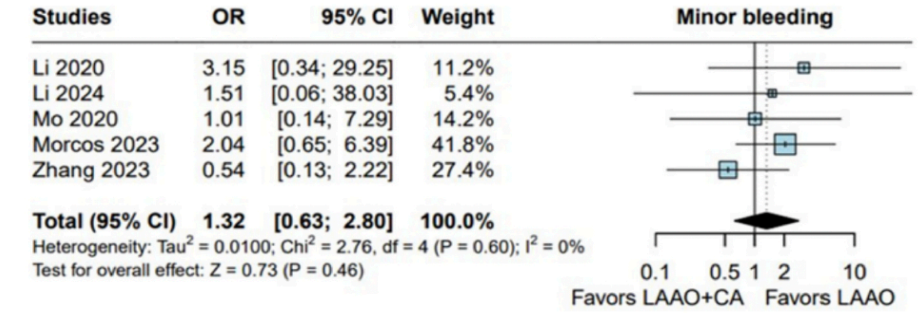

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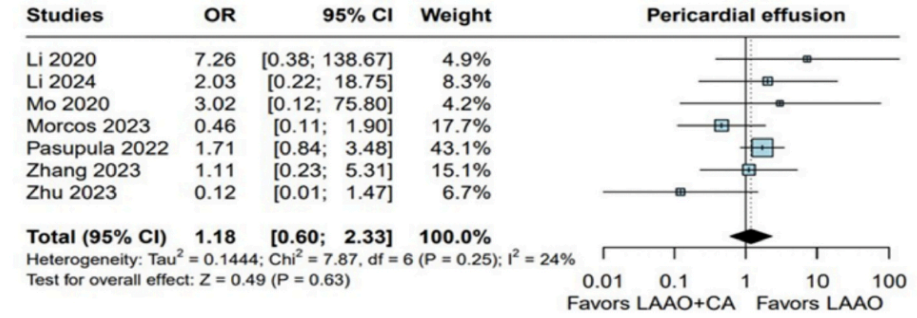

Radiofrequency or CB ablation + LAAC

Both radiofrequency ablation and CB ablation have demonstrated feasibility in a combined approach, significantly reducing ischemic and bleeding risks.

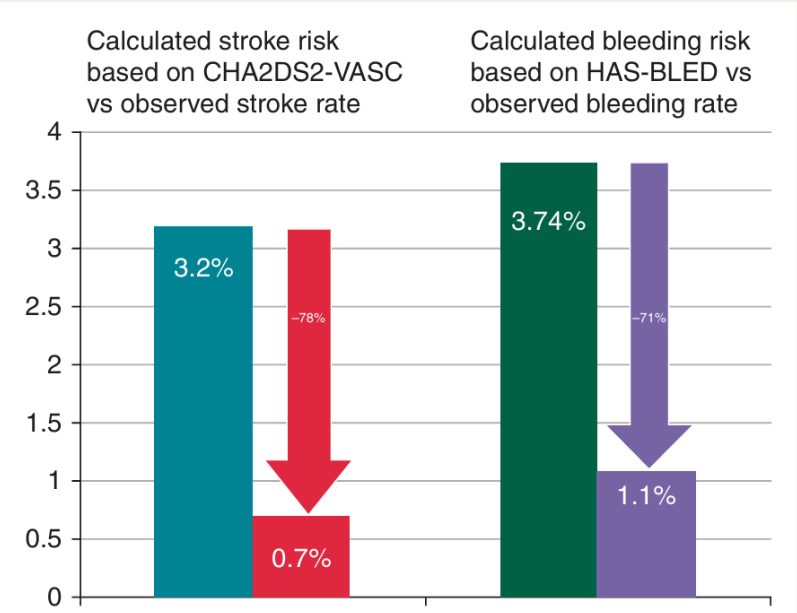

Figure 2 Efficacy of LAAC in reduction of stroke and bleeding. LAAC, left atrial appendage closure.

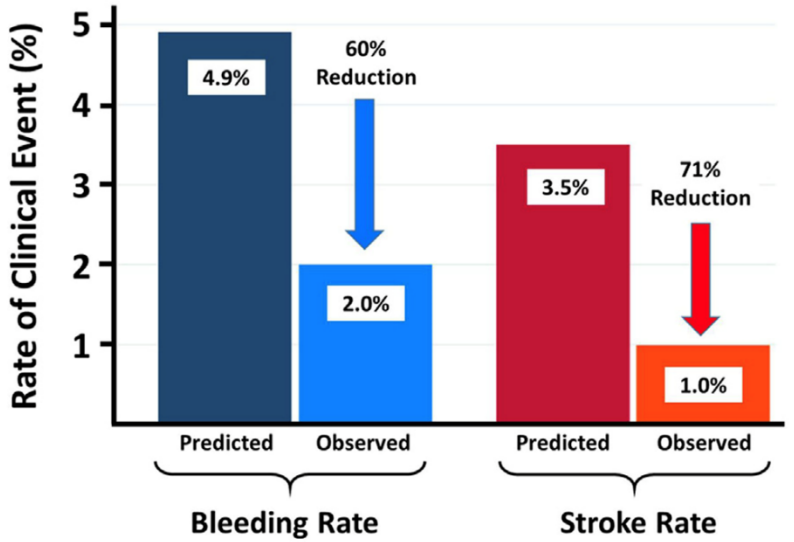

Figure 2 Annualized bleeding and stroke rate reduction from HAS-BLED and CHA_2DS_2-VASc score predicted rates in our population after the combined procedure.

Fassini G,…Tondo C, Heart Rhytm 2019

In LSPAF patients, LAA isolation may mitigate recurrence risk

PFA plus LAA occlusion

HeartRhythm
The Official Journal of the Heart Rhythm Society, The Cardiac Electrophysiology Society, and The Pediatric & Congenital Electrophysiology Society
Heart Rhythm Society SM

Pulsed field ablation with a pentaspline catheter and concomitant left atrial appendage closure for long-standing persistent atrial fibrillation: Comparison with a radiofrequency cohort

Marco Schiavone, MD, PhD,[1,12] Vincenzo Mirco La Fazia, MD,[2,12] Gaetano Fassini, MD,[1] Alessio Gasperetti, MD, PhD,[3] Sanghamitra Mohanty, MD,[2] Lorenzo Bianchini, MD,[1] Xiao-Dong Zhang, MD, PhD,[4] Massimo Moltrasio, MD,[1] Elio Zito, MD,[5] Marco Marino, MD,[6] Fabrizio Tundo, MD, PhD,[1] Giovanni B. Forleo, MD, PhD,[7] Luigi di Biase, MD, PhD, FHRS,[4] Andrea Natale, MD, FHRS,[2,8,9,10,13] Claudio Tondo, MD, PhD, FHRS[1,11,13]

OBJECTIVE

We evaluated outcomes of extensive PFA combined with LAAO, compared with radiofrequency ablation plus LAAO in patients with long-standing persistent AF.

Table 2 Baseline characteristics of patients after propensity score matching between the pulsed field ablation (PFA) and radiofrequency ablation (RF) groups.

	RF-Cohort (n = 45)	PFA-Cohort (n = 45)	*P*-value
Age, mean ± SD	69.6 ± 12.6	69.4 ± 8.8	0.915
Male sex, n (%)	32 (71.1)	29 (64.4)	0.499
BMI, median [IQR]	26.0 [24.3–31.0]	26.9 [23.2–29.0]	0.222
Hypertension, n (%)	31 (68.9)	29 (64.4)	0.655
HF, n (%)	5 (11.1)	7 (15.5)	0.535
CAD, n (%)	11 (24.4)	12 (26.7)	0.550
Diabetes, n (%)	4 (8.9)	7 (15.5)	0.334
CKD, n (%)	8 (17.8)	5 (11.1)	0.368
Previous TIA/Stroke, n (%)	11 (24.4)	10 (22.2)	0.803
Vasculopathy, n (%)	7 (15.6)	10 (22.2)	0.429
CHADS2-VASc, median [IQR]	3 [2–4]	3 [2–4]	1.000
HAS-BLED, median [IQR]	2 [2–3]	2 [2–3]	1.000
Left atrial volume (mL), median [IQR]	49 [45–60]	47 [40–56]	0.208
LVEF, mean ± SD	61.7 ± 5.4	60.3 ± 4.4	0.144
Redo ablation, n (%)	10 (22.2)	10 (22.2)	1.000

BMI = body mass index; HF = heart failure; TIA = transient ischemic attack.

METHODS

In this observational, multicenter, propensity-matched study, 90 consecutive patients with drug-refractory, long standing persistent AF underwent combined ablation (pulmonary veins, posterior wall, and LAA electrical isolation) plus LAAO (45 PFA, 45 RF). Matching was 1:1 based on age, CHA 2 DS 2 -VASc score, HAS-BLED score, and LAAO device. Follow-up was censored at 12 months.

In LSPAF patients, LAA isolation may mitigate recurrence risk

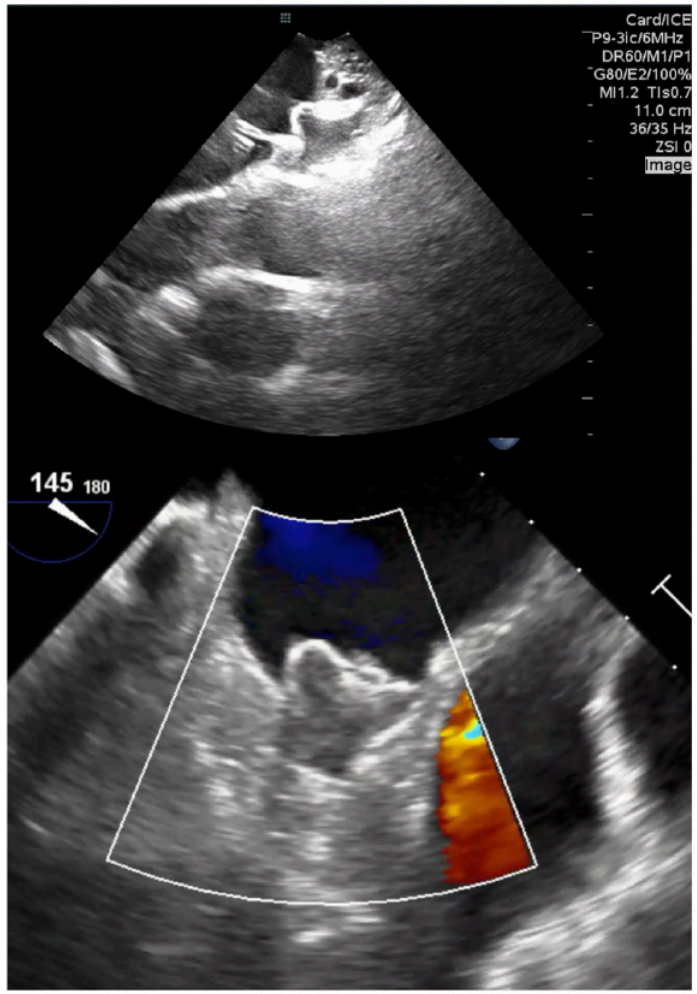

Figure 1
Intracardiac echocardiography showing Watchman device implantation (upper panel) and transesophageal echocardiography demonstrating complete sealing at 3-month follow-up in the same patient.

Table 3 Procedural characteristics of patients undergoing pulsed field ablation (PFA) vs radiofrequency ablation (RF) with concomitant left atrial appendage occlusion (LAAO).

	RF-Cohort (n = 45)	PFA-Cohort (n = 45)	*P*-value
LAA morphology, n (%)			0.976
Chicken wing	25 (55.5)	25 (55.5)	
Cauliflower	9 (20.0)	7 (15.6)	
Cactus	6 (13.3)	7 (15.6)	
Windsock	3 (6.8)	4 (8.9)	
Other	2 (4.4)	2 (4.4)	
Device type, n (%)			1.000
Amulet	6 (13.3)	6 (13.3)	
Watchman FLX	39 (86.6)	39 (86.6)	
Device size, median [IQR]			
Amulet	24.0 [22.0–28.0]		
Watchman	28.4 [20.0–35.0]		
Anesthesia type, n (%)			
Deep sedation	24 (53.3)		
General anesthesia	21 (46.6)		
Procedural time (min), ± SD	114.5 ± 11.5		
Fluoroscopy time (min), ± SD	26.7 ± 2.4		
Additional ablations beyond PVI, LAPW and LAA, n (%)	33 (73.3)		
Successful LAA closure device deployment, n (%)	45 (100)		
Multiple device deployment attempts, n (%)	6 (13.3)		
Need for device resizing, n (%)	2 (4.4)		
Periprocedural complication n (%)			
Vascular complications (any)	2 (4.4)		
Mild to moderate pericardial effusion	1 (2.2)		
Cardiac tamponade	0 (0)		
Device dislodgement	1 (2.2)		

ICE = intracardiac echo; LAAO = left atrial appendage occlusion.

Table 5 Univariable Cox regression analysis for predictors of arrhythmic recurrence. Data are presented as hazard ratios (HR) with 95% confidence intervals (CI).

	HR [CI]	p
Age	1.024 [0.980–1.071]	0.281
Male sex	0.994 [0.383–2.586]	0.991
AF duration >18 months	3.271 [1.148–9.324]	**0.027**
Radiofrequency ablation	2.333 [0.928–5.865]	0.072
BMI	0.926 [0.845–1.115]	0.257
Hypertension	1.769 [0.651–4.803]	0.263
Diabetes	0.444 [0.125–1.581]	0.210
CAD	1.422 [0.563–3.597]	0.456
LVEF	1.016 [0.968–1.067]	0.511

AF = atrial fibrillation; BMI = body mass index; CAD = coronary artery disease; CI = confidence interval; HR = hazard ratio; LVEF = left ventricular ejection fraction.

Schiavone … Tondo et al, Heart Rhythm 2026

In LSPAF patients, LAA isolation may mitigate recurrence risk

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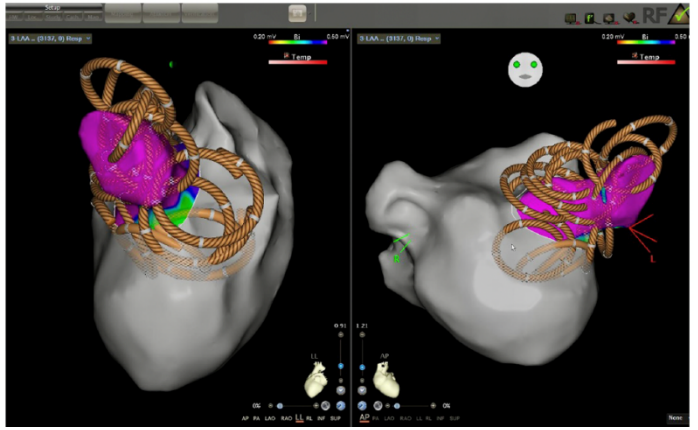

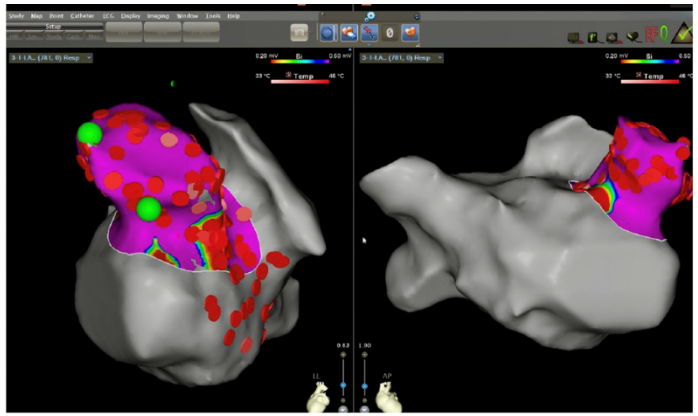

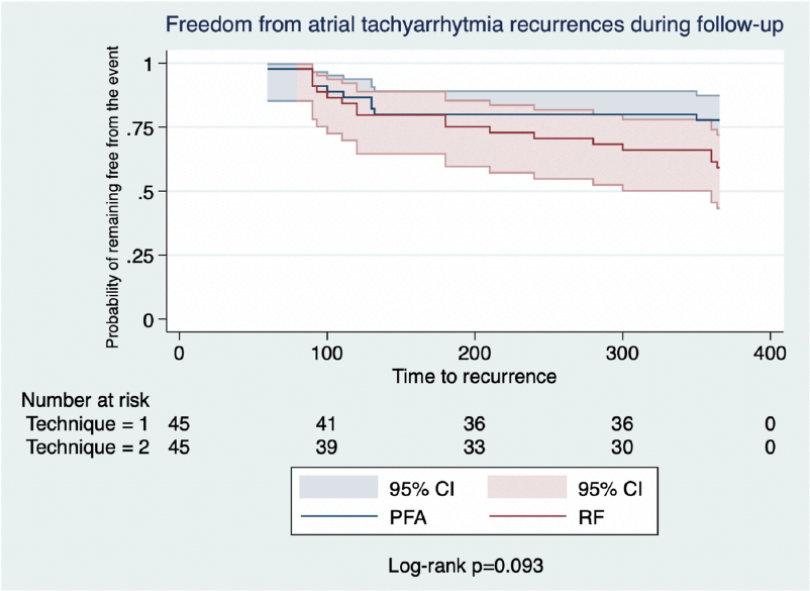

Table 4 Clinical outcomes at 12-month follow-up in patients undergoing pulsed field ablation (PFA) vs radiofrequency ablation (RF) with concomitant left atrial appendage occlusion (LAAO).

	RF-Cohort (n = 45)	PFA-Cohort (n = 45)	*P*-value
Atrial tachyarrhythmia recurrences during FU, n (%)	18 (40.0)	10 (22.2)	0.069
No AADs at last FU, n (%)	26 (57.8)	21 (46.6)	0.291
Redo ablation during follow-up, n (%)	4 (8.9)	1 (2.2)	0.360
Oral anticoagulants at last FU, n (%)	24 (53.3)	14 (31.1)	**0.033**
Leakage detected during follow-up (any), n (%)	11 (24.4)	4 (8.9)	**0.048**
Leakage >3 mm detected during follow-up, n (%)	2 (4.4)	0 (0)	0.494
Stroke during follow-up, n (%)	1* (2.2)	0 (0)	1.000
Major bleeding during follow-up, n (%)	2 (4.4)	0 (0)	0.494

*In patients with LSPAF, extensive PFA combined with LAAO resulted in **shorter procedures and similar safety compared with RF ablation.***
Overall PDL incidence was lower with PFA, that might be preferable for extensive LA ablations.

OPTION subanalysis – Do not forget bleeding risk!

ESC Europace (2026) 28, euag093
https://doi.org/10.1093/europace/euag093

CLINICAL RESEARCH

Percutaneous left atrial appendage closure following catheter ablation therapy of atrial fibrillation: outcomes stratified by bleeding risk – a sub-analysis of the OPTION study

Karen P. Phillips [1*], Devi G. Nair [2], Lucas V. A. Boersma [3], Rahul N. Doshi [4], Jeff S. Healey [5], Wael A. Jaber [6], Moussa Mansour [7], Vivek Y. Reddy [8], Claudio Tondo [9,10], Andrea Natale [11,12], Aravin Sukumar [13], Krystal Leger[13], Thomas Christen[13], Brad S. Sutton[13], and Oussama M. Wazni[6]

A significant reduction in primary safety bleeding events was noted in favor of LAAC across HAS-BLED subgroups, with ***more striking reductions noted for lower HAS-BLED scores of 0 and 1.***

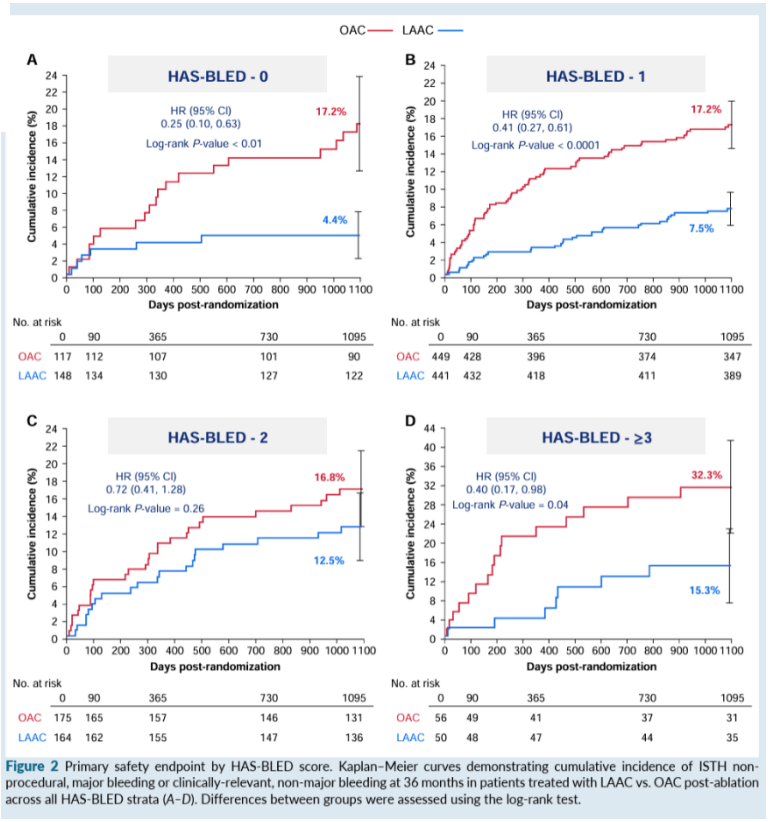

Figure 2 Primary safety endpoint by HAS-BLED score. Kaplan–Meier curves demonstrating cumulative incidence of ISTH non-procedural, major bleeding or clinically-relevant, non-major bleeding at 36 months in patients treated with LAAC vs. OAC post-ablation across all HAS-BLED strata (*A–D*). Differences between groups were assessed using the log-rank test.

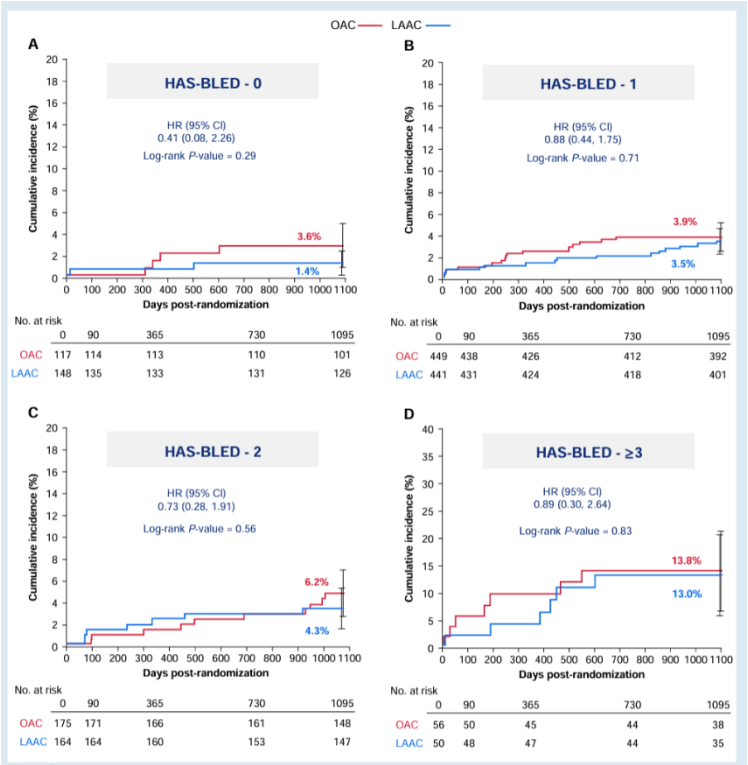

Figure 3 Secondary safety endpoint by HAS-BLED. Kaplan–Meier curves demonstrating cumulative incidence of major bleeding (procedural and non-procedure-related) at 36 months in patients treated with LAAC vs. OAC post-ablation across all HAS-BLED strata (*A–D*). Differences between groups were assessed using the log-rank test.

Cost-Effectiveness of Left Atrial Appendage Closure for Stroke Reduction in Atrial Fibrillation: Analysis of Pooled, 5-Year, Long-Term Data

Vivek Y. Reddy, MD; Ronald L. Akehurst, DSc; Meghan B. Gavaghan, MPH; Stacey L. Amorosi, MA; David R. Holmes Jr, MD

This present analysis uses the complete, 5-year pooled analysis of PROTECT AF and PREVAIL randomized controlled trial data to explore the cost-effectiveness of left atrial appendage closure relative to warfarin and nonwarfarin oral anticoagulants, whereas previously published US economic analyses have used interim data from the individual trials.

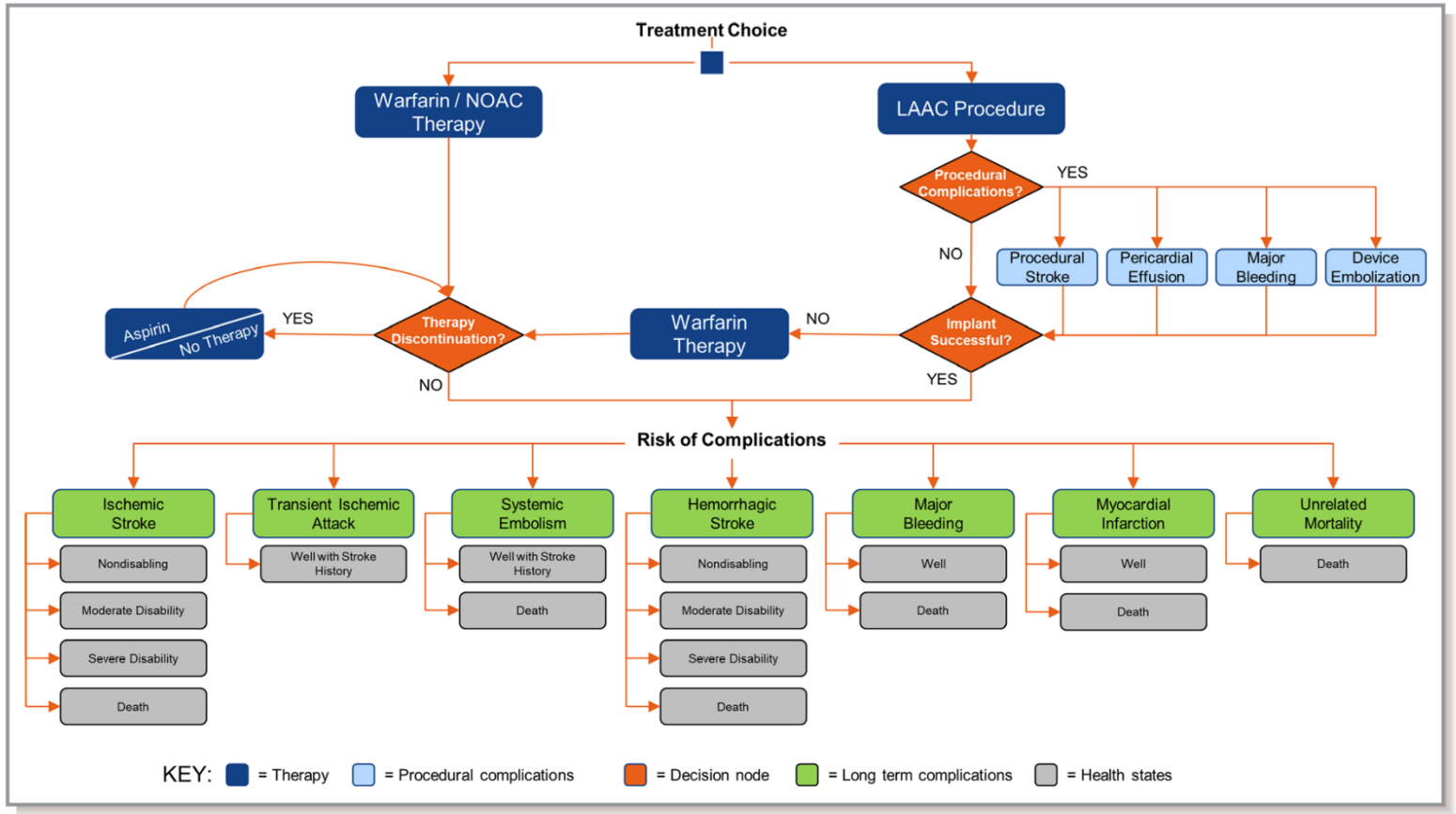

Figure 1. Model schematic depicting left atrial appendage closure (LAAC) and nonwarfarin oral anticoagulant (NOAC) patient pathways. Patient pathways for LAAC and NOAC.

Practical guide on left atrial appendage closure for the non-implanting physician: an international consensus paper

Tatjana Potpara [1,2], Marek Grygier [3], Karl Georg Häusler [4], Jens Erik Nielsen-Kudsk [5], Sergio Berti [6], Simonetta Genovesi [7,8], Eloi Marijon [9], Serge Boveda [10,11], Apostolos Tzikas [12,13], Giuseppe Boriani [14], Lucas V.A. Boersma [15], Claudio Tondo [16], Tom De Potter [17], Gregory Y.H. Lip [18,19], Renate B. Schnabel [20,21], Rupert Bauersachs [22,23], Marco Senzolo [24], Carlo Basile [25,26], Stefano Bianchi [27], Pavel Osmancik [28], Boris Schmidt [29], Ulf Landmesser [30], Wolfram Doehner [31,32,33], Gerhard Hindricks [34], Jan Kovac [35], and A. John Camm [36]*

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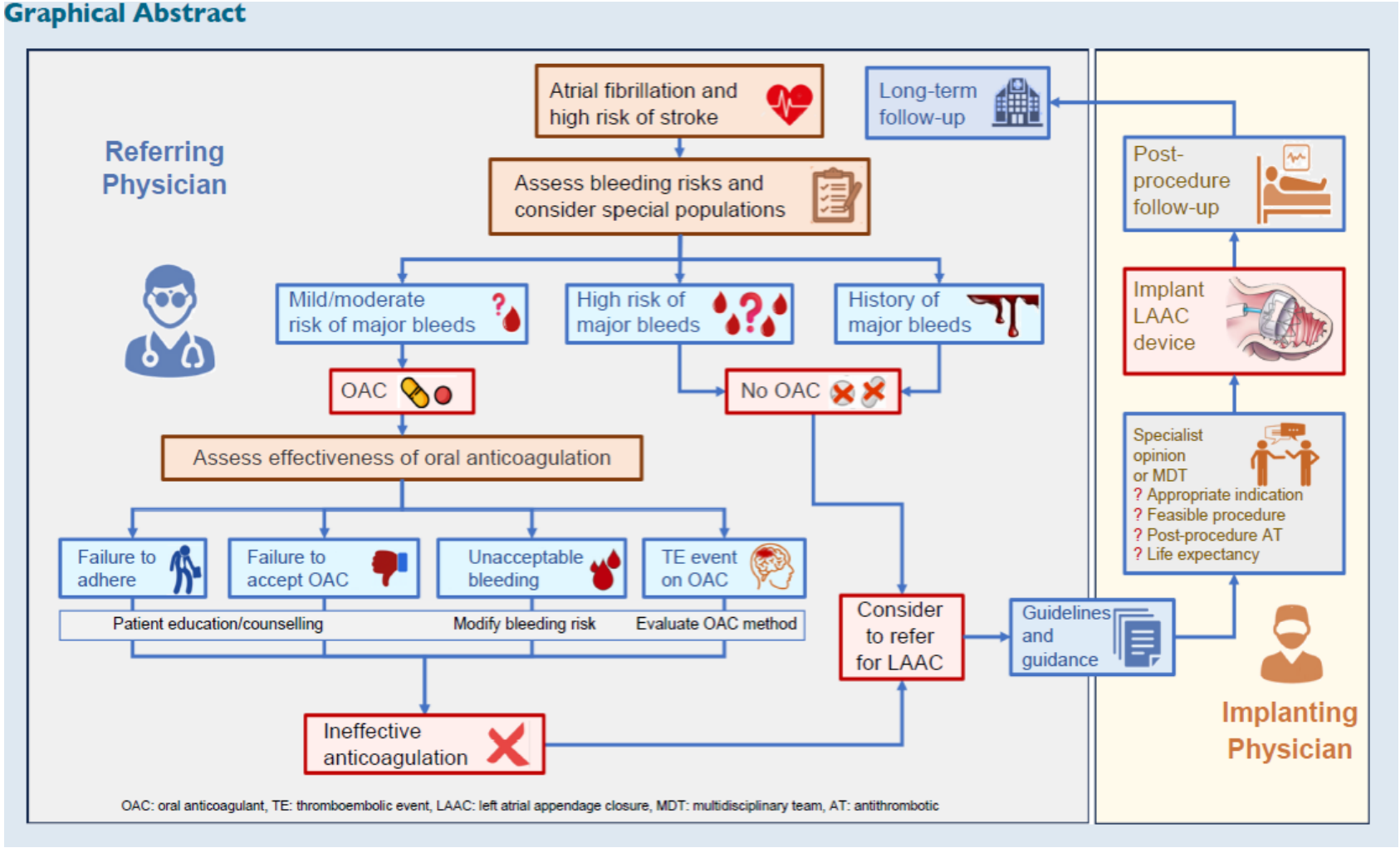
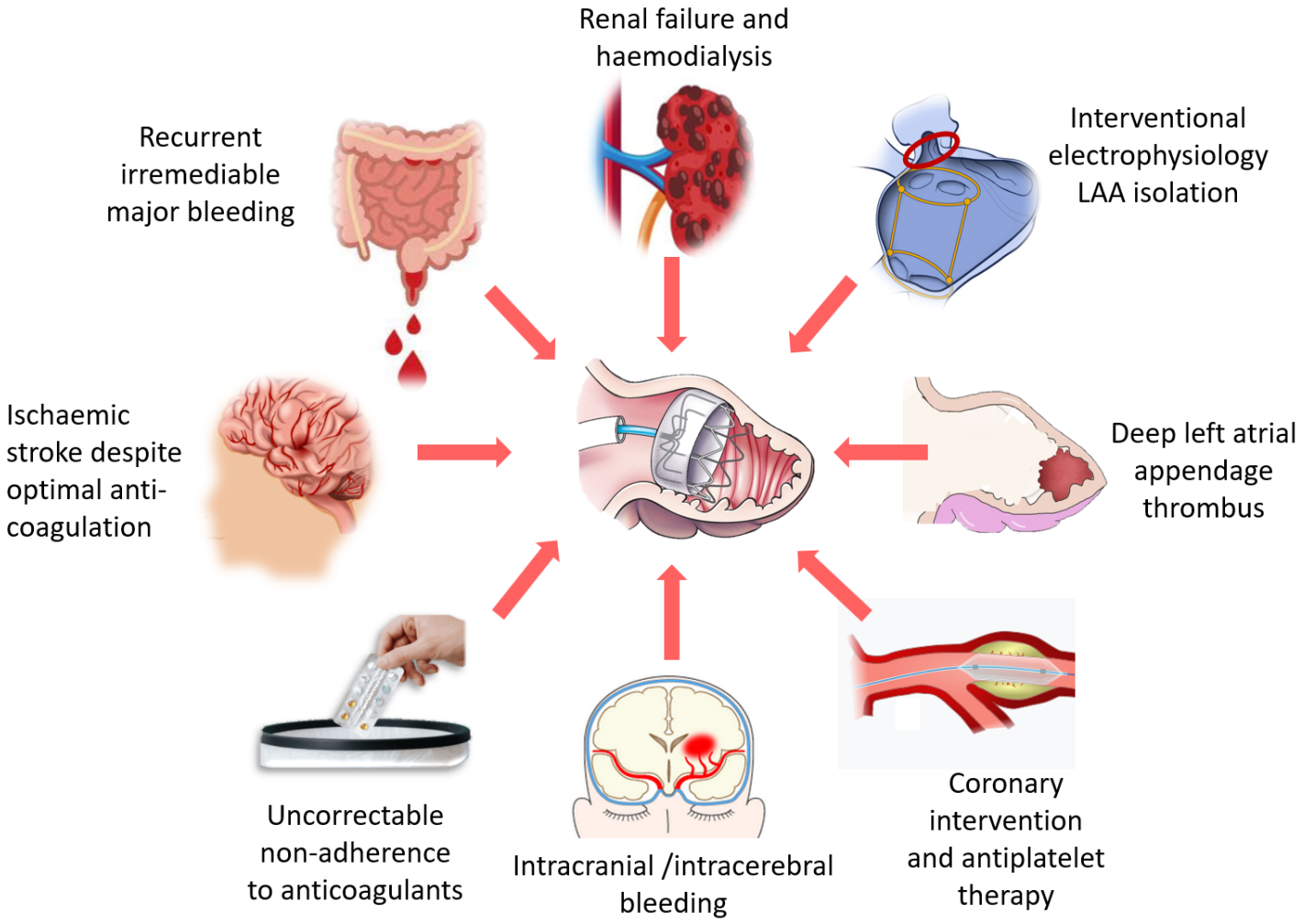
Graphical Abstract



Clinical populations where LAAC may be considered for patients with AF at-risk of stroke but refractory to or contraindicated for anticoagulation and when no otherwise satisfactory management is available



Final Remarks

Left atrial appendage closure (LAAC) appears to be cost-effective in the long term compared to oral anticoagulation (OAC), particularly in patients with contraindications to chronic OAC therapy.

However, confirmation from large-scale, long-term registry data is still needed to validate these findings.

PFA has the potential to overcome traditional challenges associated with other AF ablation techniques combined with LAAC, such as procedural efficiency, energy-related complications, and post-procedural leaks.

Adoption of a combined dedicated DRG (diagnosis-related group) for LAAC and AF ablation could support more efficient resource allocation while potentially reducing complication rates through streamlined care.

Policymakers worldwide should reevaluate reimbursement policies to facilitate broader access to combined procedures, thereby expanding LAAC indications after LAAEI.