



Left Atrial Appendage Occlusion and Beyond

CV Today Conference, Saturday, February 1, 2025

Disclosures



Boston Scientific –
Physician Advisory Board



Zoll – Speaker



St. Luke's Medical -
Medical Advisor

Objectives

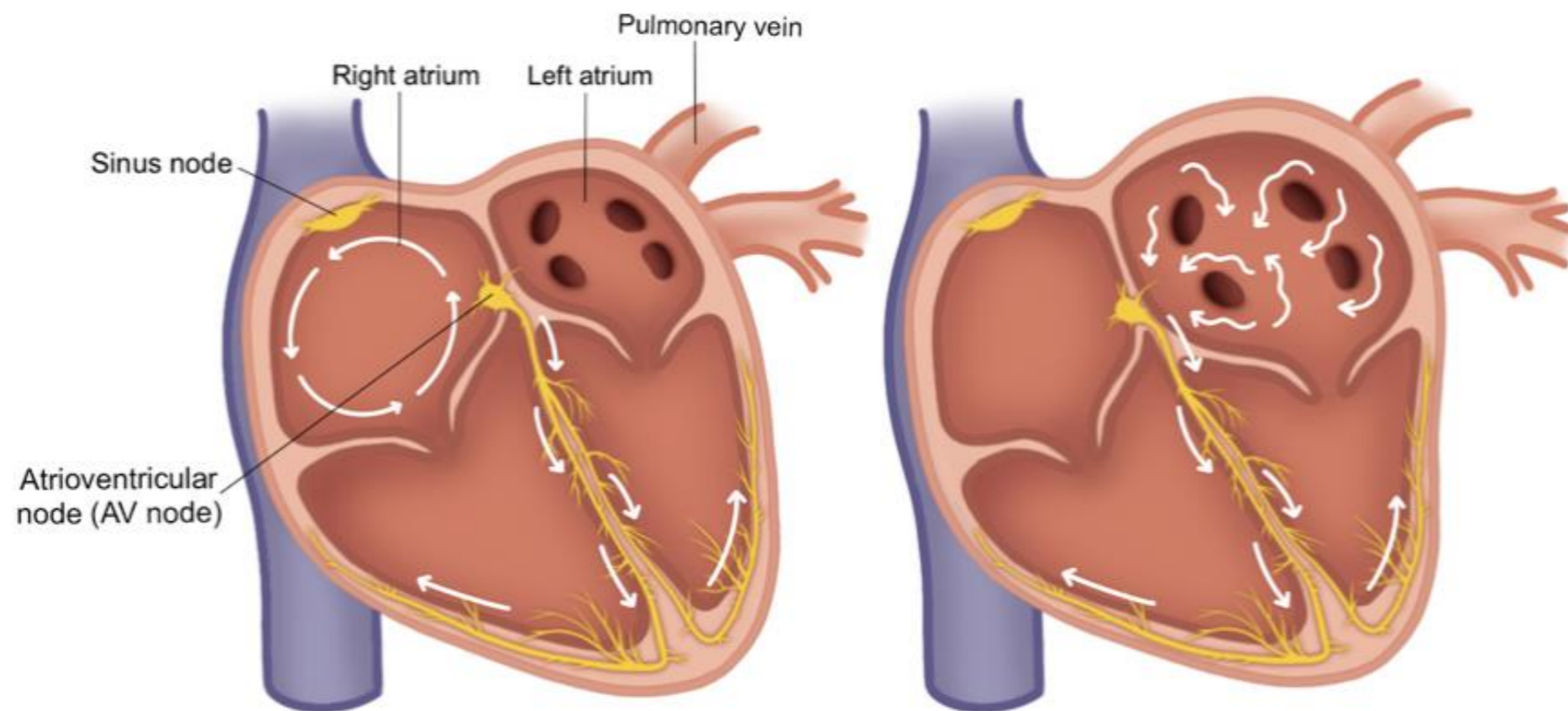
- Recognize the mechanism of atrial fibrillation
- Understand the role the LAA (left atrial appendage) plays in stroke
- CHA₂DS₂Vasc Score versus HAS-BLED Score
- Determine when a left atrial appendage occlusion strategy may be appropriate
- Know the different options for closure – percutaneous versus surgical
- Future of LAAO: current trials, expanding indications, new closure devices



Mechanism

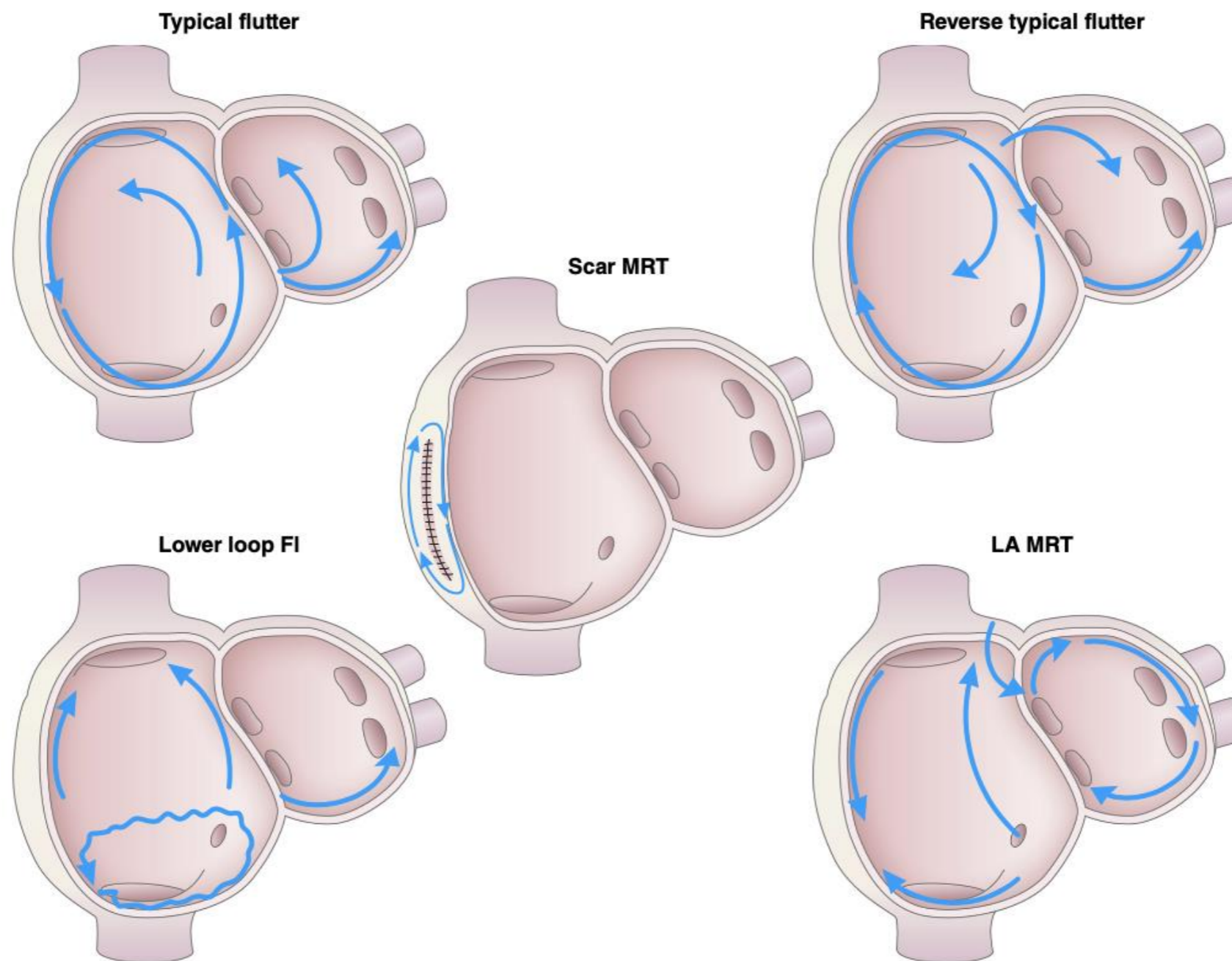
Atrial Flutter

Atrial Fibrillation



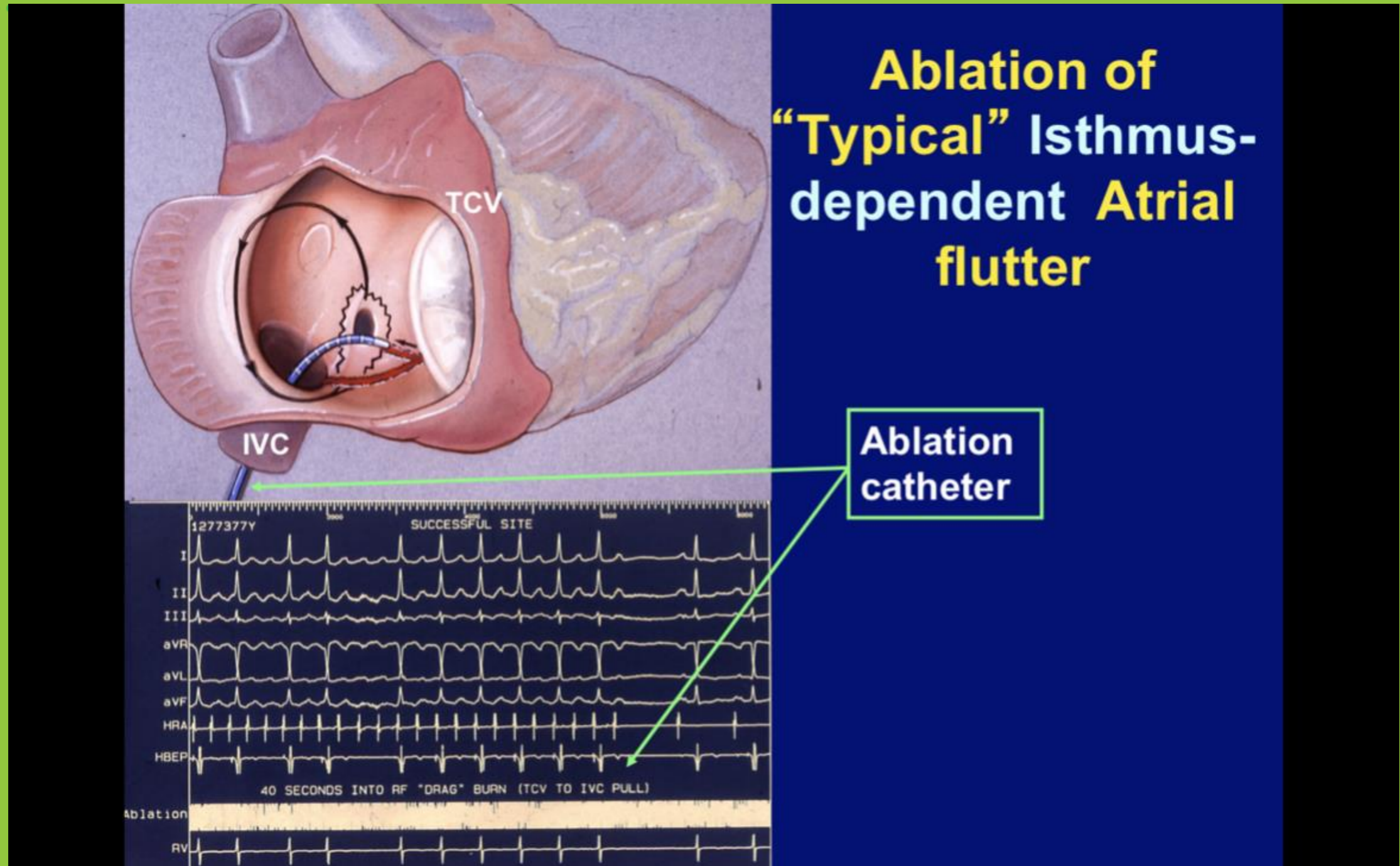
Atrial flutter - mechanism

FIGURE 6 Types of Atrial Flutter and Macroreentrant Atrial Tachycardia



The typical, reverse typical, and the lower-loop flutter all have the low right atrial isthmus incorporated in the flutter circuit. Other macroreentrant flutters include scar-mediated reentrant tachycardia and left mitral isthmus flutter. Modified with permission from Wellens et al.³ Copyright 2002 American Heart Association, Inc. FI indicates flutter; LA, left atrium; and MRT, macroreentrant.

Ablation of “typical atrial flutter”



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CLINICAL PRACTICE GUIDELINE

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

*Developed in Collaboration With and Endorsed by the American College of Clinical Pharmacy
and the Heart Rhythm Society*

Management of Atrial Fibrillation 2023 Guidelines



Long-term anti-thrombotic therapy guided by patient's risk of for thromboembolism, regardless of pattern of atrial fibrillation (paroxysmal, persistent, permanent) (Class I)



Non-valvular AF and CHA₂DS₂-VASc score \geq 2 should receive anticoagulation



Stronger consideration of AF catheter ablations

Table 6. Comparison of the CHADS₂ and CHA₂DS₂-VASc Risk Stratification Scores for Subjects With Nonvalvular AF

Definition and Scores for CHADS ₂ and CHA ₂ DS ₂ -VASc		Stroke Risk Stratification With the CHADS ₂ and CHA ₂ DS ₂ -VASc scores	
	Score		Adjusted stroke rate (% per y)
CHADS₂ acronym		CHADS₂ acronym*	
Congestive HF	1	0	1.9%
Hypertension	1	1	2.8%
Age ≥75 y	1	2	4.0%
Diabetes mellitus	1	3	5.9%
Stroke/TIA/TE	2	4	8.5%
Maximum Score	6	5	12.5%
CHA₂DS₂-VASc acronym		CHA₂DS₂-VASc acronym†	
Congestive HF	1	0	0%
Hypertension	1	1	1.3%
Age ≥75 y	2	2	2.2%
Diabetes mellitus	1	3	3.2%
Stroke/TIA/TE	2	4	4.0%
Vascular disease (prior MI, PAD, or aortic plaque)	1	5	6.7%
Age 65–74 y	1	6	9.8%
Sex category (i.e., female sex)	1	7	9.6%
Maximum Score	9	8	6.7%
		9	15.20%

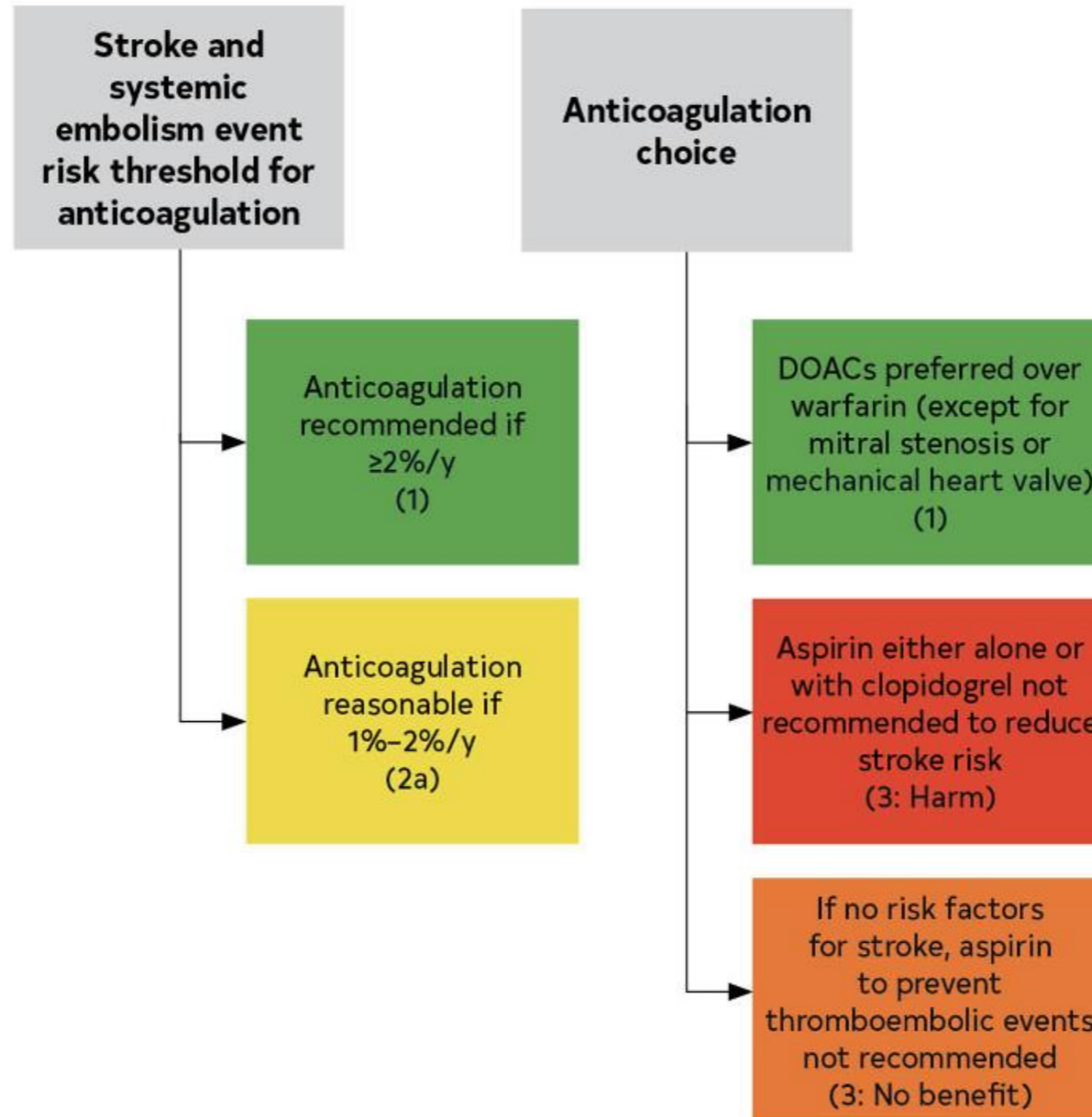
* These adjusted-stroke rates are based on data for hospitalized patients with AF and were published in 2001 (90). Because stroke rates are decreasing, actual stroke rates in contemporary nonhospitalized cohorts might vary from these estimates.

† Adjusted-stroke rate scores are based on data from Lip and colleagues (91). Actual rates of stroke in contemporary cohorts might vary from these estimates.

AF indicates atrial fibrillation; CHADS₂, Congestive heart failure, Hypertension, Age ≥75 years, Diabetes mellitus, Prior Stroke or TIA or Thromboembolism (doubled); CHA₂DS₂-VASc, Congestive heart failure, Hypertension, Age ≥75 years (doubled), Diabetes mellitus, Prior Stroke or TIA or thromboembolism (doubled), Vascular disease, Age 65–74 years, Sex category; HF, heart failure; LV, left ventricular; MI, myocardial infarction; PAD, peripheral artery disease; TE, thromboembolic; and TIA, transient ischemic attack (91, 92).

Anticoagulation

FIGURE 10 Antithrombotic Options in Patients With AF




Colors correspond to [Table 2](#). AF indicates atrial fibrillation; and DOAC, direct oral anticoagulant.



LAA Role in thromboembolism (TIA/CVA)

AF Creates Environment for Thrombus Formation in Left Atrium

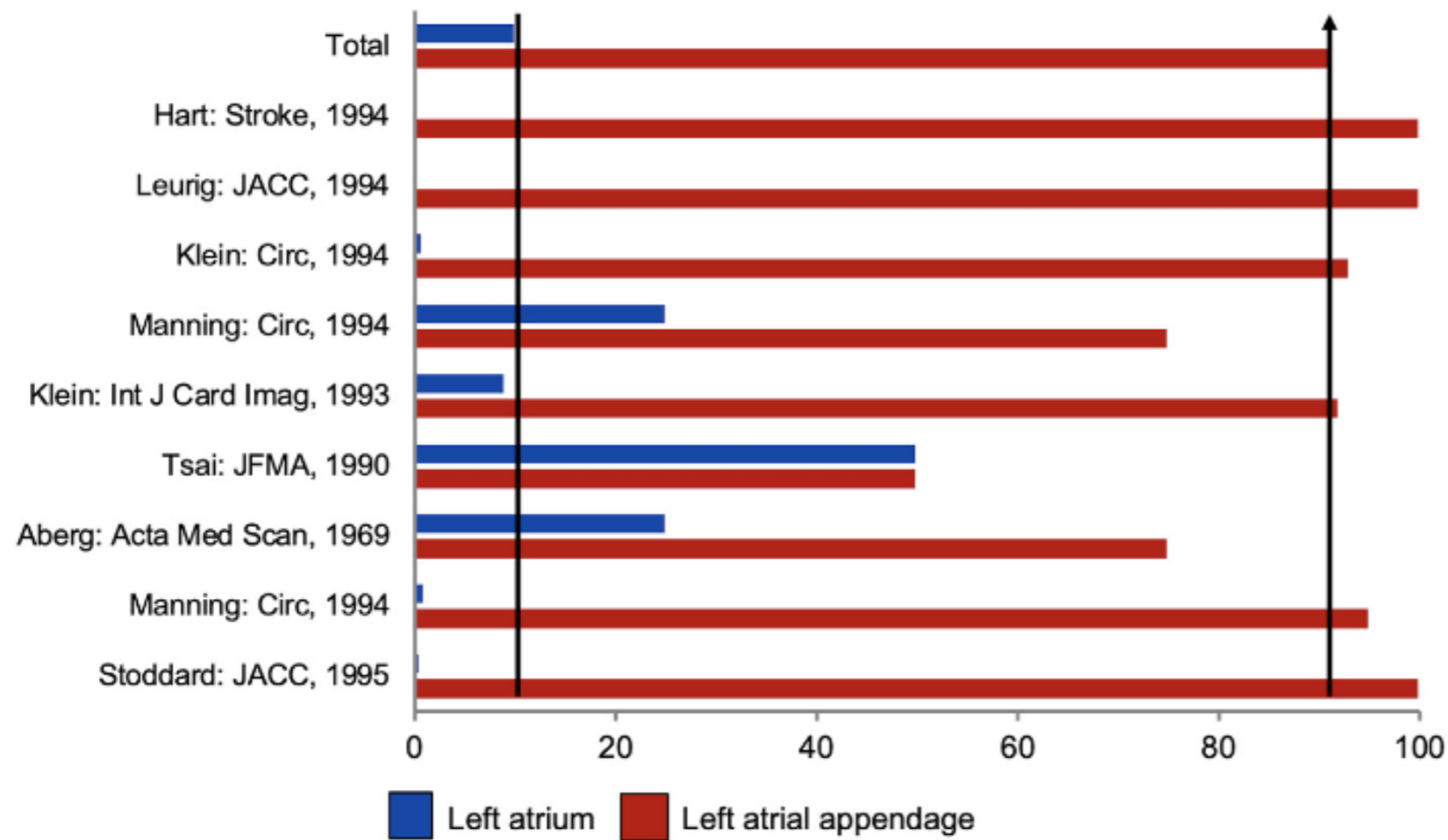


More than 90% of stroke-causing clots that come from the heart are formed in an area called the left atrial appendage (LAA).



LA Appendage, Nidus for Thrombus Formation in AF

FIGURE 1 The Left Atrial Appendage as a Nidus for Thrombus Formation in Patients With Atrial Fibrillation



91% in LAA



LAA = left atrial appendage.

Bleeding Risk

HAS-BLED score

Condition	Points
H - Hypertension	1
A - Abnormal renal or liver function (1 point each)	1 or 2
S - Stroke	1
B - Bleeding	1
L - Labile INRs	1
E - Elderly (> 65 years)	1
D - Drugs or alcohol (1 point each)	1 or 2

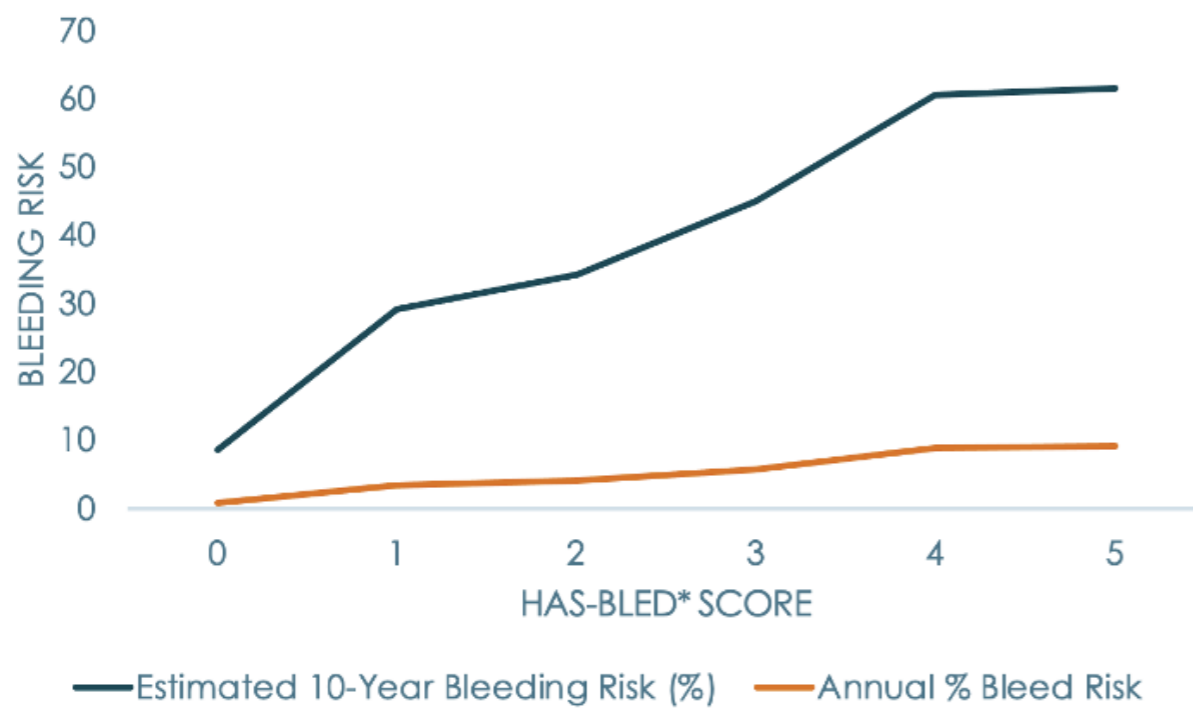
HAS-BLED score	Bleeds per 100 patient-years
0	1.13
1	1.02
2	1.88
3	3.74
4	8.70
5	12.5

Note: HAS-BLED has been validated for warfarin, but not for the new anticoagulants.

Pisters R et al. Chest 2010;138(5):1093-1100.



Bleeding Risk Over Time



CHA ₂ DS ₂ -VASc* Score	Annual % Stroke Risk	HAS-BLED Score ¹	Annual % Bleed Risk ¹	Estimated 10-Year Bleeding Risk (%)*
0	0	0	0.9	8.6
1	1.3	1	3.4	29.2
2	2.2	2	4.1	34.2
3	3.2	3	5.8	45.0
4	4.0	4	8.9	60.6
5	6.7	5	9.1	61.5

*Assumes constant risk despite increasing age, and bleeding risk is independent from bleeding risk in previous years.

CHA₂DS₂-VASc score – Congestive heart failure=1, Hypertension (SBP >160)=1, Age > 75 yrs=2, Diabetes mellitus=1, Prior stroke, TIA, or thromboembolism=2, Vascular disease (PAD, MI)=1, Age 65-74 yrs=1, Sex category (female)=1.

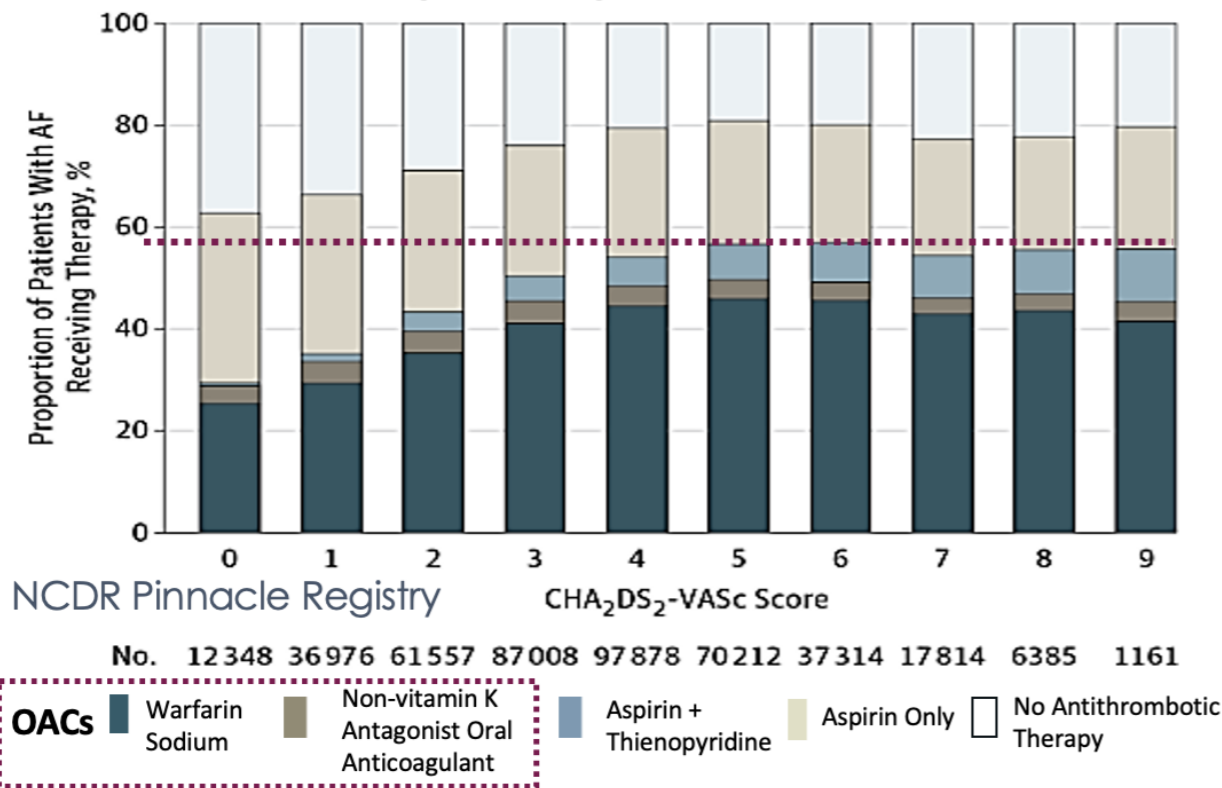
HAS-BLED score – Hypertension=1, Abnormal renal/liver function (1pt each)=1 or 2, Hemorrhagic stroke=1, Bleeding history or disposition=1, Labile INRs=1, Elderly=1, Current drugs (medication) or alcohol use (1 pt each)=1 or 2.

Compliance

Adherence to Anticoagulation Remains a Challenge

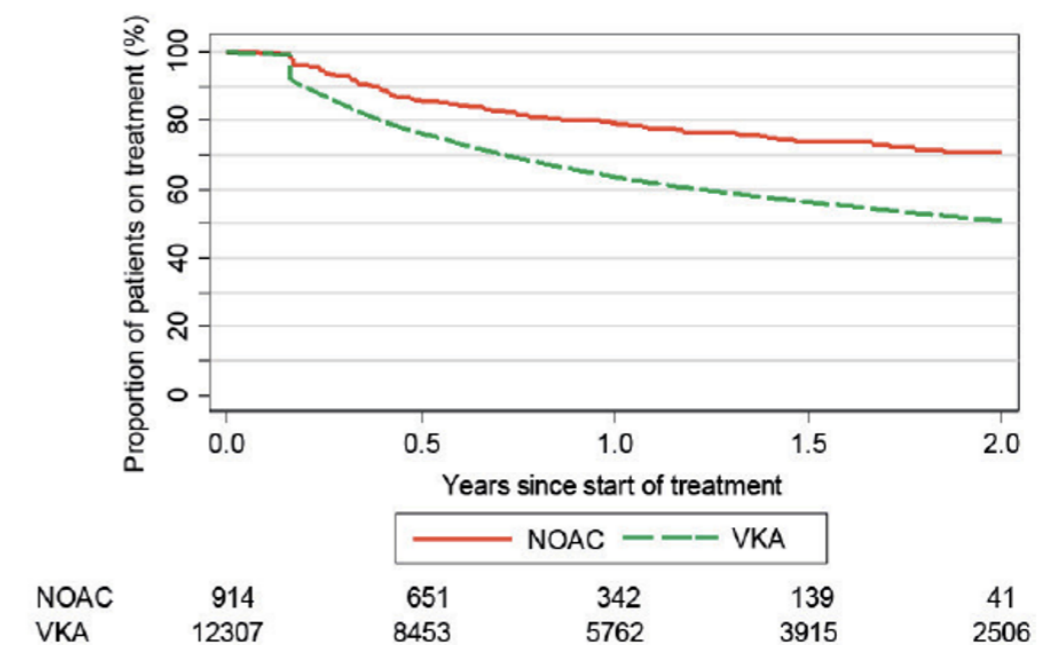
About half of patient with AF are not treated with OAC

Despite increasing risk of stroke, the use of OAC in AF patients peaks at ~50%



Of those taking OACs a significant number won't continue long-term

~30% of patients taking a DOAC and ~50% of patients taking a VKA discontinue treatment at 2 years



2019 ACC/AHA/HRS Focused Update on Atrial Fibrillation

PROVEN
SAFE
EFFECTIVE

Left Atrial Appendage Closure included in AF Guidelines

4.4. Nonpharmacological Stroke Prevention

4.4.1. Percutaneous Approaches to Occlude the LAA

Recommendation for Percutaneous Approaches to Occlude the LAA		
Referenced studies that support the new recommendation are summarized in Online Data Supplement 4 .		
COR	LOE	Recommendation
IIb	B-NR	1. Percutaneous LAA occlusion may be considered in patients with AF at increased risk of stroke who have contraindications to long-term anticoagulation (S4.4.1-1–S4.4.1-5). NEW: Clinical trial data and FDA approval of the Watchman device necessitated this recommendation.

“Oral anticoagulation remains the preferred therapy for stroke prevention for most patients with AF and elevated stroke risk. However, **for patients who are poor candidates for long-term oral anticoagulation (because of the propensity for bleeding or poor drug tolerance or adherence)**, the Watchman device provides an alternative.”

January CT, Wann LS, Calkins H, et al. 2019 AHA/ACC/HRS Focused Update of the 2014 AHA/ACC/HRS Guideline for the Management of Patients With Atrial Fibrillation: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. *Journal of the American College of Cardiology* 2019; 74(1): 104-132.

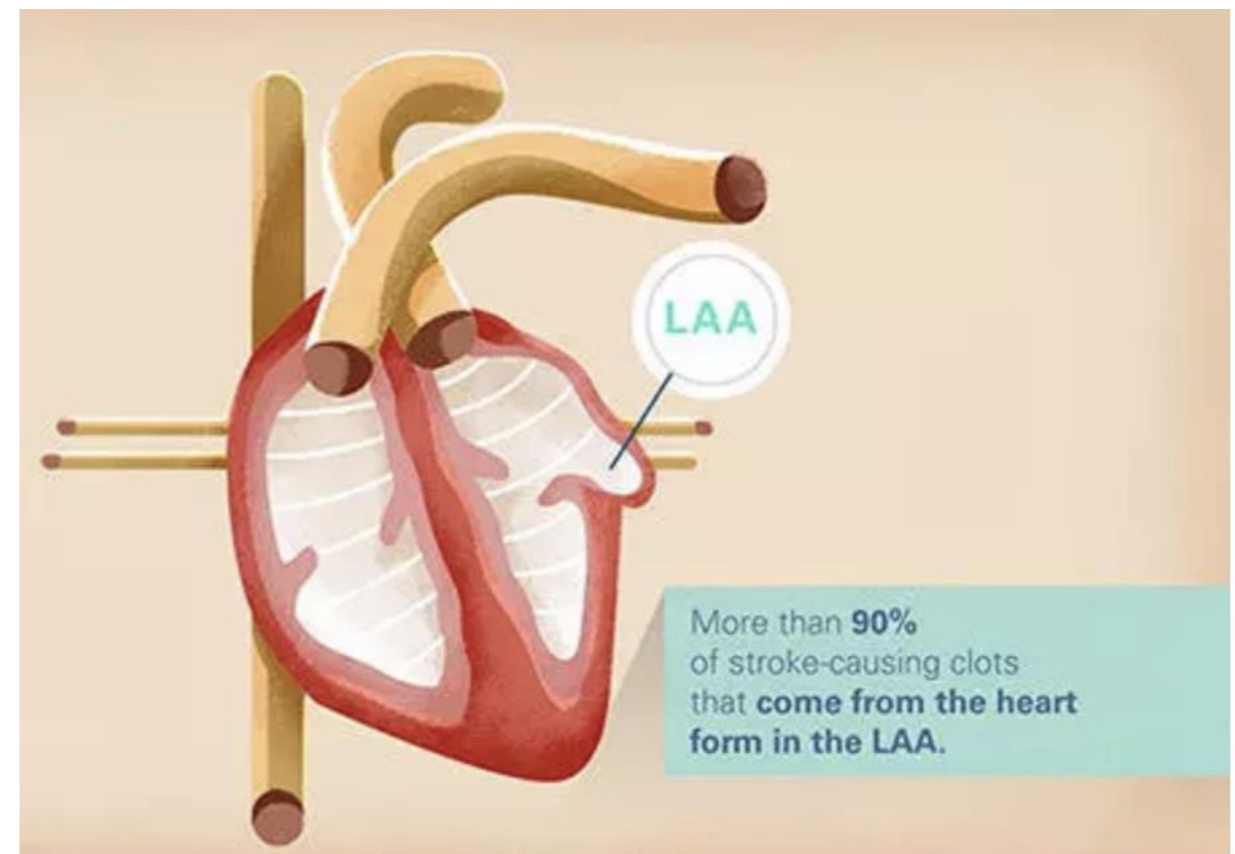
Left Atrial Appendage Occlusion

Percutaneous

- Watchman FLX Pro
- Amplatzer Amulet (2021)
- Lariat (MAZE Trial)

Surgical Approach

- Ligation
- AtriClip



Indications

Percutaneous

- $CHA_2S_2D-Vasc \geq 3$
- Increased HAS-BLED or have an appropriate reason to seek a non-pharmacological alternative to oral anticoagulation (OAC)

Surgical

- Concomitant open thoracotomy procedure
- Convergent Ablation

FIGURE 9 Computational Modeling for Optimization of Left Atrial Appendage Occluder Implantation

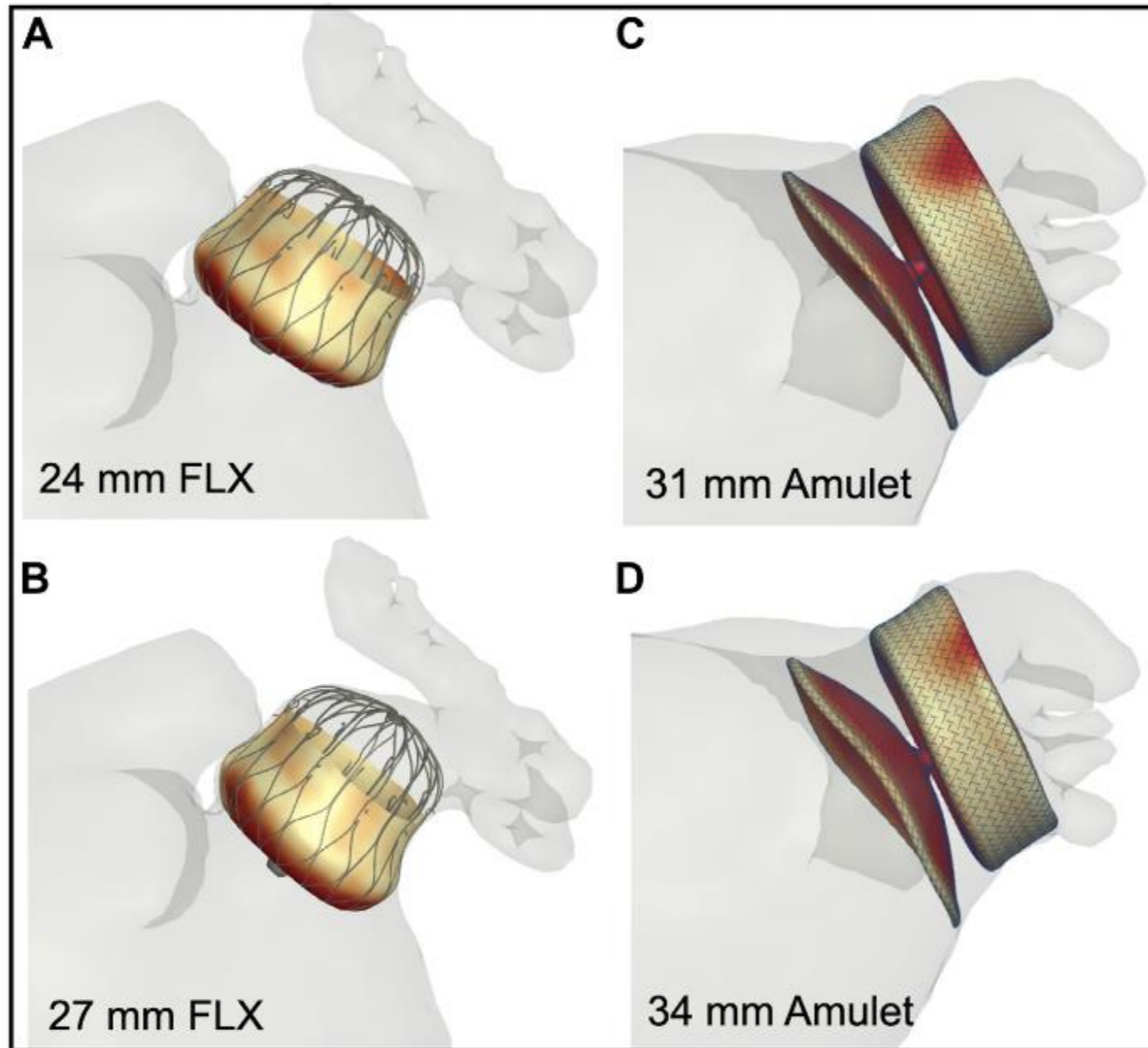
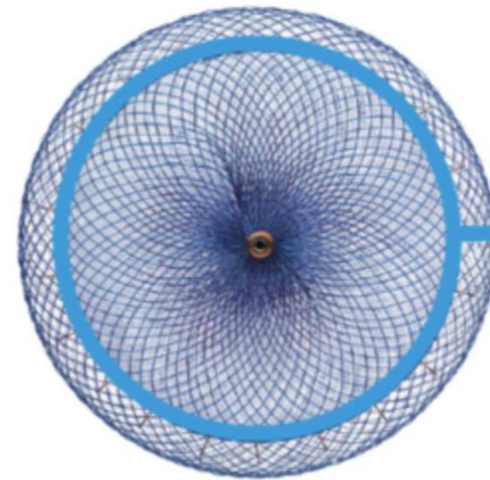


Illustration of the impact of device size and deployment location of leaks in 2 patients, one treated with the Watchman FLX device (**A, B**) and one treated with the Amulet device (**C, D**).

Amulet

More Sizes For More Anatomies

The Amulet occluder offers the most sizes to ensure a precise fit across LAA anatomies.



8 DEVICE SIZES

DEVICE
SIZE

16

18

20

22

25

28

31

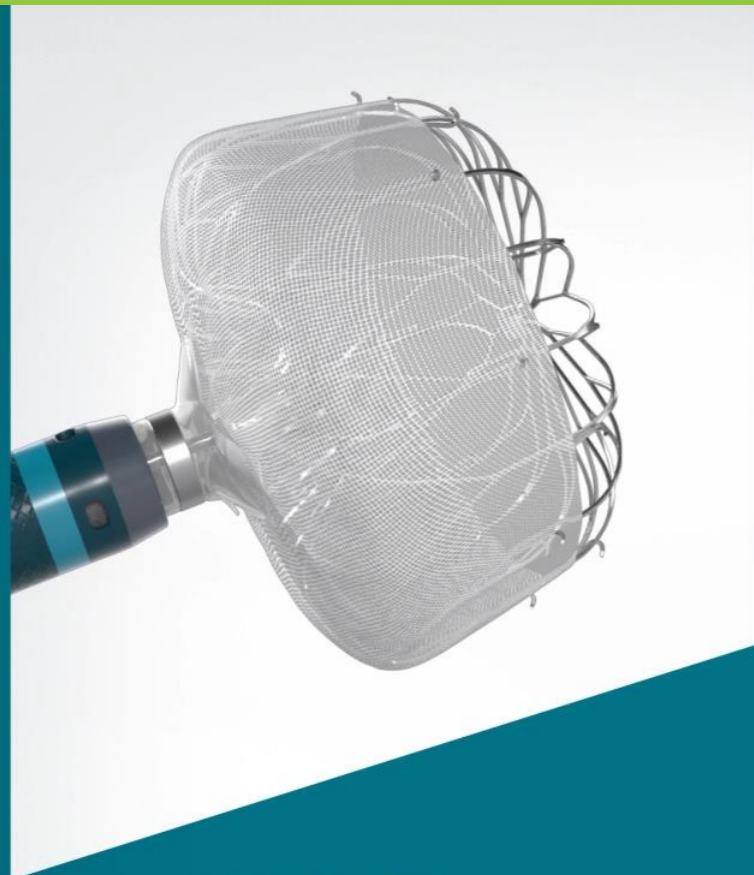
34

11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31

OSTIUM DIAMETER (MM)



Implant Technique



— ADVANCE PROCEDURAL PERFORMANCE

100% effective LAA closure at 12 months^{1*}

— ADVANCE SAFETY

0.5% major procedural complication rate¹



— EXPAND THE TREATABLE PATIENT POPULATION

*LAA closure at 12 months is defined as any peri-device flow with jet size <5mm per core laboratory-assessed TEE

**Implant success defined as successful delivery and release of a WATCHMAN FLX device into the LAA

¹Kar, S., et al, Primary Outcome Evaluation of the Next Generation LACC Device: Results from the PINNACLE FLX Trial, Circulation, 2021



Procedure



Minimally Invasive
Permanent Procedure



1 Hour
Typical Procedure Takes
Less than an Hour



24 Hour
Average Hospital Stay

1

Using a standard percutaneous technique, a guidewire and vessel dilator are inserted into the femoral vein



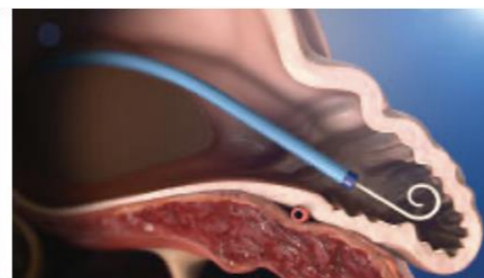
2

The implant procedure is performed with fluoroscopy and transesophageal echocardiography (TEE). The interatrial septum is crossed using a standard transeptal access system.



3

The access sheath is advanced over the guidewire into the left atrium and then navigated into the distal portion of the LAA over a pigtail catheter.



4

WATCHMAN is then deployed and released in the LAA.



5

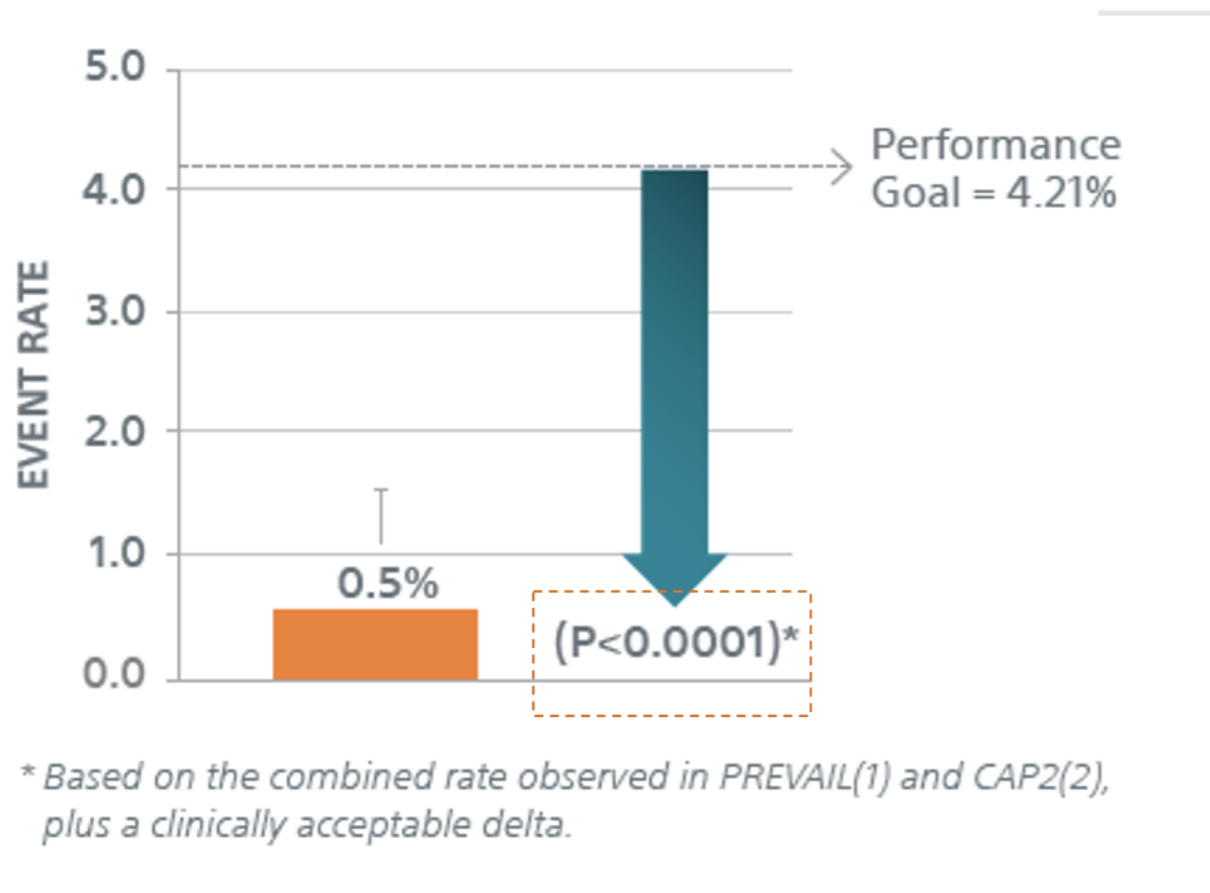
Heart tissue grows over the WATCHMAN Implant, and the LAA is permanently sealed. Patients remain on OAC for at least 45 days post-procedure. TEE is used to confirm seal.



Safety

PINNACLE FLX

Primary Safety Endpoint Met with Low 0.5% Event Rate¹



0.5%

Major Procedural
Complication Rate

0%

All-cause Death

0%

Pericardial Effusions
Requiring Open
Cardiac Surgery

0%

Device Embolization

*Occurrence of one of the following events between the time of implant and within 7 days following the procedure or by hospital discharge, whichever is later: all-cause death, ischemic stroke, systemic embolism, or device or procedure related events requiring open cardiac surgery or major endovascular intervention

¹Doshi, SK. Presented at HRS 2020.



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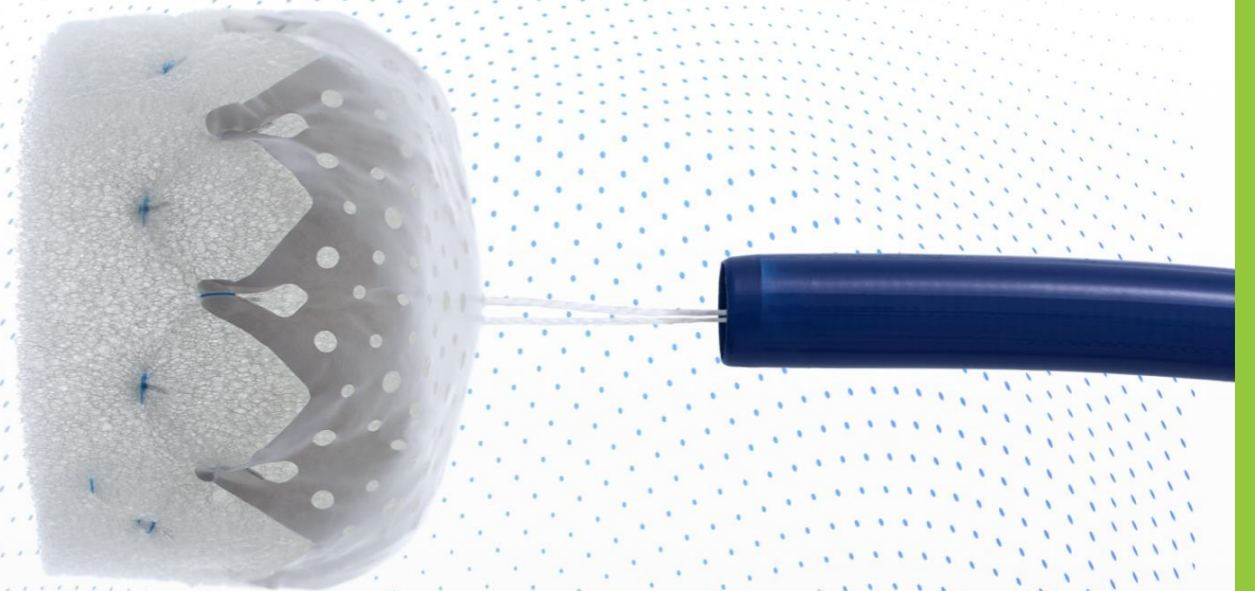
Future Devices

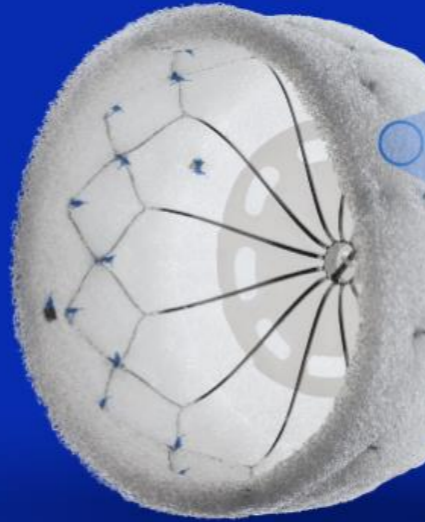


Conformal

The first & only LAAO device to use conformable foam to seal the LAA

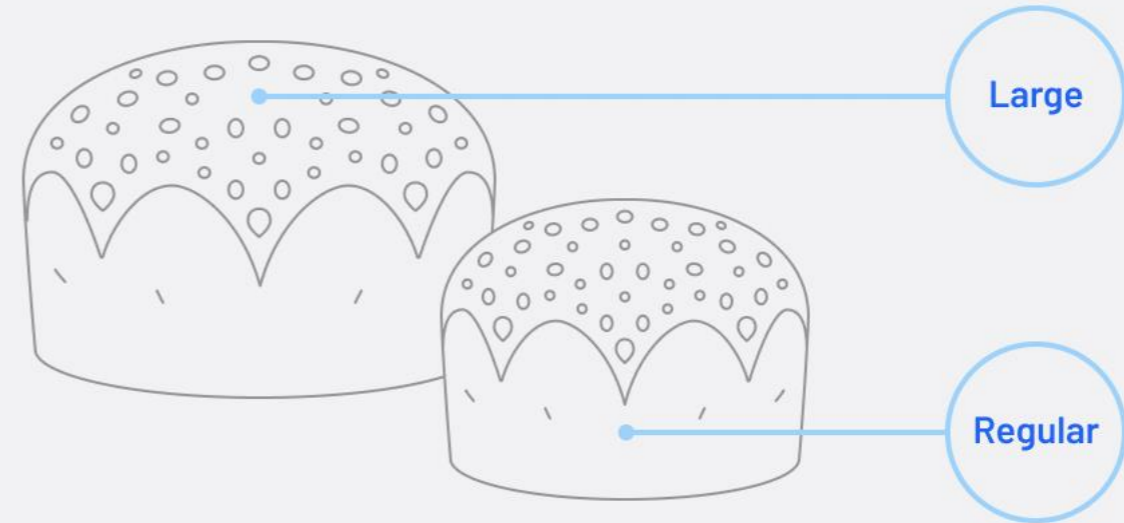
Designed to reduce the risk of stroke without the need for anticoagulants.





It's in the Small

The foam-based implant is designed to fit a patient's unique anatomy, enabling treatment of patients with only two device sizes. This procedure by allowing off-axis pos



Sizing Made Simple

With only 2 sizes, imaging requirements are minimal which has the potential to transform LAAO to a same day procedure, moving clinical practice away from general anesthesia and overnight hospitalizations.



Case Questions



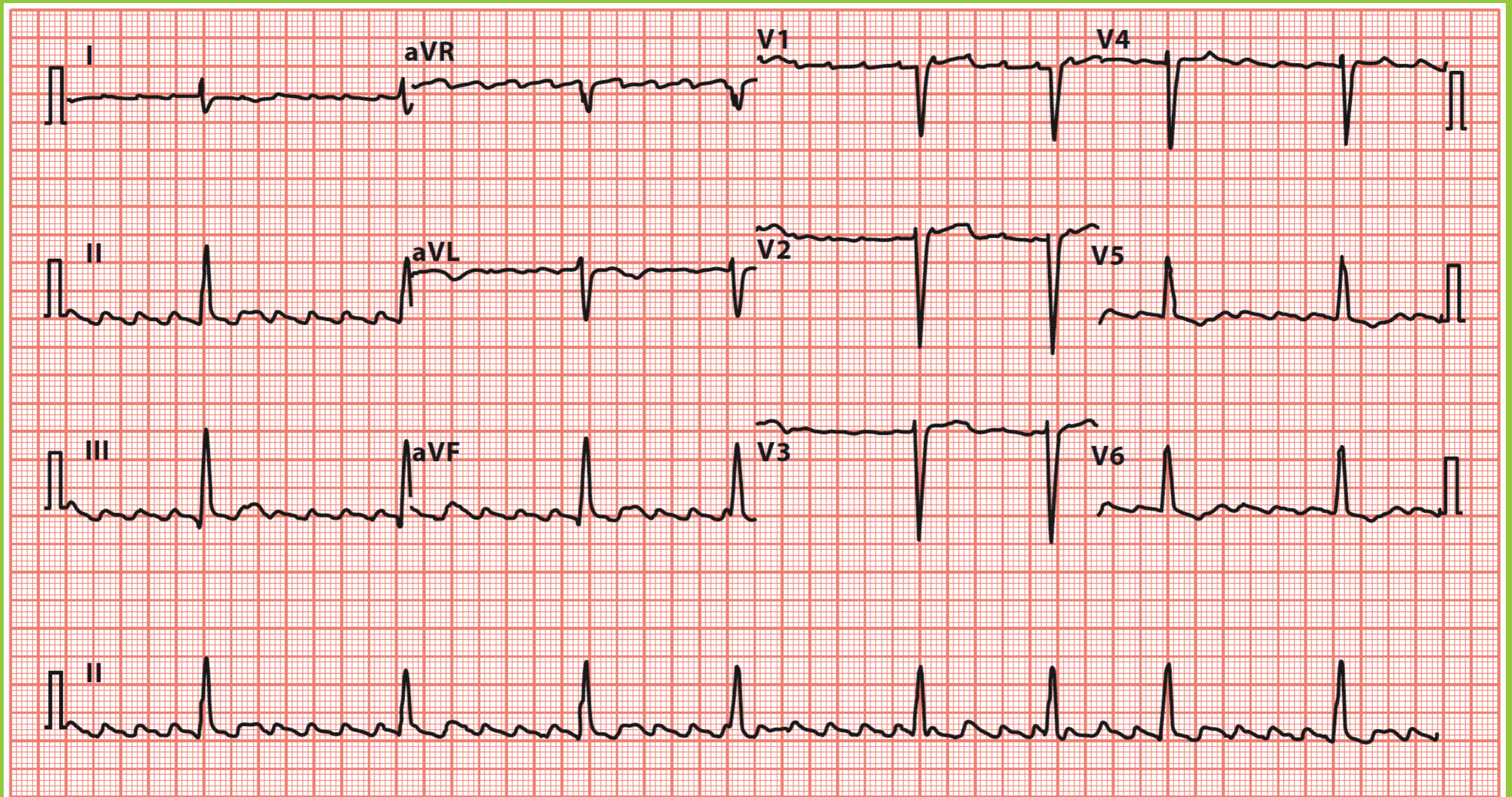
A 67-year-old woman with a history of breast cancer treated with mastectomy and chemotherapy 4 years ago undergoes 30-day continuous outpatient telemetry as part of her experimental chemotherapy protocol. She is found to have a 16-hour and a 22-hour episode of AF on day 11 and 14 of monitoring, with 15 other episodes lasting up to 1 hour in duration. She is asymptomatic and her heart rates range from 55- 122 bpm, with mean heart rate of 82 bpm during the episodes. Her hematocrit is 34. Other CBC results, blood chemistries, and thyroid function tests are normal.

Based on her CHA₂DS₂-VASc score, her symptoms, and the duration of the episodes, which of the following is the most appropriate step in her management?

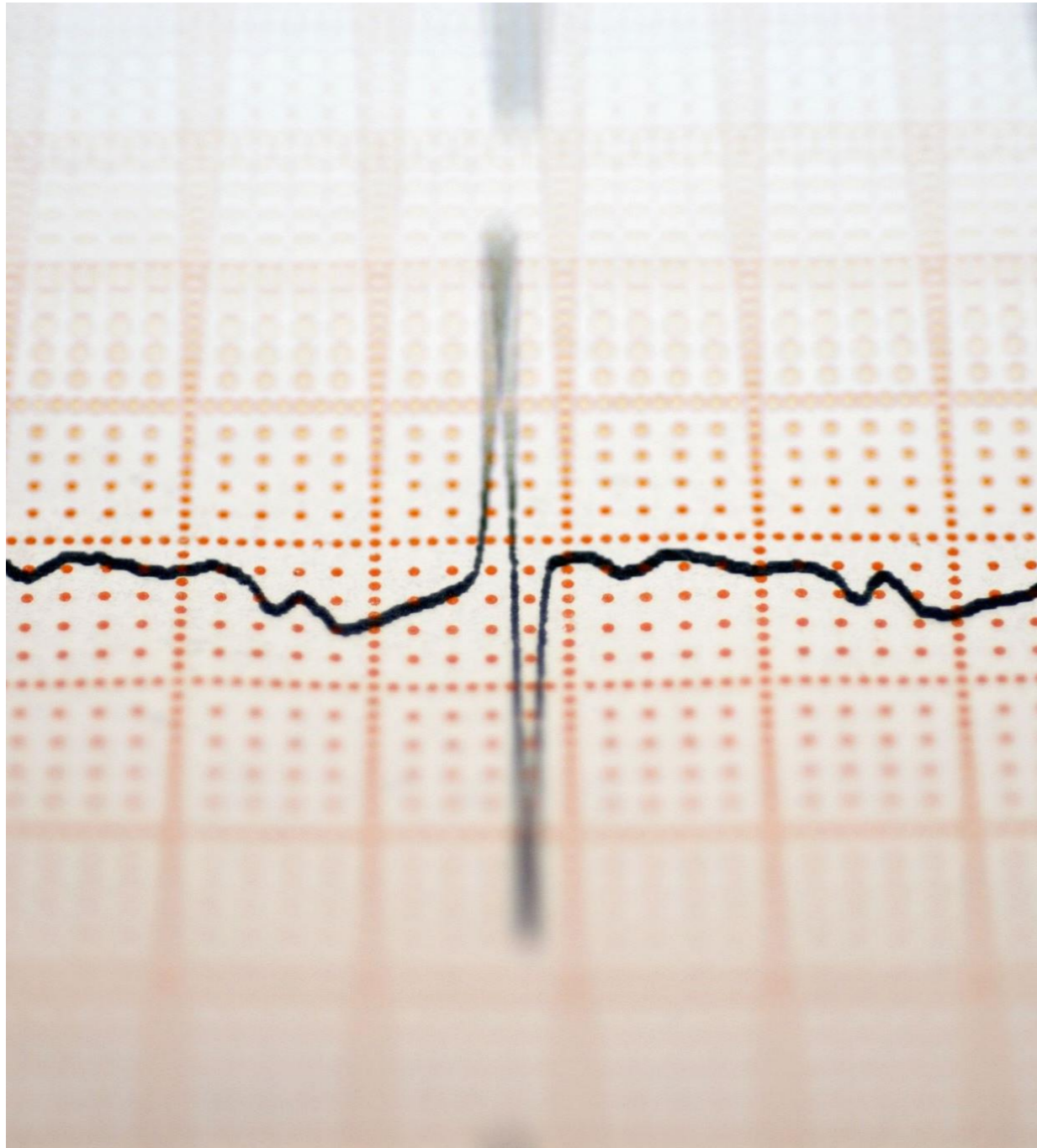
- A. No further therapy.
- B. Aspirin.
- C. Warfarin.
- D. Clopidogrel.
- E. Left atrial occlusion device.



68-year-old male with Type II diabetes, hypertension is referred for left atrial appendage occlusion device. He was found incidentally to have atrial flutter during a routine colonoscopy and feels he is not tolerating apixaban due to upper extremity bruising and bleeding easily.



The best option for this patient?



- A. Proceed with left atrial appendage occlusion device
- B. Continue with a rate control and anticoagulation strategy
- C. Cardiovert and then consider discontinuing anticoagulation
- D. Proceed with an atrial flutter ablation

66-year-old female, who had a Watchman FLX placed over one year ago presents now persistent atrial fibrillation; in the past she was paroxysmal but and never had episodes over 2 hours. She is symptomatic and is contemplating an ablation. She is only maintained on ASA 81 mg daily. Other medical diagnosis include Type II diabetes and hypertension. Elevated HAS-BLED due to multiple severe GI bleeds due to diverticulosis.

45-day TEE post Watchman revealed well seated 27 mm Watchman with no residual leaks or thrombus.

The patient is asking about a cardioversion prior to her ablation.

What is the BEST option prior to and post cardioversion?

A. Full anticoagulation with a DOAC, 3-weeks prior and 4-weeks post cardioversion

B. TEE-guided cardioversion with 4-weeks of anticoagulation post (DOAC)

C. Continue with ASA and proceed with TEE-guided cardioversion with no anticoagulation.

D. No TEE needed, proceed with cardioversion

How about my patient who had a surgical appendage ligation?



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
PUBLICATIONS ▾



ORIGINAL ARTICLE



Left Atrial Appendage Occlusion during Cardiac Surgery to Prevent Stroke

Authors: Richard P. Whitlock, M.D., Ph.D. , Emilie P. Belley-Cote, M.D., Ph.D., Domenico Paparella, M.D., Jeff S. Healey, M.D., Katheryn Brady, B.Sc., Mukul Sharma, M.D., Wilko Reents, M.D.,  +24, for the LAAOS III

Investigators* [Author Info & Affiliations](#)

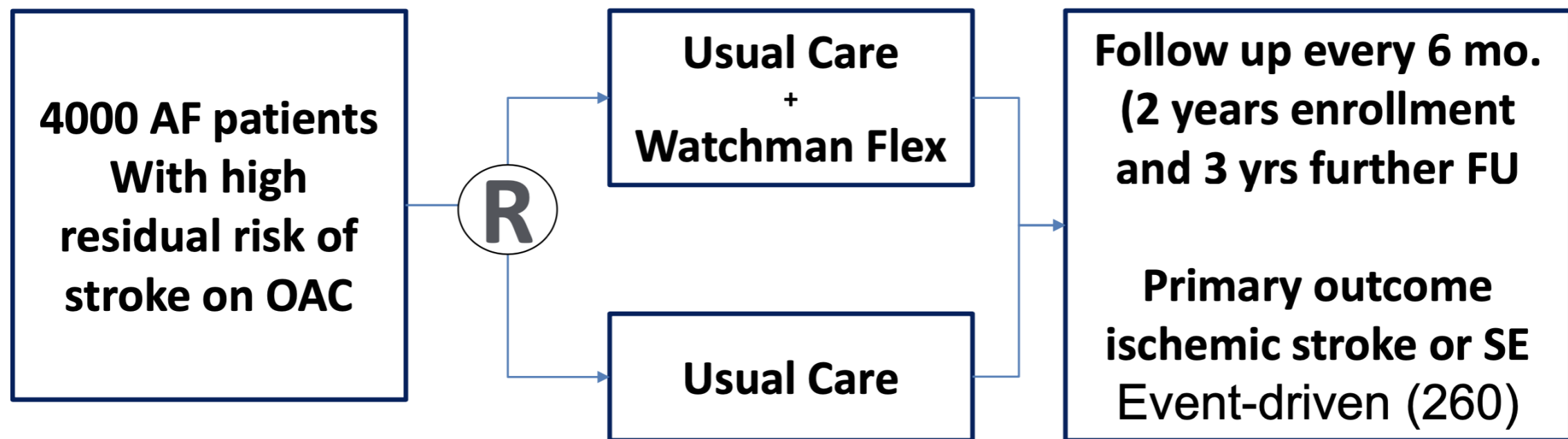
Published May 15, 2021 | N Engl J Med 2021;384:2081-2091 | DOI: 10.1056/NEJMoa2101897 | [VOL. 384 NO. 22](#)

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What about my patient who had a stroke on full anticoagulation?

LAAOS-4



Patients must have all of

1. CHA₂DS₂-VASc score of ≥ 4
2. Plan to treat with OAC
3. Permanent/persistent AF
 - or paroxysmal AF with stroke history

What is the best anticoagulation regimen post LAAO?

1. Watchman FLX PRO

- ASA 81 mg daily (indefinitely) and DOAC or warfarin
- In 45 days, post TEE/CT – discontinue DOAC/warfarin, start clopidogrel for 6 months (duration from the time of implant)
- ASA 81 mg daily (indefinitely) and clopidogrel for 6 months

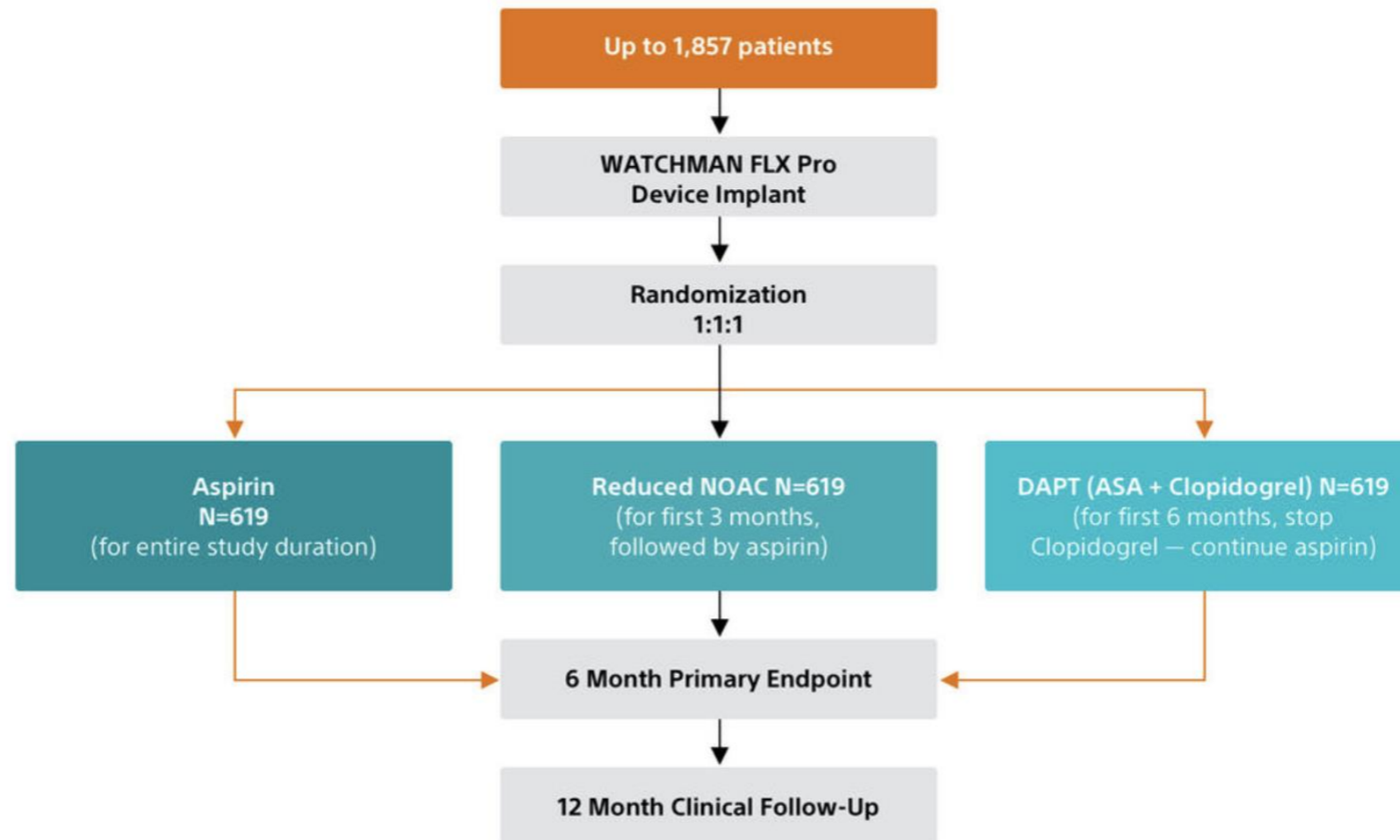
2. Amulet

- ASA 81 mg daily (indefinitely) and clopidogrel for 6 months



SIMPLAAFY Clinical Trial

Trial Design and Primary Endpoints



Primary Endpoints:

- Reduced dose NOAC Primary Endpoint: Composite rate of all death, all stroke, systemic embolism and major bleeding at 6-months after randomization
- Aspirin Primary Endpoint: Composite rate of all death, all stroke, systemic embolism and major bleeding at 6-months after randomization

Key Points:

Anticoagulation based on thrombotic risk, irrespective of AF pattern

Consideration of percutaneous left atrial appendage occlusion if relative or absolute contraindication to anticoagulation

Anticoagulation post LAA occlusion: ASA 81 mg daily + clopidogrel 75 mg daily for 6 months then ASA 81 mg daily, indefinitely

Percutaneous versus Surgical Closure



Questions?

