Managing AFib with the WATCHMAN™ Implant

Chirag Chauhan, MD, MS, FACC, FSCAI
Oussama Lawand, MD, FHRS
Srinivas Iyengar, MD
Boulder Heart
720-295-7947

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A "Heart" Decision:

Balancing Bleeding Risks and Stroke Protection

Atrial Fibrillation Overview

How the Heart Works

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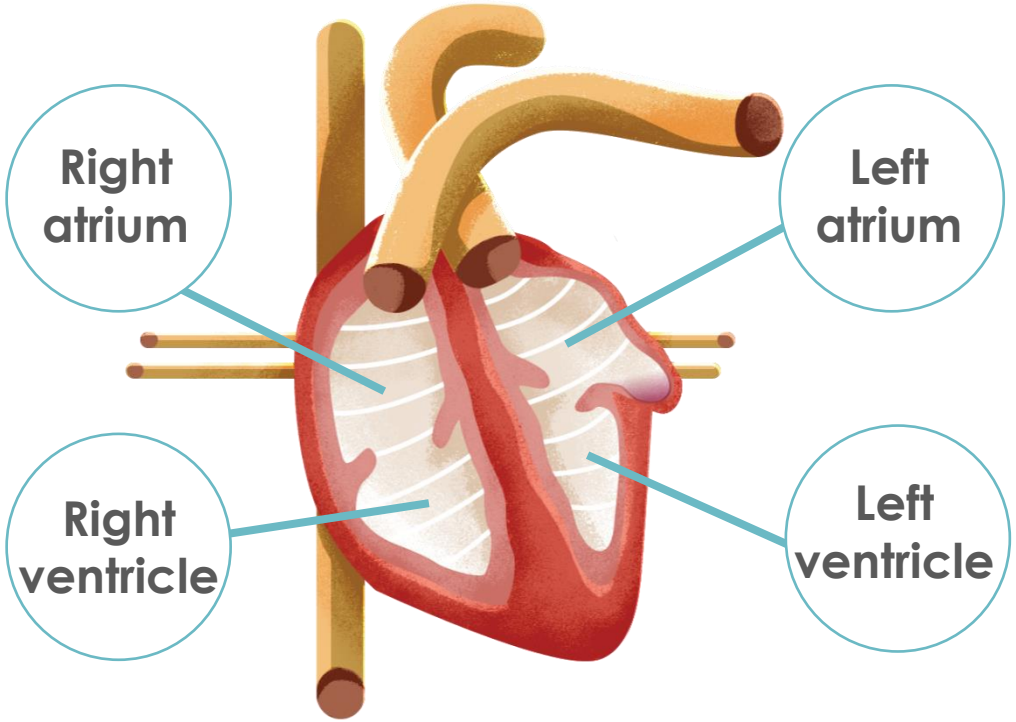
- The heart is divided into four chambers
  - **Atria:** two small, upper chambers
  - **Ventricles:** two larger, lower chambers



- Together, they pump blood to and from other parts of your body

What is Atrial Fibrillation?

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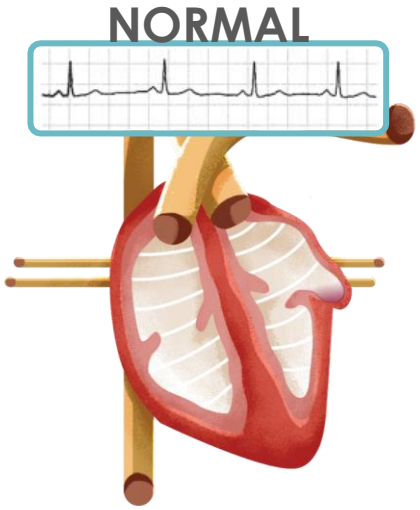
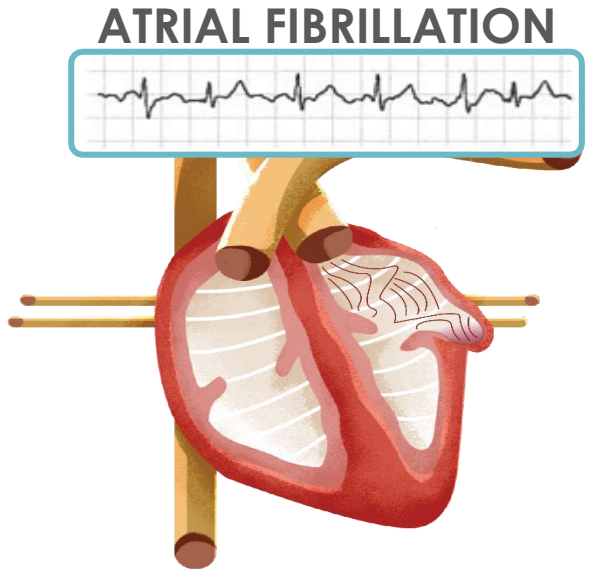
- Atrial Fibrillation, or AFib, is a heart condition that causes an irregular rhythm
- It happens when the upper chambers of the heart ("atria") beat irregularly due to disorganized electrical signals in the heart
- The rhythm does not communicate normally with the bottom chambers ("ventricles")





You are not alone

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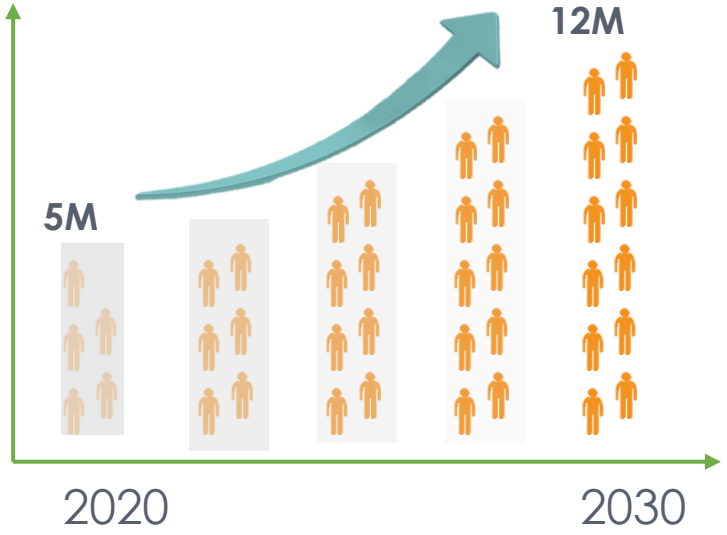
- Atrial Fibrillation is a common cardiac arrhythmia and is a growing problem



- **~5 M people with AFib in U.S.**
- **By 2030, up to 12 million Americans may be affected**

- Significant impact on your quality of life

- Treatment options are available

https://pubmed.ncbi.nlm.nih.gov/23831166/

Diagnosis

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- An ECG is mandatory
  - Not every "irregular heart rhythm" is AFib
- PVCs, PACs, multiple skipped beats can all mimic symptoms of AFib
- AFib does not have to be chronic
  - Can be short-lasting or come/go (i.e., PAF)
- But AFib episodes can be unpredictable, so an ECG recorded at your doctor's office may appear to be normal
  - If this happens, your doctor may ask you to wear a portable monitor, such as an event monitor, or a Holter monitor, to record your heart's electrical signals

Types of Atrial Fibrillation

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- **Paroxysmal**
  - Comes and goes – can terminate spontaneously
  - Usually, can stop within 48 hours
- **Persistent**
  - Lasts longer than one week
- **Long Standing Permanent**
  - Lasts for longer than 12 months
- **Permanent**
  - Heart likely cannot be restored to normal rhythm

What Causes Atrial Fibrillation?

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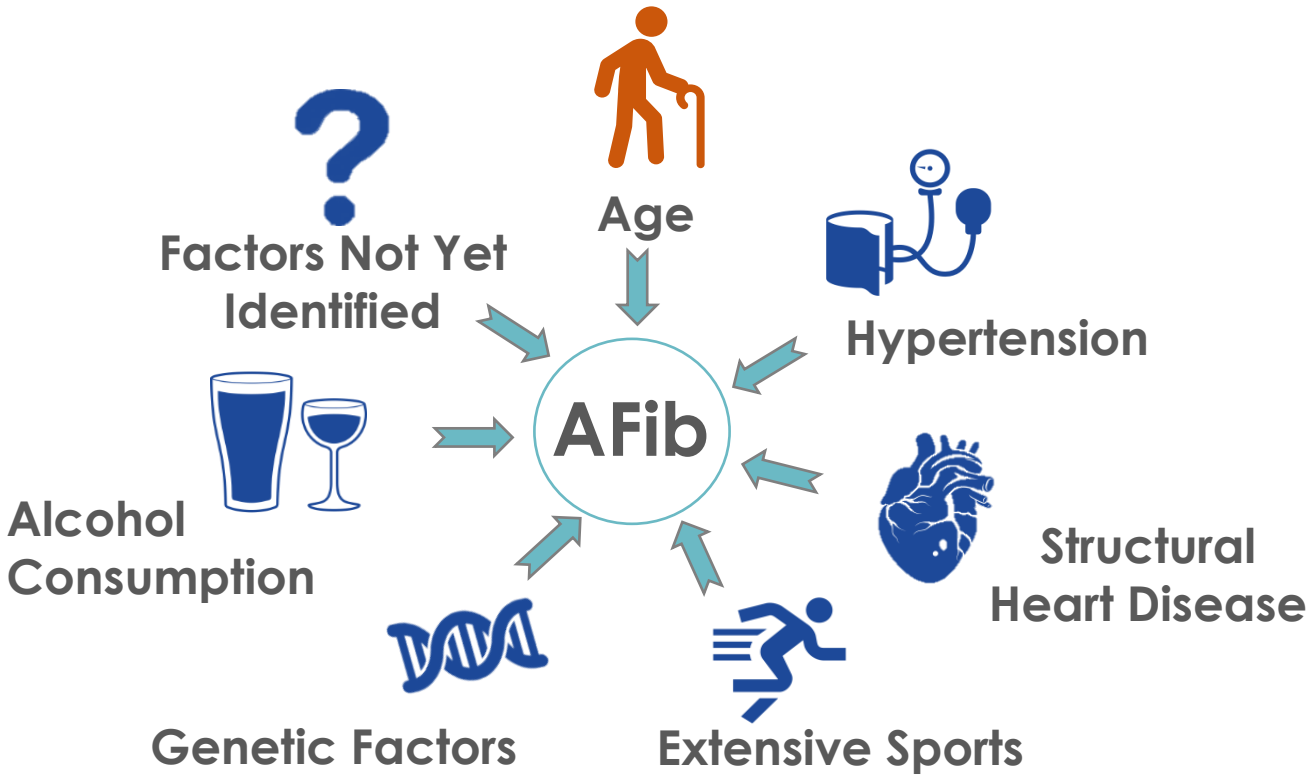
- As you grow older, the risk of AFib increases, especially after age 60

- High blood pressure
- Heart attacks
- Previous heart surgery
- Coronary artery disease
- Abnormal heart valves
- Heart problems you're born with
- Improper functioning of the heart's natural pacemaker
- Chronic lung disease
- Hyperthyroidism or other metabolic imbalances
- Stress due to surgery, pneumonia, or other illnesses
- Viral infections
- Sleep apnea
- Exposure to certain stimulants, including some medications, caffeine, tobacco, and alcohol



Signs and Symptoms of AFib

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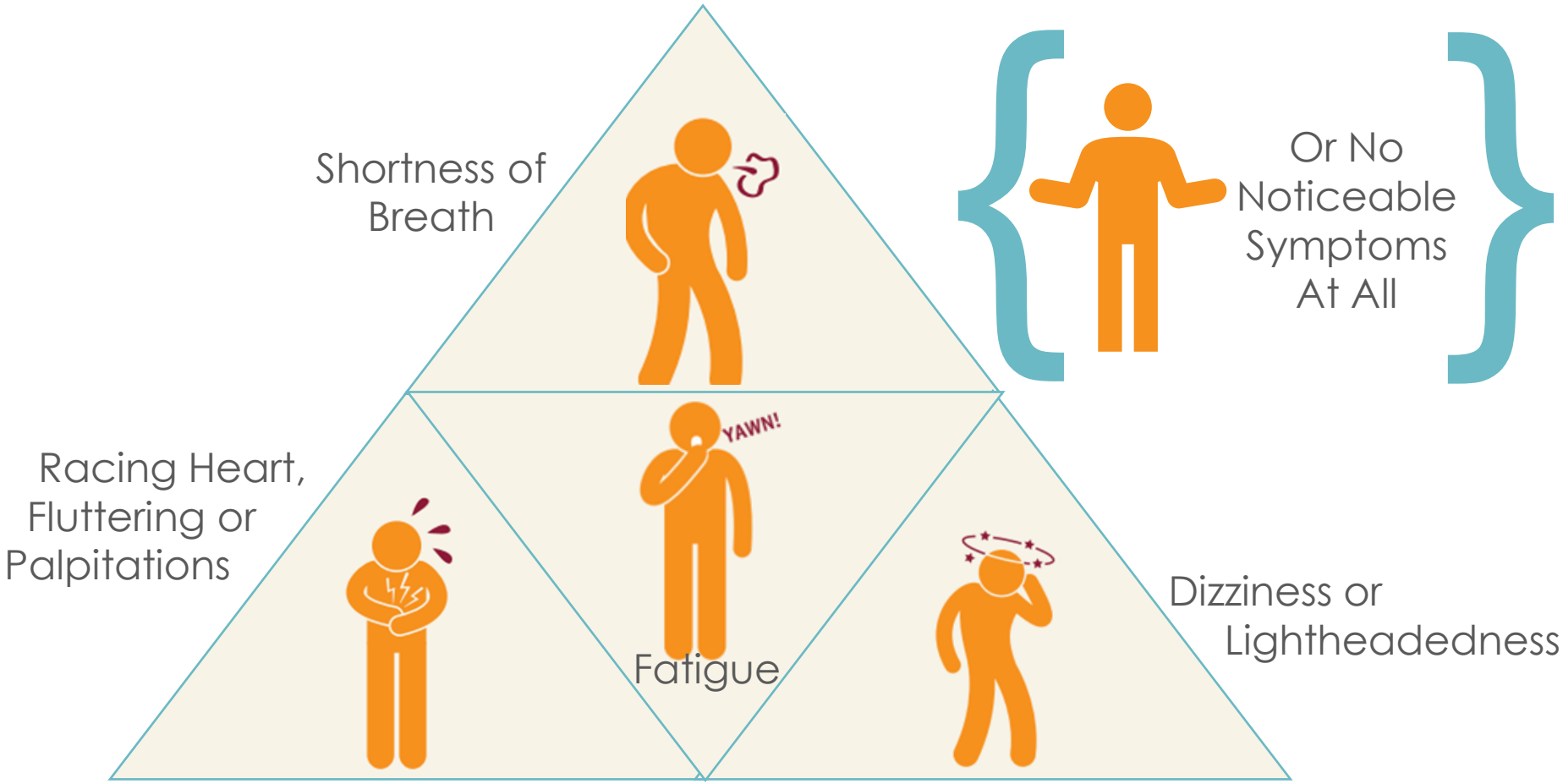

Did you know?

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- People with AFib may be at greater risk for stroke than people with normal heart rhythms

National Stroke Association. Making the AFib-Stroke Connection. https://www.stroke.org/sites/default/files/resources/AFib-Connection%20for%20hcp.pdf. Published 2012

Why AFib Matters

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- AFib can put you at risk for other complications:
  - **Blood Clots:** The irregular heart rhythm can cause blood to pool and form clots in an area of your heart called the Left Atrial Appendage (LAA)
  - **Stroke:** If a blood clot forms in the LAA, it can escape and travel through to the brain and cause a stroke
  - **Heart Failure:** If atrial fibrillation continues over a long period of time, the decreased efficiency of the heart can lead to heart failure

Blood Clots & Stroke Risk

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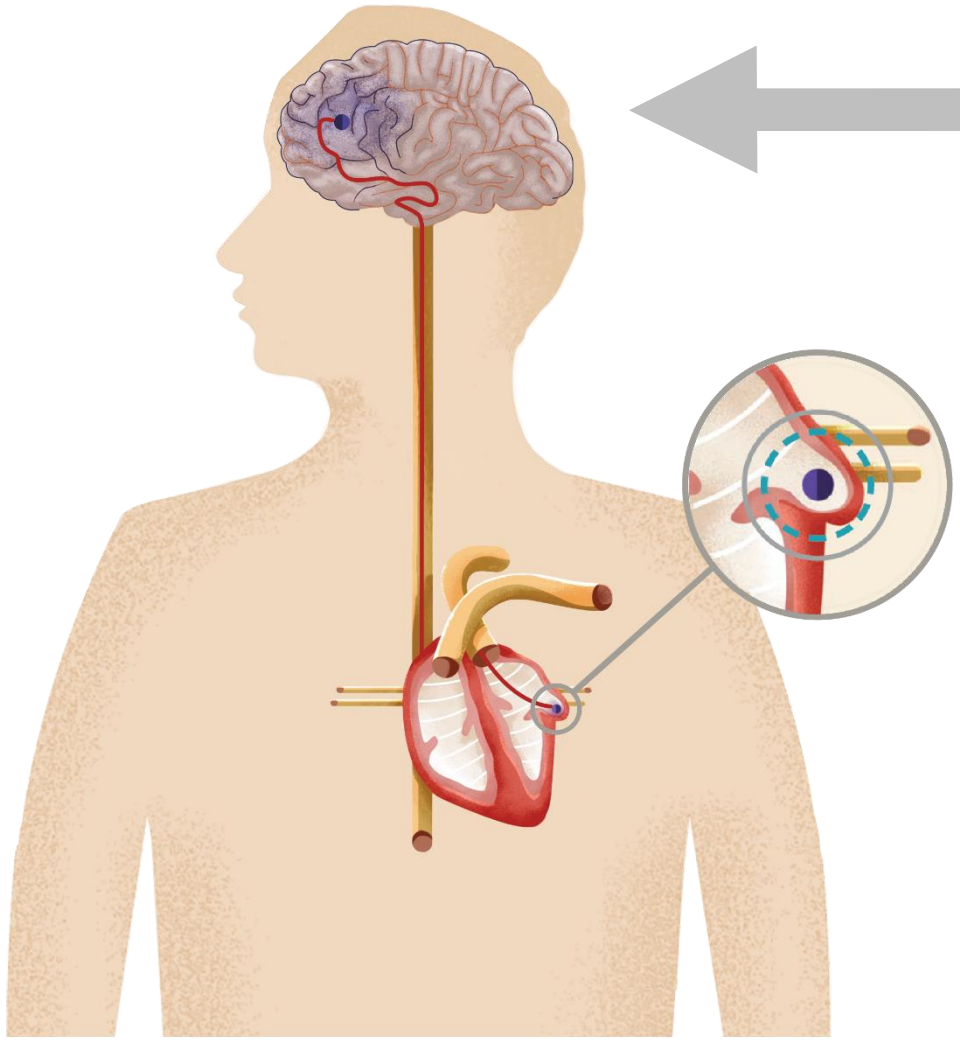

- The clot lodges itself in the blood vessels of the brain, restricting blood flow and causing a stroke
- The blood clot dislodges from the LAA and travels through arterial system
- The stagnant blood becomes an ideal environment for a blood clot to form
- AFib causes blood to pool in the left atrial appendage

Did you know?

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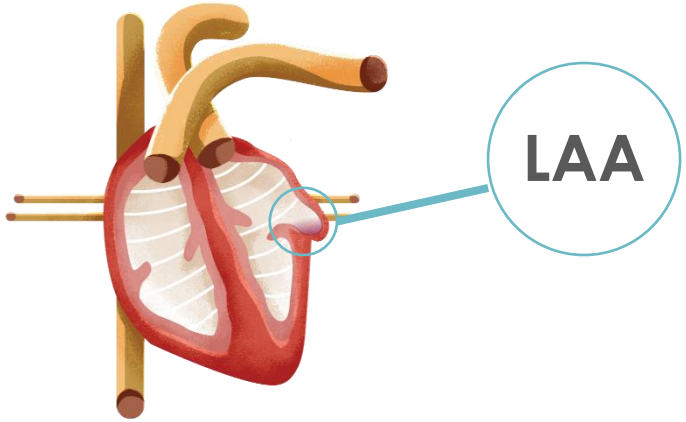
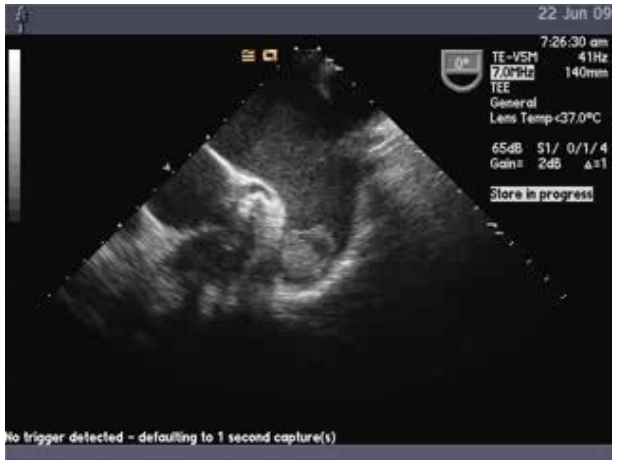
- Approximately **1 in 3** people with atrial fibrillation will have a stroke in their lifetime

- More than **90%** of stroke-causing clots that come from the heart originate in the left atrial appendage (LAA)





- AFib-related strokes are more frequently fatal and disabling

- Blackshear JL, Odell JA. Appendage obliteration to reduce stroke in cardiac surgical patients with atrial fibrillation. ***Ann Thorac Surg****. 1996;61:755-759.*
- McGrath ER, Neurology. 2013 - Tu HT, Int J Stroke. 2013

Symptoms of a Stroke

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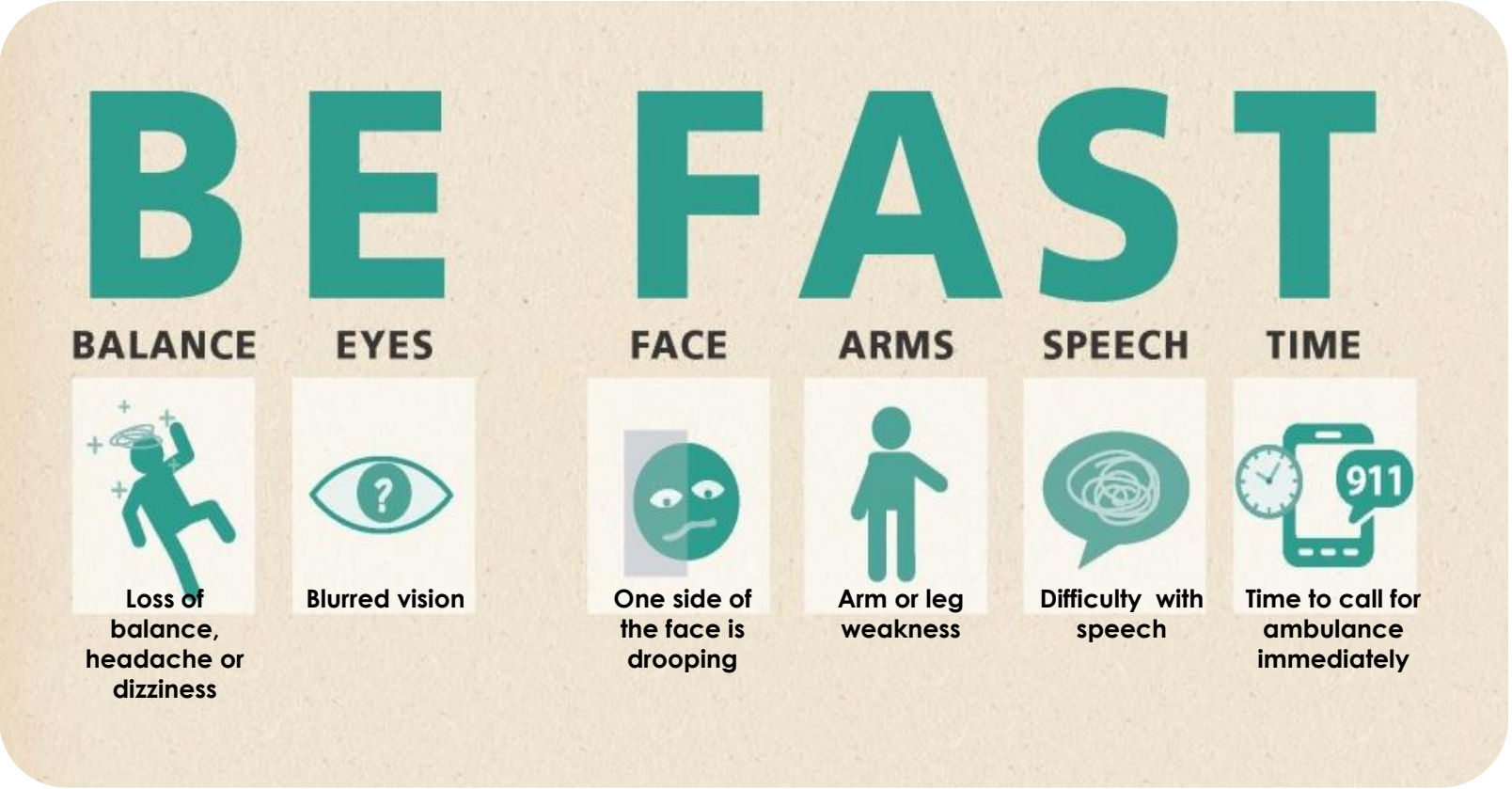
Learn the warning signs and act FAST



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Treatment Options

Goals of Treatment

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- Medications for Rhythm & Rate
- Procedures to Eliminate AFib
- Lifestyle Changes

- Oral Anticoagulant Medications
- Left Atrial Appendage Closure

How is AFib Managed?

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Rate Control

- Treatment to make sure the heart doesn't beat too quickly during AFib

Rhythm Control

- Treatment to restore the heart's rhythm to a normal state and keep it there

Lifestyle Changes

- Get regular exercise, eat a heart-healthy diet, don't smoke, watch alcohol and caffeine intake

Atrial Fibrillation Procedures

- Cardioversion or Ablation procedures to restore rhythm

Reducing the Risk of AFib-Related Stroke

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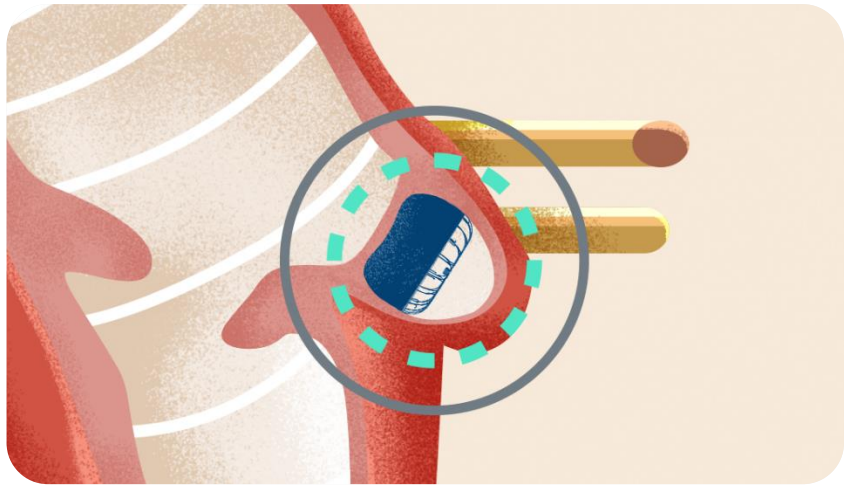
- Treatment options are available to protect you from stroke or related complications from blood clots

- **Oral Anticoagulation Medicine (Blood Thinners)**

- **Left Atrial Appendage Closure (LAAC) Devices**



Oral Anticoagulant Medications (Blood Thinners)

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- **Common blood thinners include:**
  - Warfarin (Coumadin®)
  - Eliquis®
  - Pradaxa®
  - Xarelto®
  - Savaysa®
- Most people can take blood thinners for years without serious side effects
- But because blood thinners help prevent clots by thinning the blood, they also increase the risk of bleeding

Talk to Your Doctor

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- When considering your treatment options, your cardiologist will weigh your risk of a stroke against your risk of a serious bleeding problem

Risk of a stroke

Risk of a serious bleed

CHA_2DS_2VASc Score (Stroke Risk)[3]

	Condition	Points
C	Congestive heart failure	1
H	Hypertension (SBP>160)	1
A_2	Age ≥ 75 years	2
D	Diabetes mellitus	1
S_2	Prior stroke, TIA or thromboembolism	2
V	Vascular disease (PAD, MI)	1
A	Age 65-74 years	1
Sc	Sex category (Female)	1
	TOTAL POINTS	

Score	Yearly Stroke Risk (%)		
	No Warfarin	With Aspirin[2]	With Warfarin[2]
0	0	0	0
1	1.3	1.0	0.5
2	2.2	1.8	0.8
3	3.2	2.6	1.1
4	4.0	3.2	1.4
5	6.7	5.4	2.3
6	9.8	7.8	3.4

HAS-BLED Score (Bleeding risk with warfarin)[4]

	Condition	Points
H	Hypertension	1
A	Abnormal renal/liver function (1 pt each)	1 or 2
S	Hemorrhagic Stroke	1
B	Bleeding history or disposition	1
L	Labile INRs	1
E	Elderly	1
D	Current drugs (medication) or alcohol use (1pt each)	1 or 2
	TOTAL POINTS	

Score	Yearly Major Bleeding Risk %
0	1.13
1	1.02
2	1.88
3	3.74
4	8.70
5+	Not well validated

Left Atrial Appendage Closure

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- Closing the Left Atrial Appendage (LAA) is an effective way to reduce stroke risk in people with AFib not caused by heart valve problems

- A Left Atrial Appendage Closure (LAAC) Implant is a permanent implant designed to close off the LAA so blood clots can't form there and escape to cause a stroke

Left Atrial Appendage Closure Implants

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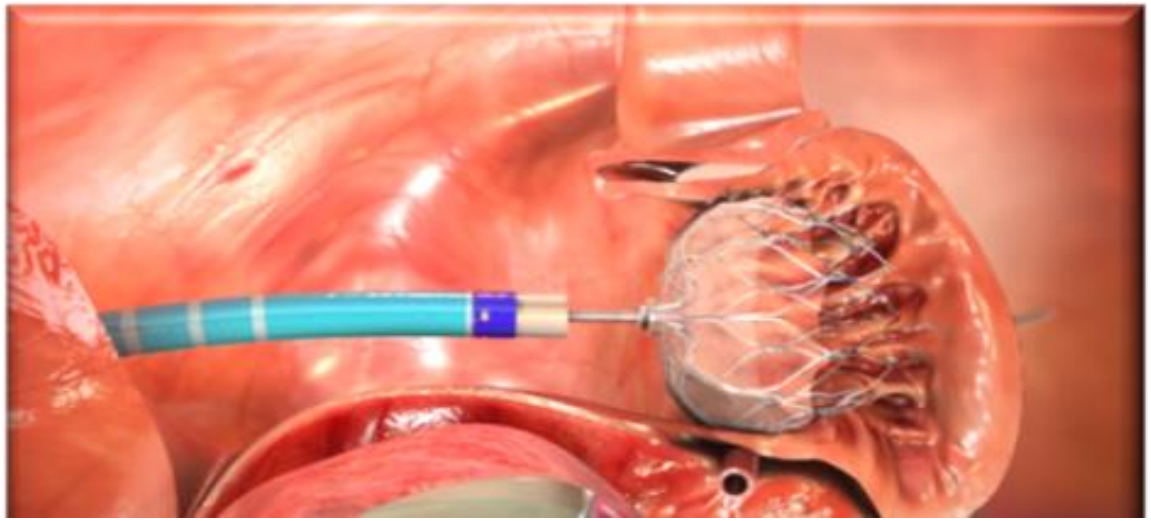
- LAAC Implants require a one-time, minimally invasive procedure that may reduce stroke risk for a lifetime
- They are an effective stroke risk alternative to blood thinners
- LAAC Implants reduce stroke risk without the worries that come with a lifetime of blood thinners
- The WATCHMAN™ Left Atrial Appendage Closure Implant is about the size of a quarter and made from very light and compact materials commonly used in many other medical implants



The Watchman™ Implant Clinical Evidence

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In a clinical trial,

96% of people were able to stop taking blood thinners

just 45 days after getting the WATCHMAN Implant[6]

The WATCHMAN™ Implant Procedure

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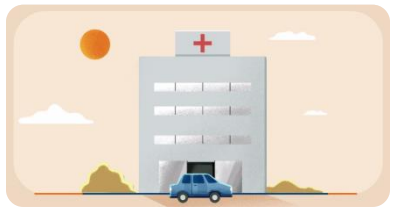
- The WATCHMAN Implant is safe and minimally invasive
  - does not require open heart surgery
  - cannot be seen outside the body
- The procedure is typically done under general anesthesia
- Typically takes less than an hour

People commonly stay in the hospital overnight and leave the next day



THE WATCHMAN™ Implant Procedure

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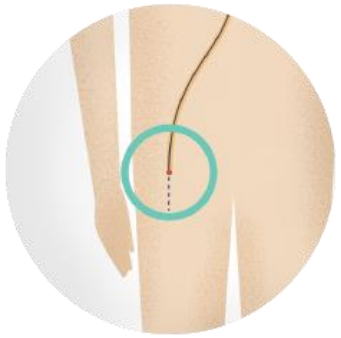
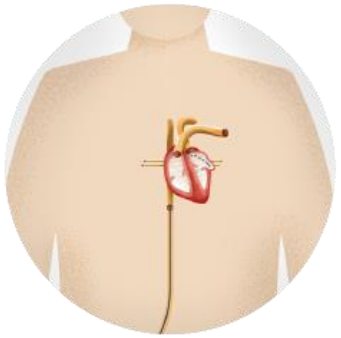


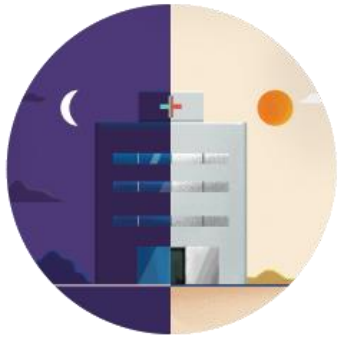
1.

To place the WATCHMAN, Implant, your doctor makes a small cut in your upper leg and inserts a narrow tube.



2.

Your doctor then guides the WATCHMAN Implant through the tube, into your LAA.



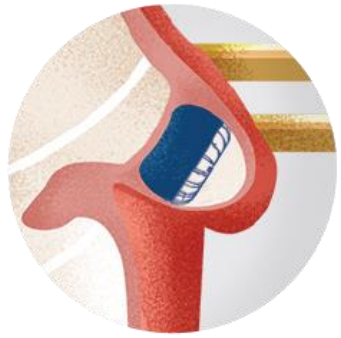
3.

The procedure is done under general anesthesia and typically takes About an hour.

People who get the WATCHMAN Implant usually stay in the Hospital overnight and go home the next day.

4.

After the procedure, you'll take blood thinners until your LAA is permanently closed off – usually just 45 days.



5.

During that time, heart tissue grows over the WATCHMAN Implant to form a barrier against blood clots.

The WATCHMAN™ implant has been studied for more than 20 years

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- The WATCHMAN Implant is an **FDA-approved implant** proven to safely and effectively lower stroke risk in patients with AFib not caused by heart valve problems

FDA APPROVED

The Watchman™ implant has a long and proven safety record

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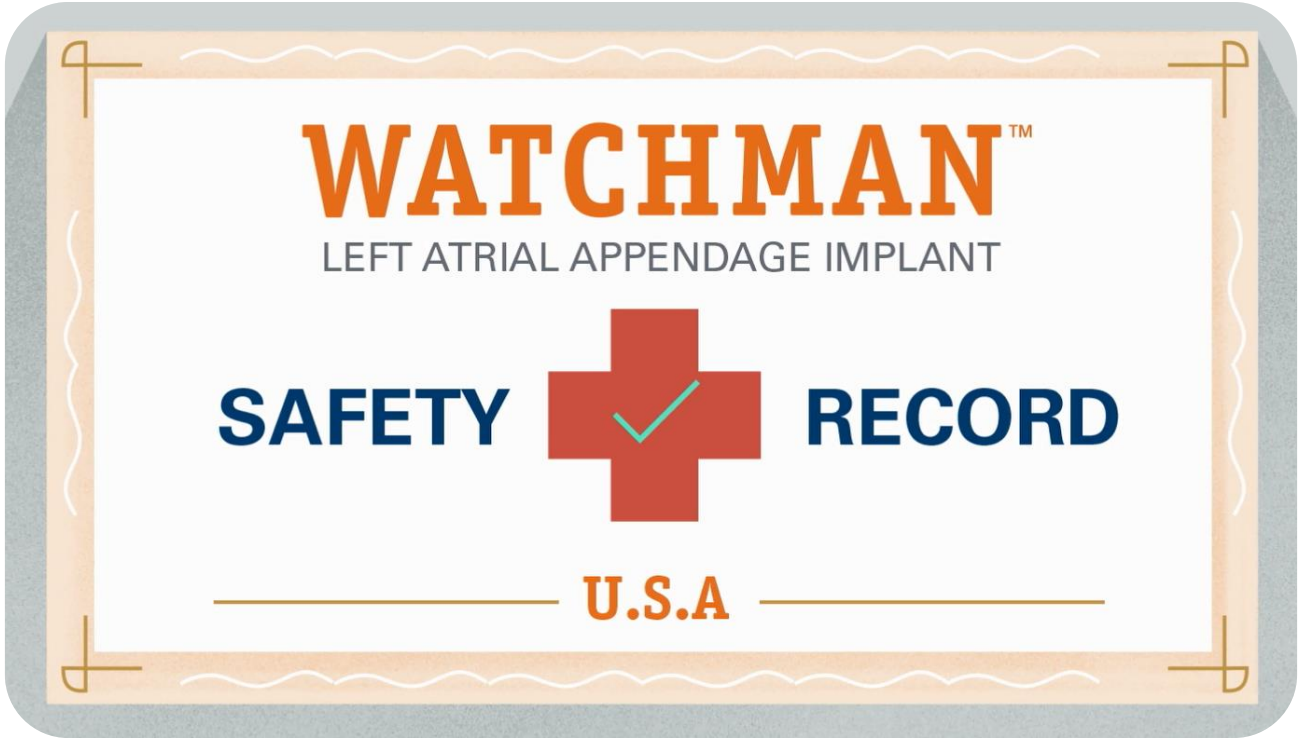
Worldwide, **more than 200,000 people** have received the WATCHMAN Implant and is the most implanted LAAC device in the United States.



Who is the WATCHMAN™ implant for?

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- The WATCHMAN Implant may be right for you if:

  ✓You have Atrial Fibrillation not caused by heart valve problem (NVAF)

  And

  ✓You've experienced bleeding while taking blood thinners

  Or

  ✓You have a lifestyle, job or health condition that puts you at risk for bleeding

People Who Should NOT be Considered for the WATCHMAN™ Implant

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- People who SHOULD NOT receive the WATCHMAN Implant include but are not limited to those who:

  - ✓Cannot take oral anticoagulants, aspirin or clopidogrel (Plavix®)
  - ✓Should not or cannot undergo heart catheterization procedures
  - ✓Have an allergy or sensitivity to nitinol (nickel and titanium)
  - ✓Have a left atrial appendage that does not fit the WATCHMAN Implant
  - ✓Are taking blood thinners for a condition other than atrial fibrillation

WATCHMAN Is a Safe, Effective, One-time Procedure For Appropriate Patients

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- The WATCHMAN Implant has been proven to be a safe and effective alternative to long-term oral anticoagulants (OACs)[1]
- Left atrial appendage closure (LAAC) with WATCHMAN may eliminate the need for long-term warfarin use in patients with non-valvular atrial fibrillation (NVAF) who have a reason to seek an alternative to OACs
- The WATCHMAN Implant has been proven to offer stroke risk reduction comparable to anti-coagulants—and also reduces the long-term risk of bleeding associated with anti-coagulants use.[2]

WATCHMAN FLX™

LEFT ATRIAL APPENDAGE CLOSURE DEVICE

- Holmes DR . JACC 2014;64(1):1-12.
- Holmes DR. JACC 2015;65(24):2614-2623.

Thank You!!

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Oussama Lawand MD, FHRS
Clinical Cardiac Electrophysiology
Boulder Heart

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1- AFib Ablation

2- Intracardiac Echo (ICE)

3- ICE Guided LAAO

4- Concomitant Procedures

AFib Ablation: Faster, Simpler

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Shift from radiofrequency guidance to pulsed field ablation has simplified the workflow and reduced overall procedure time

- Treat atrial fibrillation by electrically isolating the pulmonary veins
- Historically guided by radiofrequency energy with point-by-point lesion creation
- Now increasingly guided by pulsed field ablation for selective tissue effect
- Procedure simplified through fewer lesion steps and more predictable tissue response
- Clinical workflow shortened leading to reduced procedure time and improved efficiency

AF Ablation: RF to PFA

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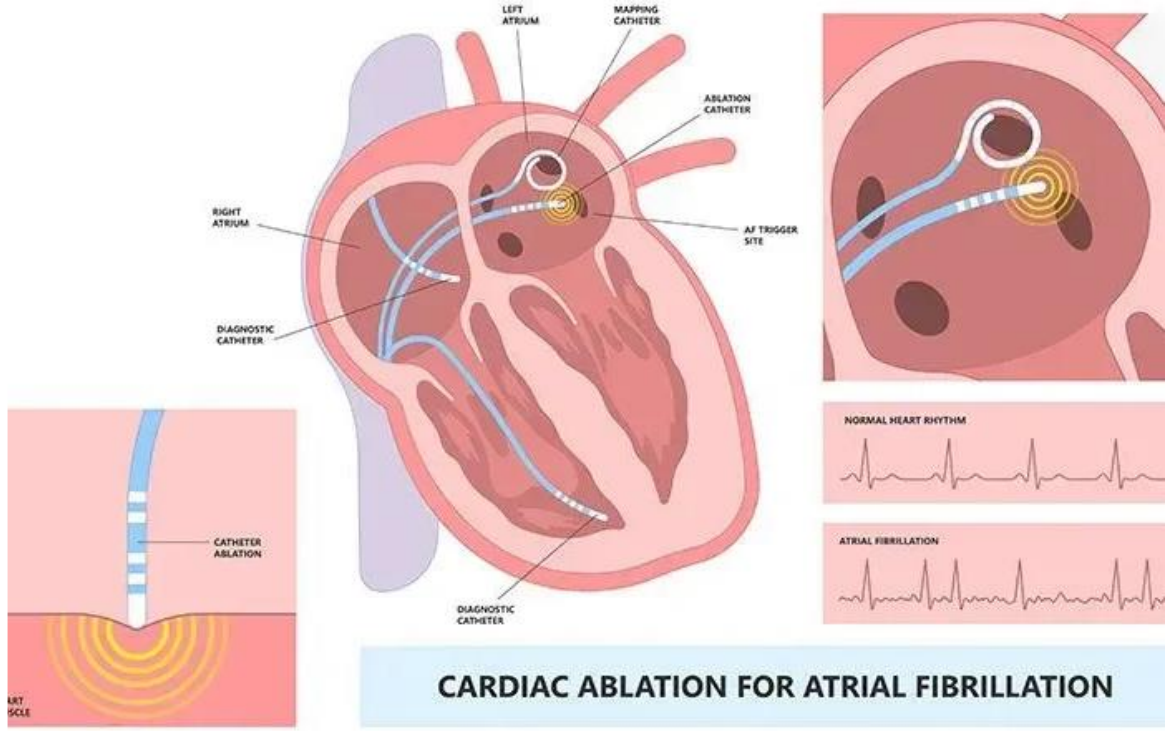
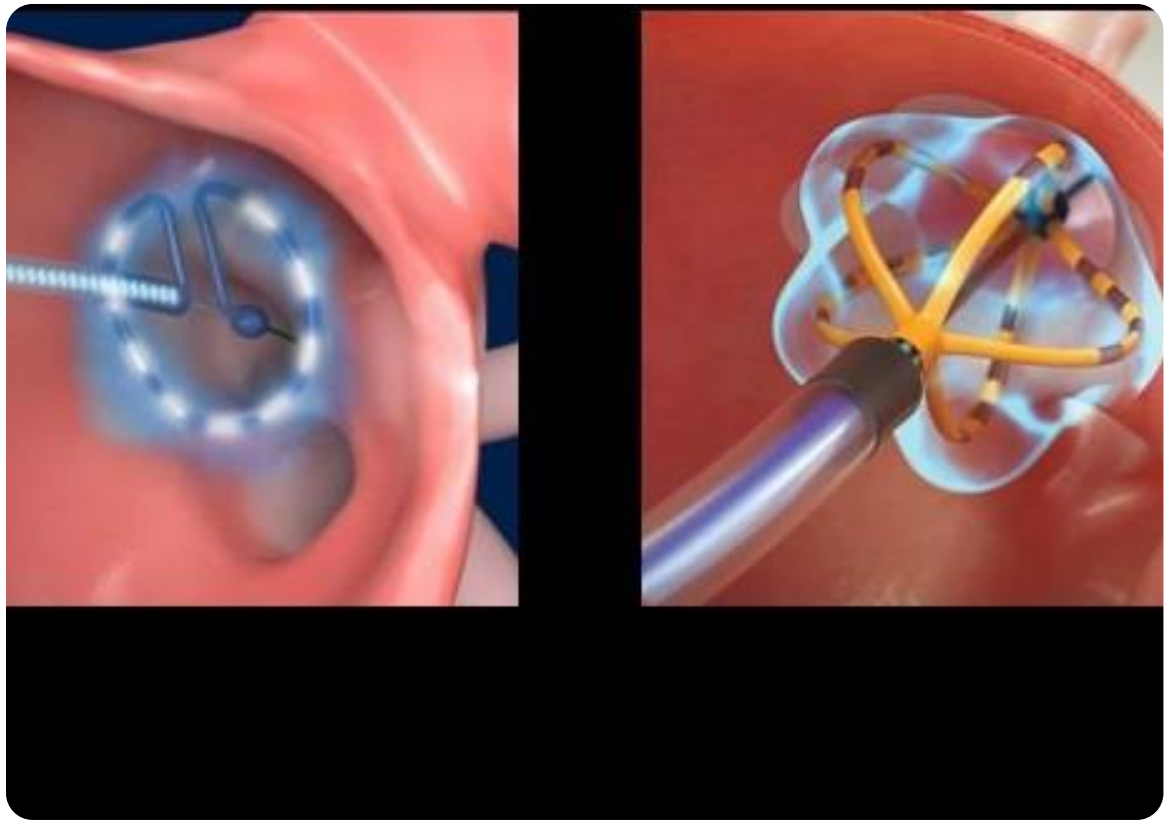
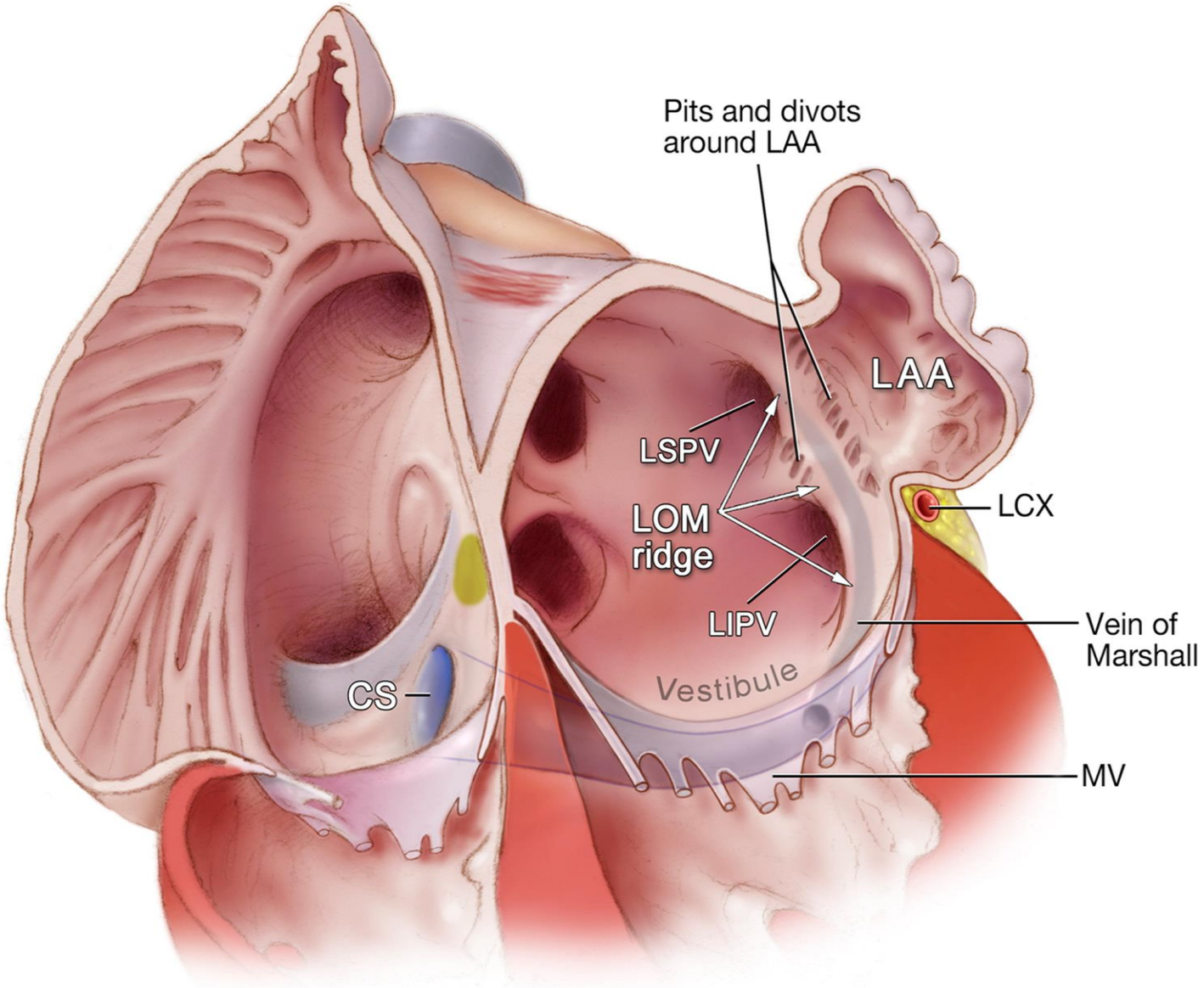
High-resolution image of atrial fibrillation ablation catheters for clinical presentation






Pits and divots
around LAA
LAA
LSPV
LOM
ridge
LCX
LIPV
Vein of
Marshall
Vestibule
CS
MV

Intracardiac Echocardiography in AFib Ablation

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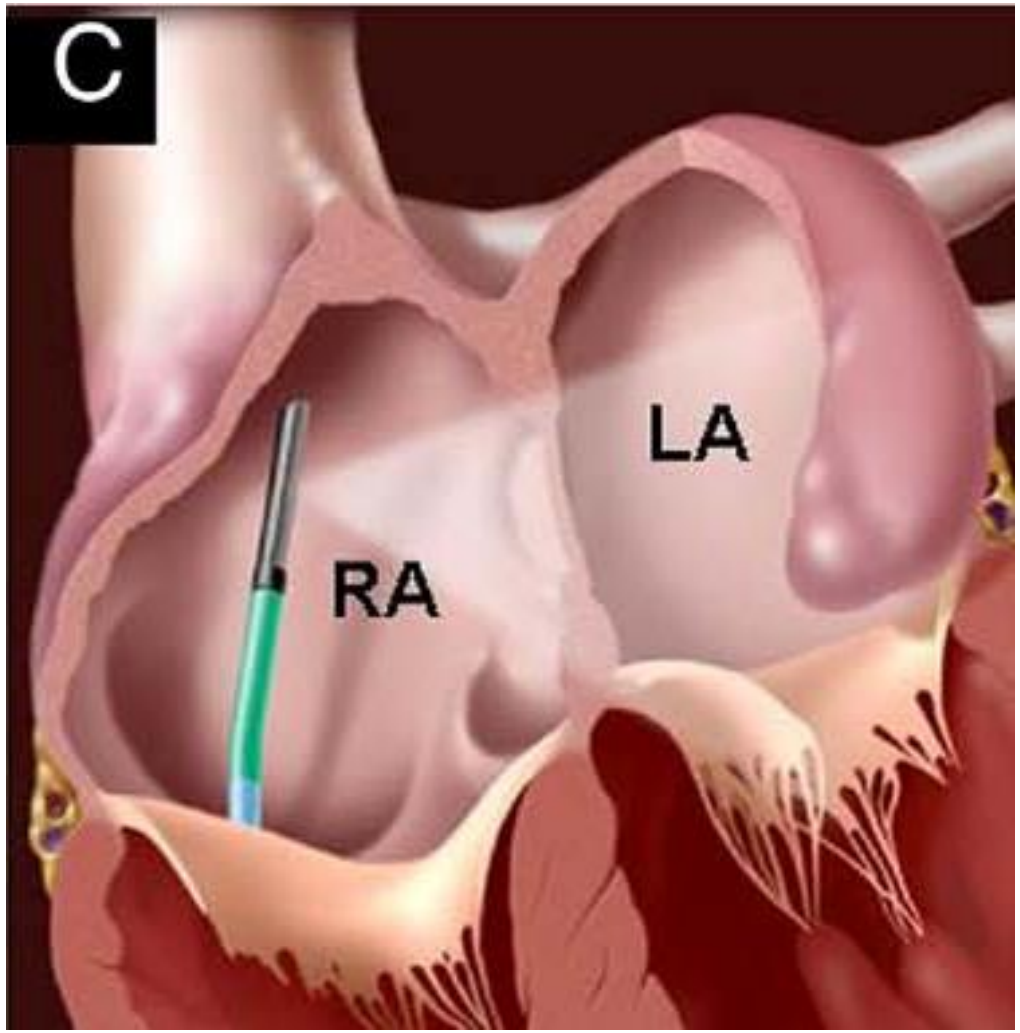
- Real-time imaging of cardiac structures including septum, pulmonary veins, and **left atrium**
- Guides transseptal puncture by showing septal thickness and needle position
- Displays catheter tip contact, lesion formation, and immediate complications
- Displays catheter tip contact, lesion formation, and immediate complications
- Detects pericardial effusion early to allow prompt intervention
- Supports mapping by confirming anatomy relative to electroanatomic maps
- Reduces fluoroscopy use and radiation exposure during procedures
- Can be used to guide left atrial appendage occlusion by visualizing ostium, device position, and seal



ICE-Guided LAAO Roadmap

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01 Why ICE guided LAAO?

02 Operator Skillset

03 Imaging Technology

04 Concomitant Procedures

Intra cardiac echo (ICE) guided LAAO

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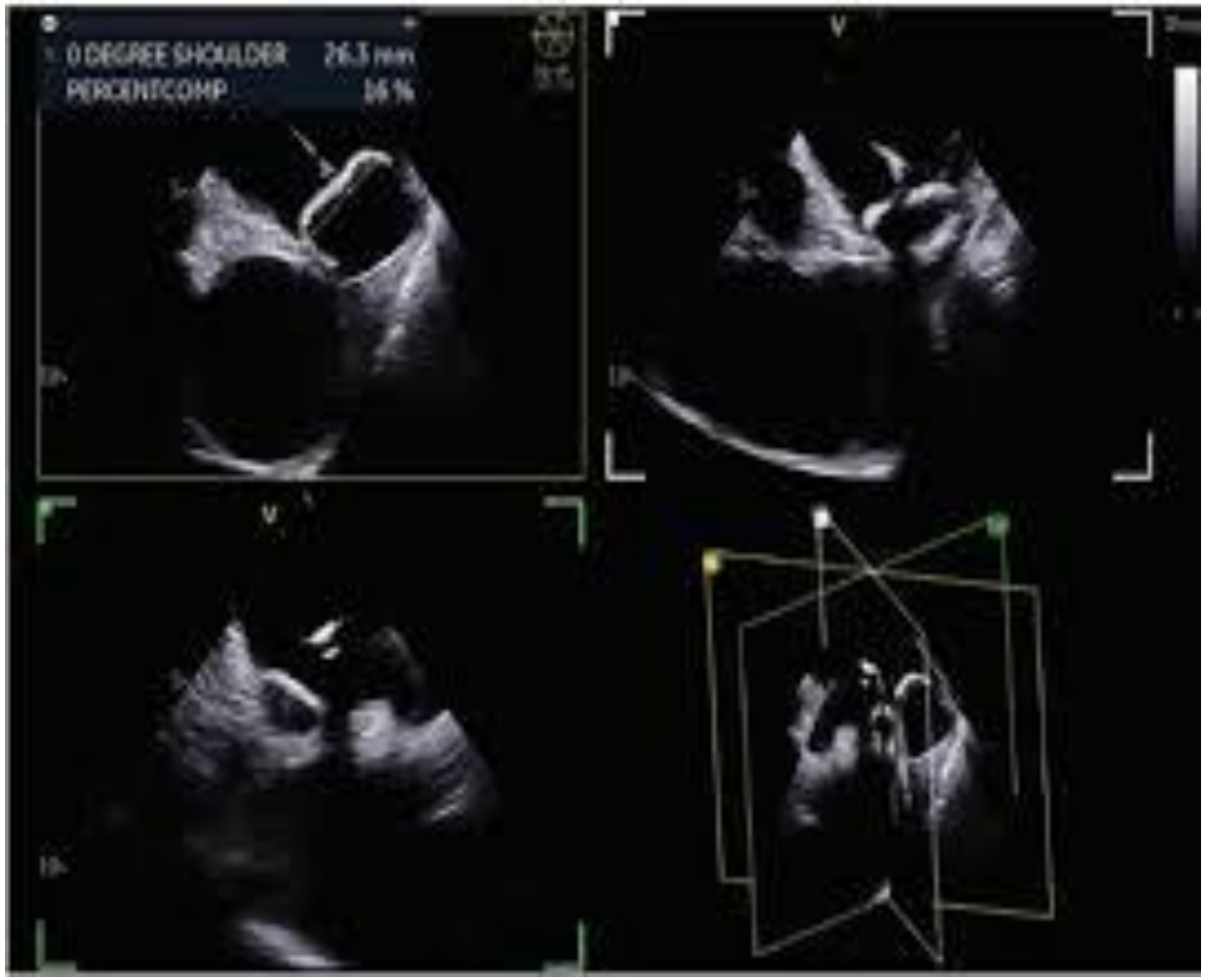
Allows for a seamless transition between the AF ablation and the LAAO as the imaging catheter is already in the heart

It must be advanced into the left atrium which takes skill

1. Stand Alone LAAO
2. Concomitant AF ablation and LAAO



Why ICE guided LAAO?

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Clinical scenarios where intracardiac echocardiography improves left atrial appendage occlusion planning, guidance, or combined procedures

Workflow Considerations:

- Contraindication to TEE
- When general anesthesia is undesirable and conscious sedation is preferred

Workflow Considerations

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- No need to coordinate with general cardiologist when schedule is tight
- Avoid holding up an echo tech—service is strapped for echo techs
- Perform LAAO seamlessly after ablation for concomitant procedures
- Respect staff workload while maintaining procedural safety
- Lab effiency

When to Avoid Transesophagel Echocardiograhpy

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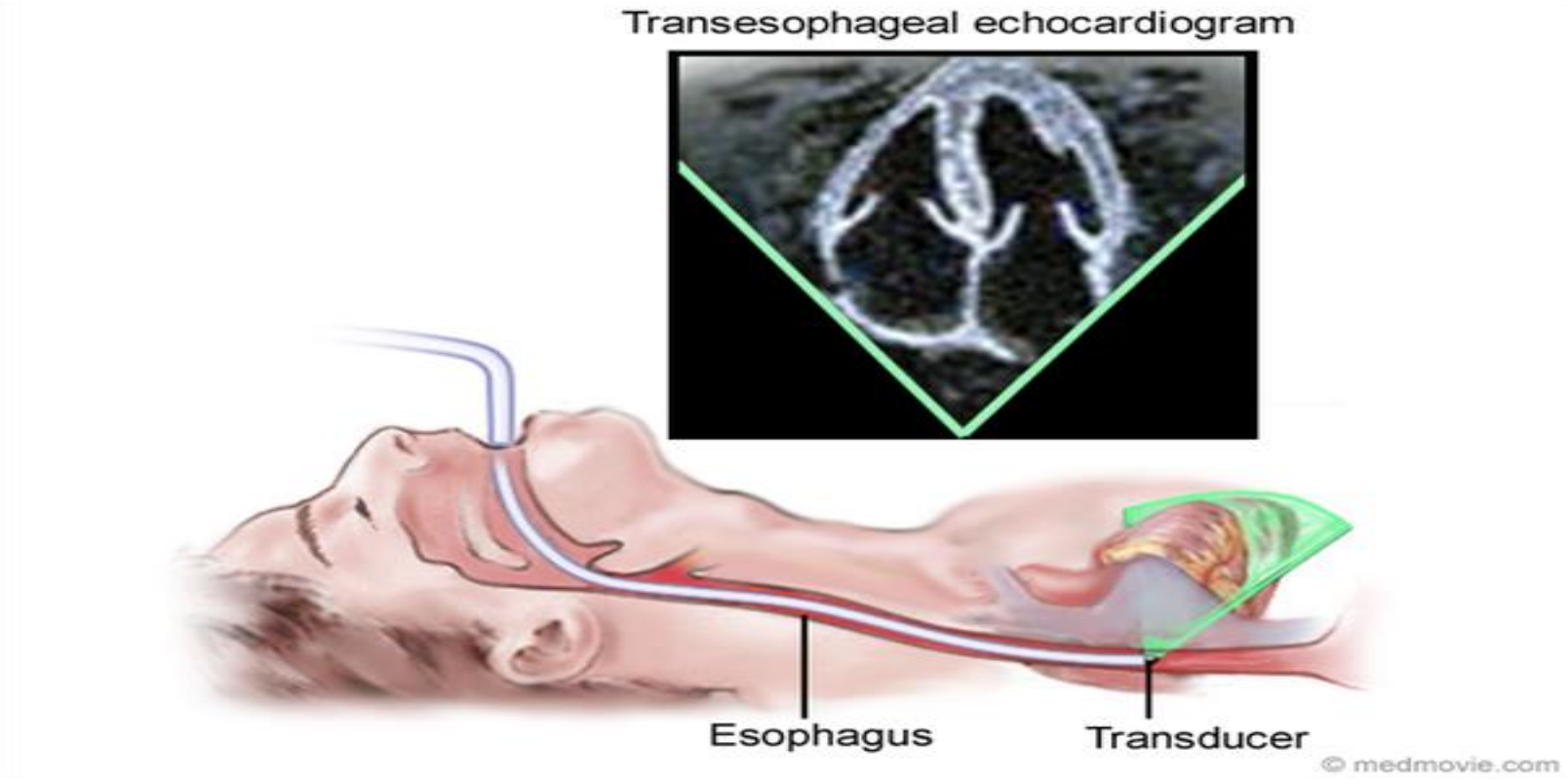
- Esohpageal Varicese
- Esophageal Stricture
- Esophageal Mass



Why to avoid general anesthesia in some patients

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- Severe cardiopulmonary disease raising risk of hemodynamic instability
- Difficult airway or prior failed intubation increasing aspiration risk
- Obstructive sleep apnea with high perioperative respiratory risk
- Severe obesity complicating ventilation and airway management
- Neuromuscular disorders affecting respiratory function

Operator Skillset for ICE-Guided LA Procedures

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- Operator must have experience with ICE, critical when maneuvering the ICE catheter in the left atrium
- The ICE catheter must be advanced from the RA to the LA by the operator
- Operator owns the intraprocedural images and interpretation
- ICE echo tech supports the operator and ensures **PASS** criteria are met
- PASS checklist: Position, Anchor, Seal and Size — confirm each step during deployment
- Maintain clear communication between operator and echo tech throughout the procedure

ICE: From 2D Imaging to 4D "live 3D" imaging

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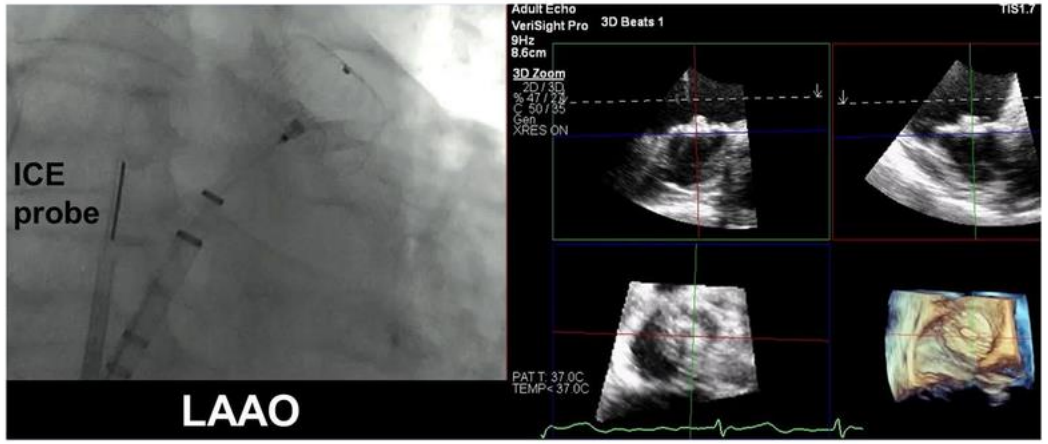
- Early ICE: 2D planar imaging/limited resolution
- 3D ICE: volumetric imaging for true anatomical context and depth perception
- Nuvision ICE delivers real-time 3D guidance for precise device navigation
- Improves procedural speed and confidence with continuous volumetric views
- Enables better assessment of complex anatomy and device-tissue interaction
- Supports intra-procedural decision making and post-procedure review



Clinical Indications for LAAO

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When to consider left atrial appendage occlusion and when to combine it with atrial fibrillation ablation for optimal patient outcomes

- Patients with Nonvalvular atrial fibrillation who have an elevated stroke risk and a contraindication to long-term oral anticoagulation
- Consider concomitant AF ablation plus LAAO for patients with symptomatic AF with stroke risk and anticoagulation issues

Essential ICE-LAAO Skillset

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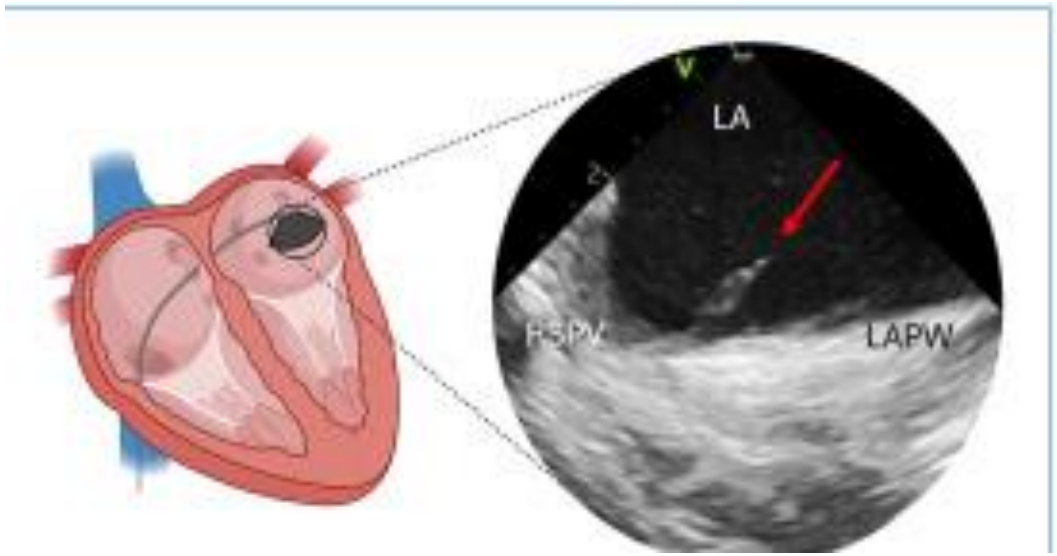
ICE-guided LAAO requires mastery of specialized left atrial



Left Atrial ICE

Master navigation of the probe through the transseptal puncture to obtain standard LAA views (0, 45, 90, and 135 degrees) for effective visualization.

Transseptal Puncture

Execute precise punctures guided by ICE, while interpreting artifacts and anatomical markers to ensure accurate device sizing throughout the procedure.

When to Consider AF Ablation and LAAO

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Two clinical scenarios to evaluate bleeding risk, symptom burden, and candidacy for atrial fibrillation ablation and left atrial appendage occlusion

Patient referred for AF ablation

- Assess bleeding risk and ability to tolerate long term oral anticoagulation. If high bleeding risk or OAC intolerance, consider concomitant LAAO. Weigh stroke risk against procedural risks when planning combined therapy.

Patient referred for LAAO

- Determine if patient is symptomatic from uncontrolled atrial fibrillation. If symptomatic, consider adding AF ablation at time of LAAO for rhythm control. Balance symptom relief goals with procedural complexity and patient preference.

AFib Ablation First? LAAO First?

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- Generally, better not to ablate in the presence of a recently implanted watchman device. Has not endothelialized yet.
- Concomitant AF ablation + LAAO vs separating them a few weeks apart

Concomitant or Separate Them?

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- Consider separating them if AFib ablation is complex/takes longer then expected
- Consider separating them if LAA anatomy complex

Concomitant AF Ablation & LAAO

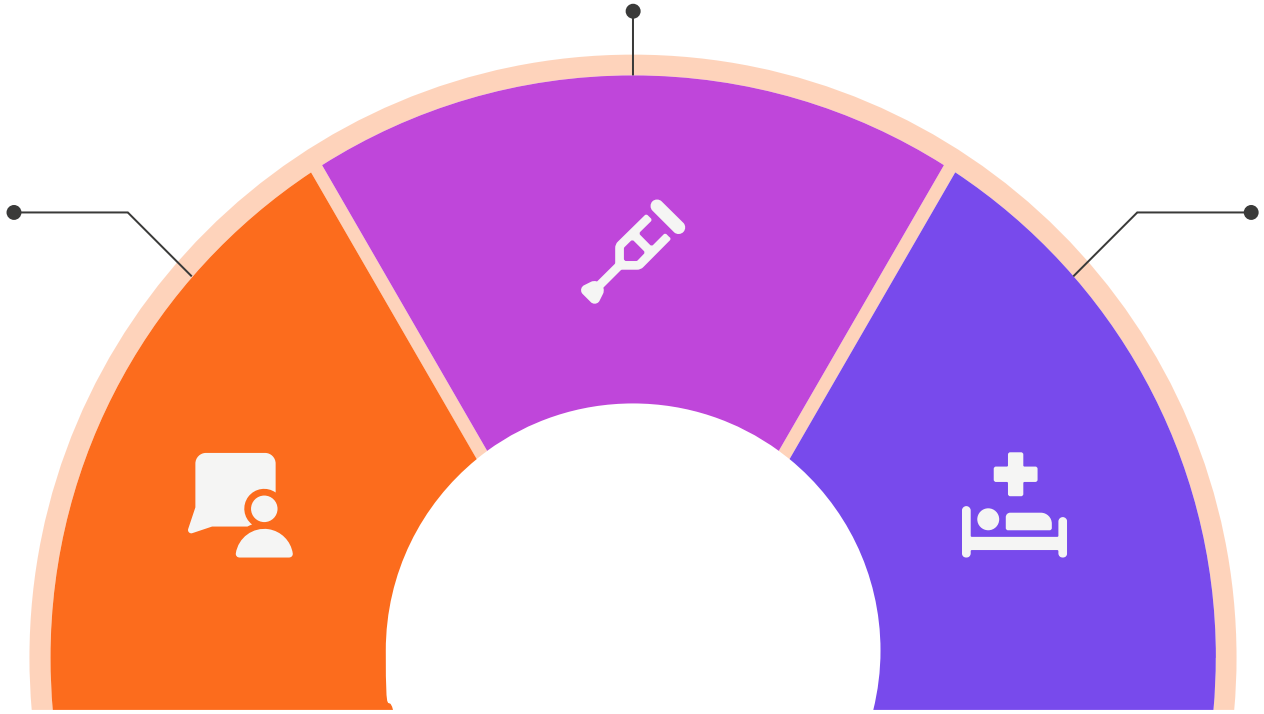
Boulder Community Health

Risk Reduction

Lower cumulative procedural risks and hospitalizations for eligible high-risk patients.

Unified Strategy

Address AF rhythm and LAAO stroke risk in one single procedure.



Target Patients

Resource utilization
Time in the hospital

Standardizing the Concomitant Procedural Sequence

Boulder Community Health

1

Single Access

Use ICE to guide a single puncture for both the ablation catheter and the Watchman delivery system for the procedure.

2

Ablation First

Perform AF ablation first to achieve rhythm control .

3

LAA Assessment

Re-evaluate LAA anatomy with ICE post-ablation to ensure the LAA dimensions have not changed

4

LAAO

Exchange the ablation sheath for the LAAO delivery system and deploy the device under ICE guidance to complete the procedure.

5

Final Check

Use ICE to confirm the PASS criteria (Position, Anchor, Size, Seal) and check for any signs of pericardial effusion.

Thank you!

Boulder Community Health

Srinivas Iyengar, MD
Interventional Cardiology & Cardiology
Boulder Heart

Animation

https://www.youtube.com/watch?v=B1_bajZTQfU

Boston Scientific
Advancing science for life™

WATCHMAN™
INTEGRATED LAAC SOLUTIONS

CHAMPION-AF Trial Outcomes

Late-Breaking Clinical Science at ACC Scientific Expo 2026 with Simultaneous Publication in the New England Journal of Medicine

HCP Presentation

CHAMPION-AF Overview

Study Objective & Rationale

CHAMPION-AF is a prospective, randomized, multi-center, global investigation to study left atrial appendage closure with the WATCHMAN FLX™ LAAC Device as a first-line alternative to oral anticoagulation in a broad non-valvular atrial fibrillation population, including those who are at low-to-moderate risk of bleeding from the use of oral anticoagulation.

- 2019 AHA/ACC/HRS Focused Update on Atrial Fibrillation: LAAC was added to the guidelines for patients who are poor candidates for long-term oral anticoagulation as a 2b class of recommendation.
- 2023 AFib Guidelines: LAAC is class 2a recommendation for patients with non-reversible, severe bleeding risks (major GI/pulmonary/GU bleeding, spontaneous intracranial/intraspinal bleeding, or serious bleeding from untreatable recurrent falls); patients with general high bleeding risk remain class 2b.
- The primary objective of the CHAMPION-AF trial is to determine if left atrial appendage closure with the WATCHMAN FLX™ device is a reasonable first-line alternative compared with non-vitamin K oral anticoagulants (NOACs) in patients with non-valvular atrial fibrillation.

SK Doshi et al. Left Atrial Appendage Closure or Anticoagulation for Atrial Fibrillation. New England Journal of Medicine, March 2026.

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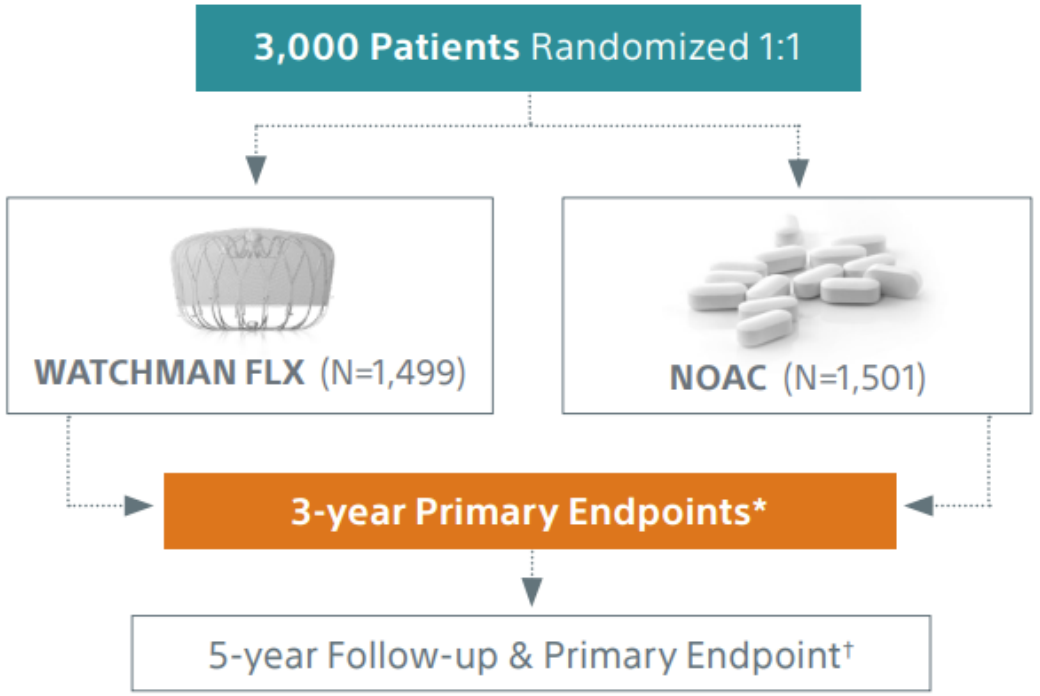
CHAMPION-AF Overview

Trial Design & 3-year Endpoints



Patients did not need to have an appropriate rationale to seek a non-pharmacologic alternative to OAC to participate in this study nor was there a requirement for documented shared decision making.

3-year Endpoints

Primary Efficacy (Non-inferiority)

Composite of cardiovascular (CV) death (including hemorrhagic or unexplained death), all stroke (ischemic and/or hemorrhagic), or systemic embolism.

Primary Safety (Superiority)

Non-procedural bleeding (ISTH major bleeding and modified* clinically relevant non-major bleeding).

Secondary Safety (Non-inferiority)

Procedural and non-procedural ISTH major bleeding.

Secondary Net Clinical Benefit (Non-inferiority & Superiority)

Composite of cardiovascular (CV) death, all stroke, systemic embolism, and non-procedural bleeding (ISTH major bleeding and modified* clinically relevant non-major bleeding).

***Modified ISTH clinically relevant non-major bleeding:** does not fit criteria for the ISTH definition of major bleeding but requires hospitalization or increased level of care.

*Study success is defined as meeting both 3-year primary endpoints
†5-year primary endpoint is non-inferiority for the occurrence of ischemic stroke or systemic embolism

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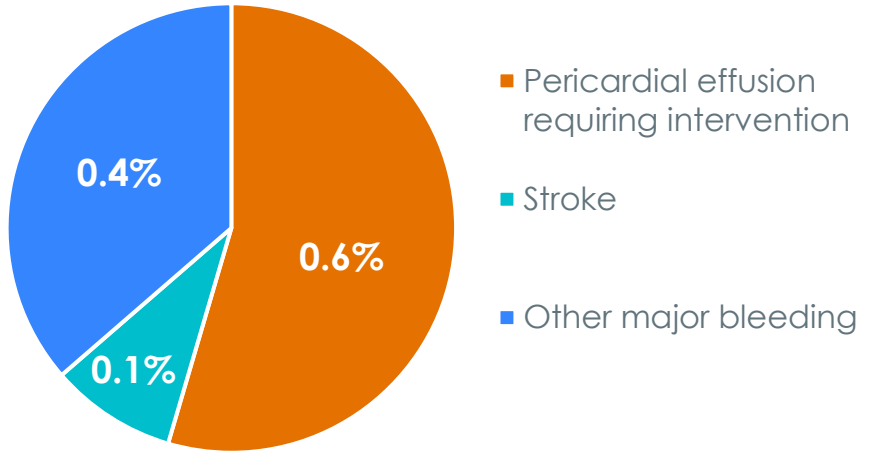
Key Patient Demographics & Procedural Characteristics

	NOAC (n=1501)	WATCHMAN FLX (n=1499)
Age, yr (Avg ± SD)	71.8±7.5	71.6±7.5
Female	31.5%	32.4%
Caucasian	85.0%	85.1%
CHA_2DS_2-VASc score (Avg ± SD)	3.5±1.3	3.5±1.2
HAS-BLED score (Avg ± SD)	1.3±0.8	1.3±0.8
Prior ischemic stroke	7.6%	7.9%
Prior hemorrhagic stroke	0.7%	0.3%
History of congestive heart failure	22.4%	21.2%
History of major bleeding	3.3%	3.5%
Paroxysmal AF	68.5%	69.3%
Persistent AF	25.4%	23.9%
Permanent AF	6.1%	6.8%
Prior atrial fibrillation ablation	46.9%	48.7%

99%

procedural success† across 141 implanting centers reinforces the simplicity of the WATCHMAN FLX™ platform on a global scale

Serious Adverse Events Within 7 Days of Procedure*
(N=1408 attempted implants)



***There were no deaths, device embolization or systemic embolism**
†Device successfully deployed and released

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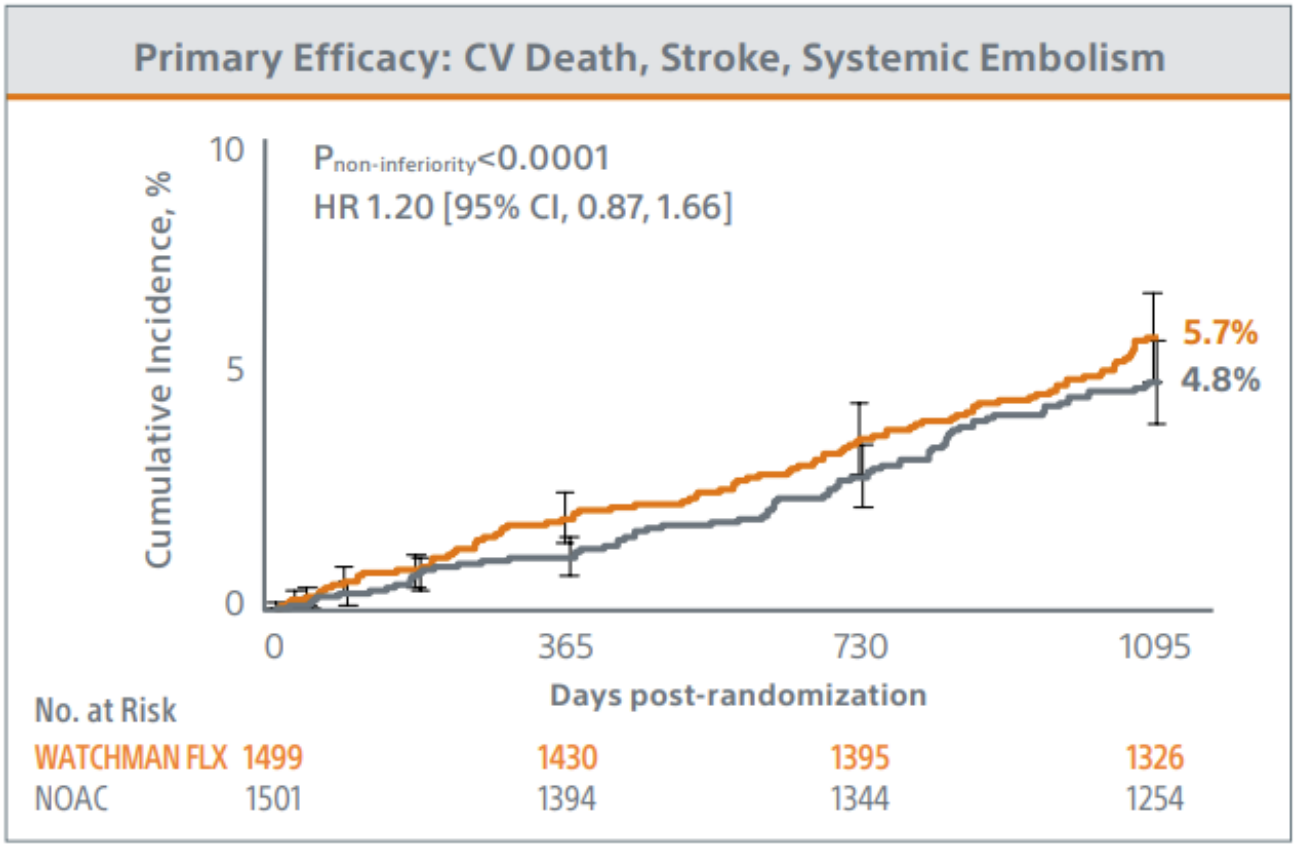
Primary Efficacy Endpoint (ITT)

WATCHMAN FLX™ demonstrated statistical non-inferiority to NOACs



WATCHMAN FLX demonstrated statistical non-inferiority to NOACs for the occurrence of cardiovascular (CV) death (hemorrhagic and/or unexplained death), stroke (ischemic and/or hemorrhagic), or systemic embolism.

(5.7% vs. 4.8%; $P_{non\text{-}inferiority}$ <0.0001).

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Primary Efficacy Individual Components (ITT)

The annualized average difference in ischemic stroke & systemic embolism rates was 0.33%/year.

	NOAC (n=1501)	LAAC (n=1499)	Hazard Ratio [95% CI]
Cardiovascular/Unexplained Death	36 (2.7%)	38 (2.7%)	1.01 [0.64, 1.59]
Stroke	33 (2.5%)	50 (3.6%)	1.46 [0.94, 2.27]
Ischemic	27 (2.0%)	45 (3.2%)	1.61 [1.00, 2.59]
Hemorrhagic	5 (0.4%)	5 (0.4%)	0.96 [0.28, 3.32]
Undetermined	1 (0.1%)	0 (0.0%)	0.00 [NA, NA]
Systemic embolism	2 (0.1%)	0 (0.0%)	0.00 [NA, NA]

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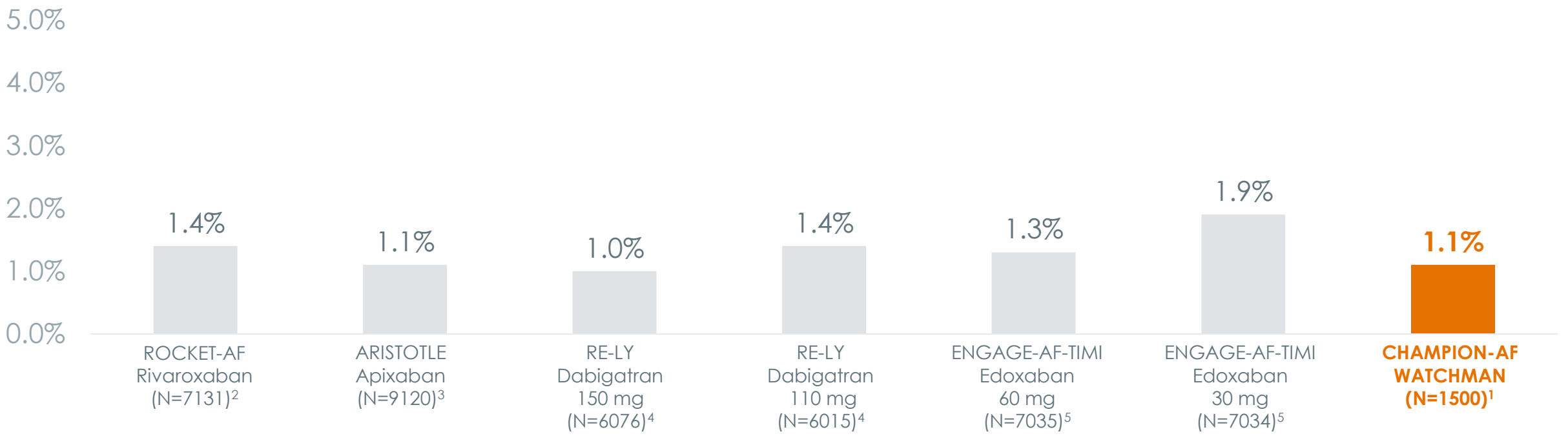
Ischemic Stroke/Systemic Embolism (SE) Across Landmark Trials

The WATCHMAN FLX™ device demonstrated a 1.1% annualized ischemic stroke/SE rate, aligned with ischemic stroke/SE rates observed in prior, seminal clinical trials of NOACs, suggesting both strategies may be effective for a broader population of patients with NVAF who are seeking a stroke risk reduction therapy.



Results from different clinical investigations are not directly comparable. Information provided for educational purposes only. CHAMPION-AF NOAC arm annualized ischemic stroke/SE rate: 0.7%.

1. SK Doshi et al. Left Atrial Appendage Closure or Anticoagulation for Atrial Fibrillation. New England Journal of Medicine, March 2026. 2. Patel, M. Rivaroxaban versus Warfarin in Nonvalvular Atrial Fibrillation. NEJM 2011; 365(10):883-891. 3. Granger, C. Apixaban versus Warfarin in Patients with Atrial Fibrillation. NEJM 2011; 365(11):981-992 4. Connolly, S. Dabigatran versus Warfarin in Patients with Atrial Fibrillation. NEJM 2009; 361(12): 1139-1151. 5. Giugliano, R. Edoxaban versus Warfarin in Patients with Atrial Fibrillation. NEJM 2013; 369(22): 2093-2104.

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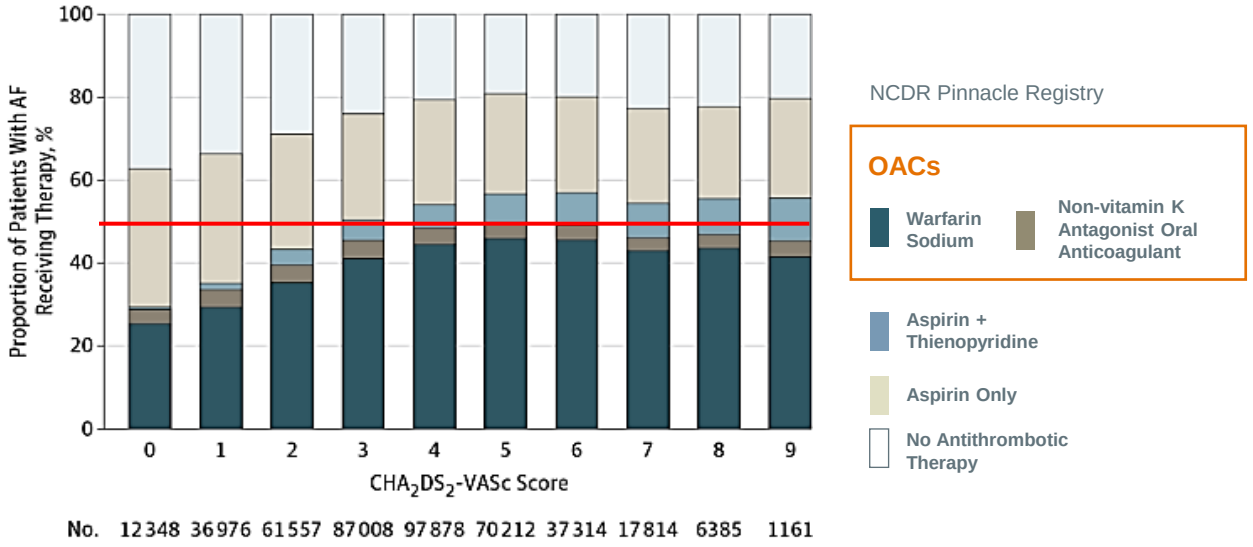
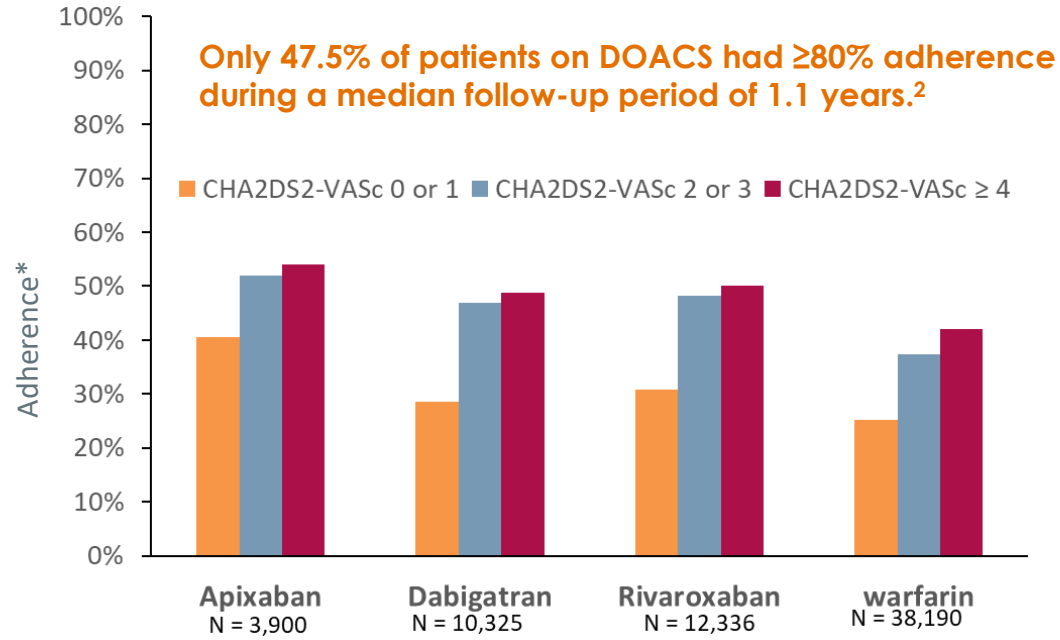
87% NOAC adherence in CHAMPION-AF does not reflect reality for most patients

Only about half of patients with AFib are treated per guidelines

Despite increasing risk of stroke, the use of OAC in AFib patients peaks at ~50%[1]

OAC adherence below 80% can increase stroke risk by up to 64%.[3]



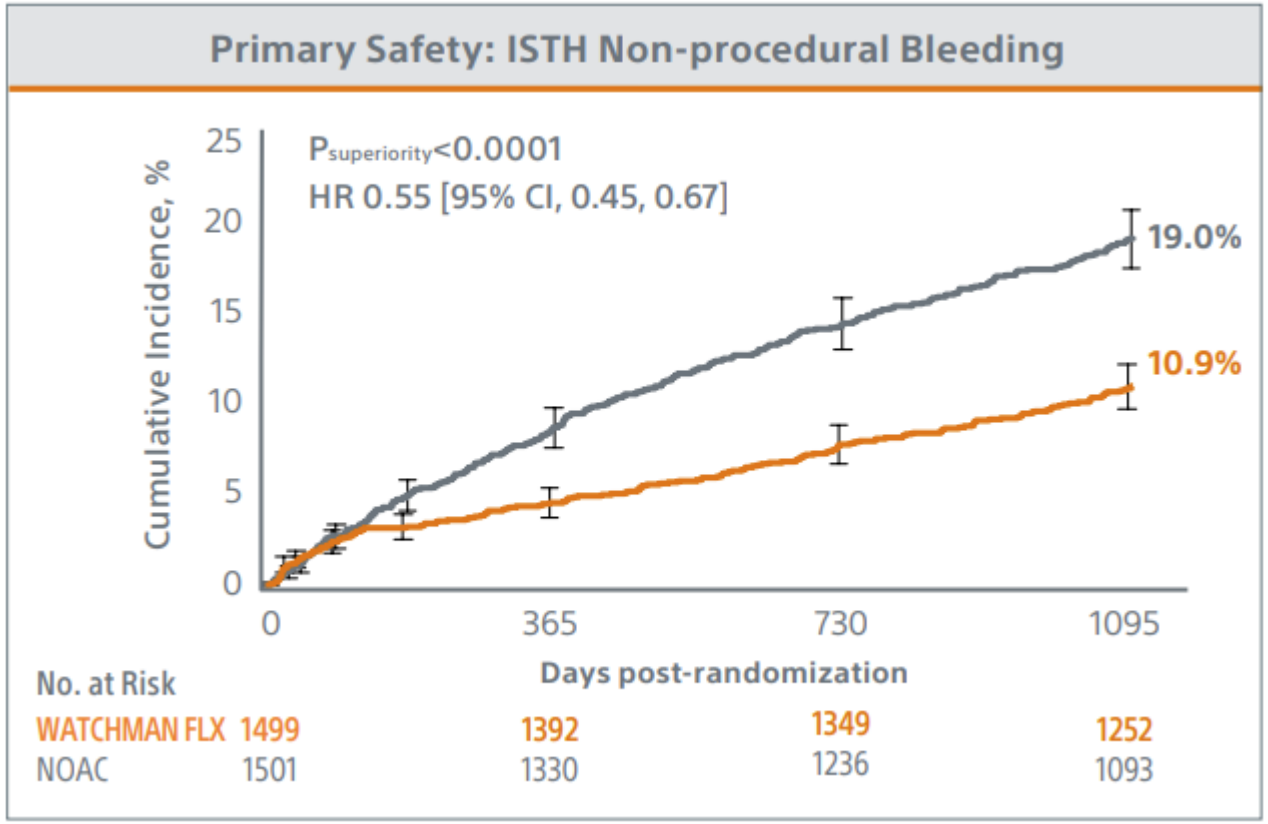


*Predicted probability of adherence; reported adherence rates adjusted for confounders

1. Hsu, J et al. JAMA Cardiol. Published online March 16, 2016. doi:10.1001/jamacardio.2015.0374
2. Yao X et al. J Am Heart Assoc. 2016;5(2): e003074.
3. Grymonprez M, et al. Cardiovascular Drugs and Therapy, vol. 39, no. 1, Feb. 2025, pp. 107-17.

Primary Safety Endpoint (ITT)

WATCHMAN FLX™ demonstrated statistical superiority to NOACs



WATCHMAN FLX demonstrated statistical superiority to NOACs for the occurrence of ISTH non-procedural major bleeding and modified* clinically relevant non-major bleeding.

(10.9% vs. 19.0%; $P_{superiority}$ <0.0001)

▼45%

Relative reduction in ISTH major and modified* clinically relevant non-procedural bleeding at 36 months.

***Modified ISTH clinically relevant non-major bleeding:** does not fit criteria for the ISTH definition of major bleeding but requires hospitalization or increased level of care.

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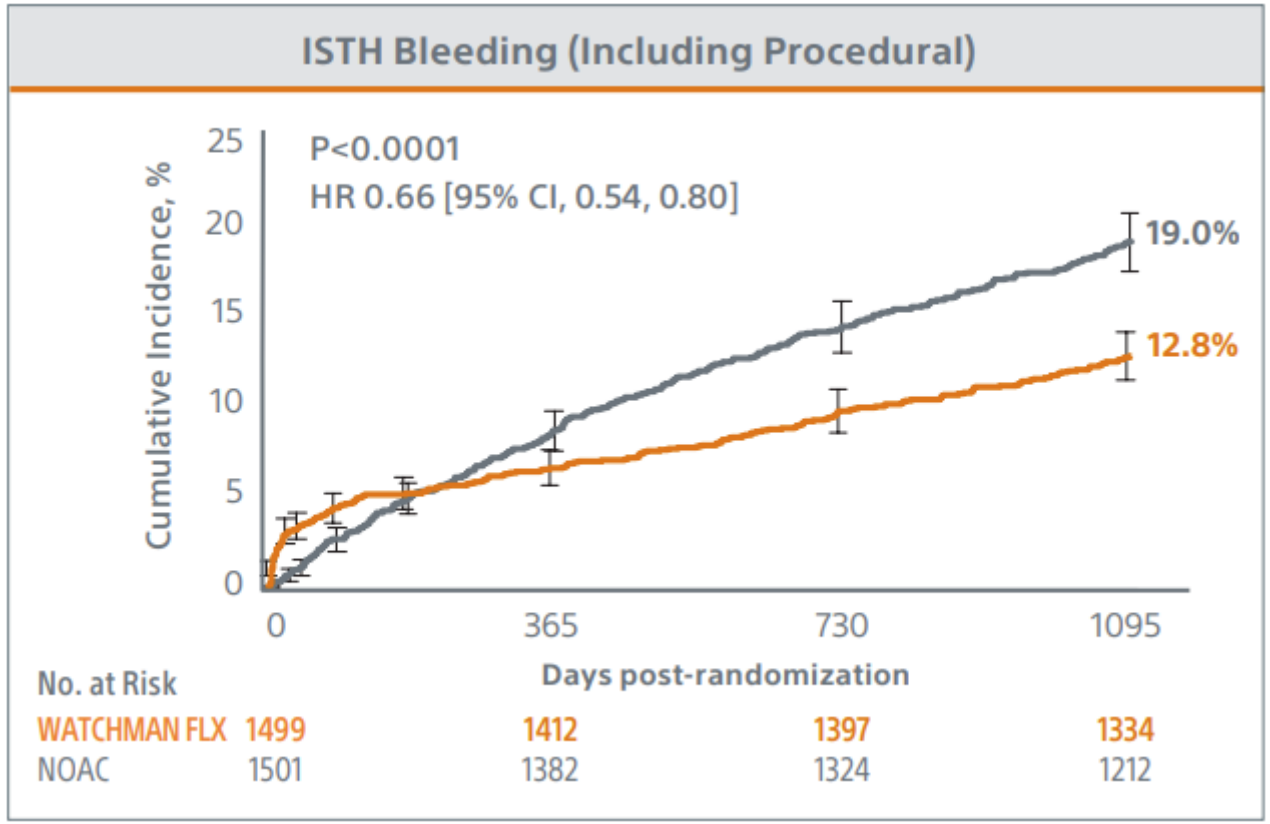
ISTH Bleeding (Including Procedural)

WATCHMAN FLX™ demonstrated a statistically significant reduction compared to NOACs



Reaffirming superiority of the primary safety endpoint, **WATCHMAN FLX demonstrated a statistically significant 34% risk reduction in ISTH bleeding (including procedural)** at 36 months.

▼34%

Relative reduction in ISTH major and modified* clinically relevant non-major bleeding (including procedural).

***Modified ISTH clinically relevant non-major bleeding:** does not fit criteria for the ISTH definition of major bleeding but requires hospitalization or increased level of care.

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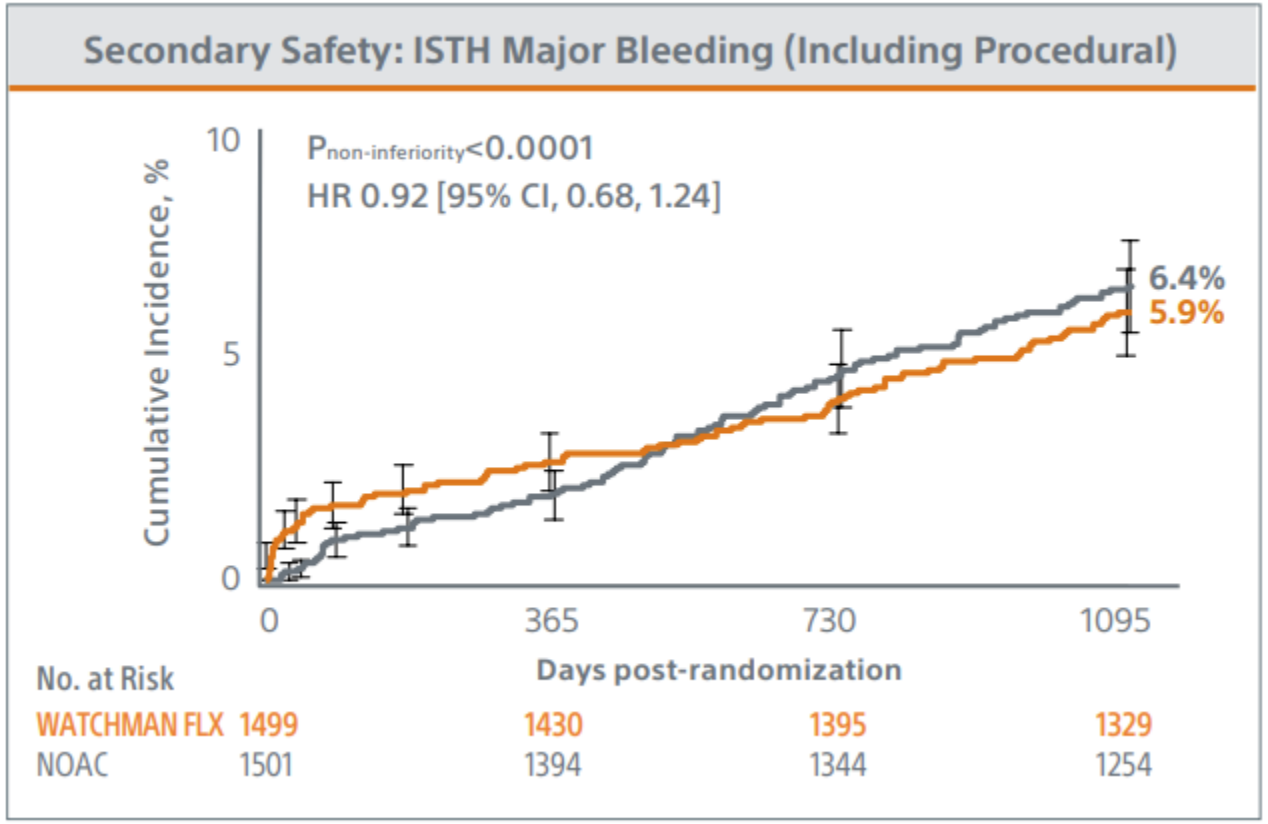
Secondary Safety Endpoint (ITT)

WATCHMAN FLX™ demonstrated statistical non-inferiority vs. NOACs



WATCHMAN FLX demonstrated statistical non-inferiority to NOACs for the occurrence of ISTH major bleeding, including procedural bleeding.

(5.9% vs. 6.4%; $P_{non\text{-}inferiority}$ <0.0001).

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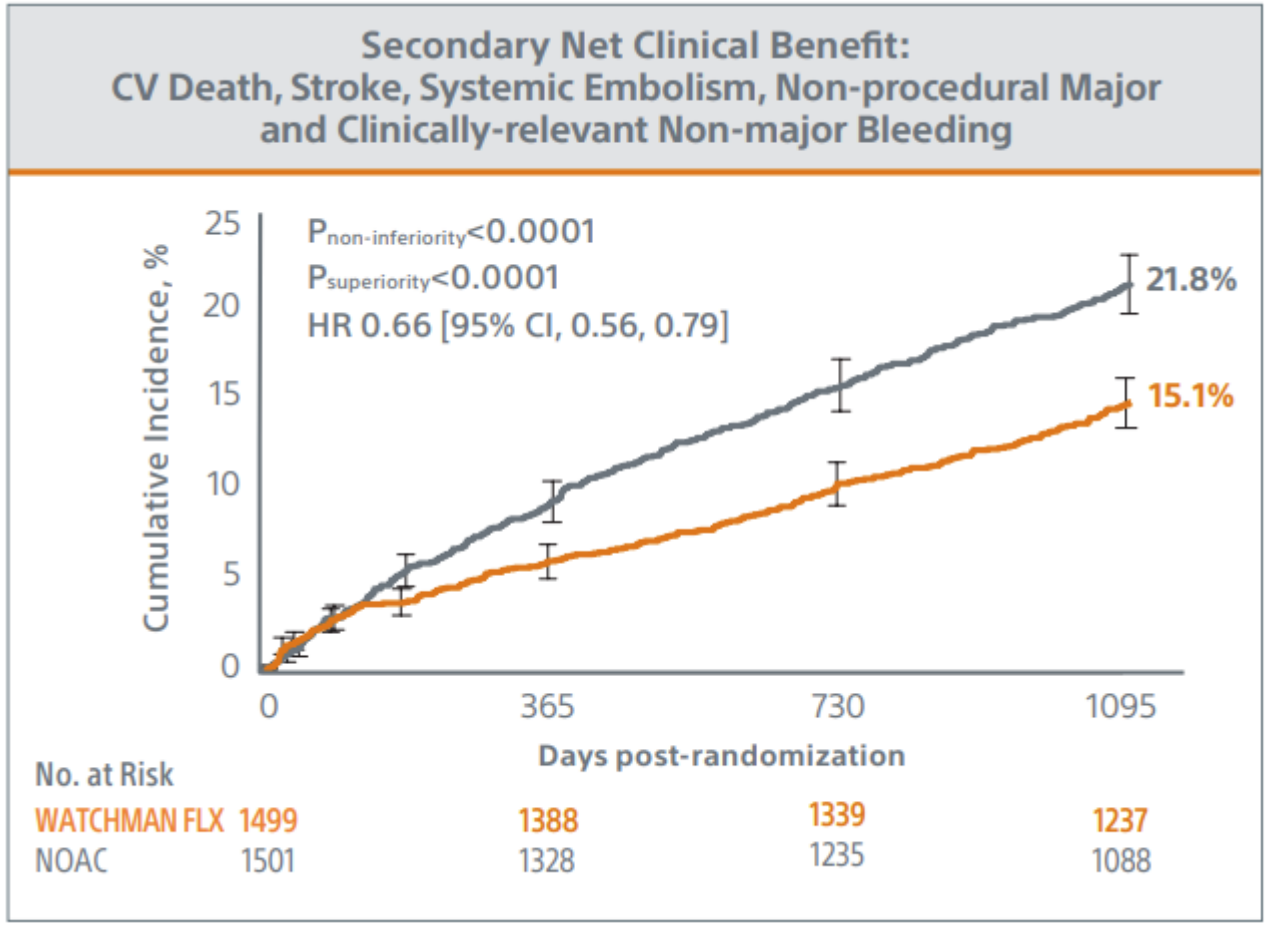
Secondary Net Clinical Benefit Endpoint (ITT)

WATCHMAN FLX™ demonstrated a superior net clinical benefit vs. NOACs



WATCHMAN FLX demonstrated statistical superiority to NOACs for the occurrence of cardiovascular (CV) death, stroke, systemic embolism, and non-procedural major and modified clinically-relevant non-major bleeding.

(15.1% vs. 21.8%; $P_{superiority}$ <0.0001).

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Imaging Outcomes

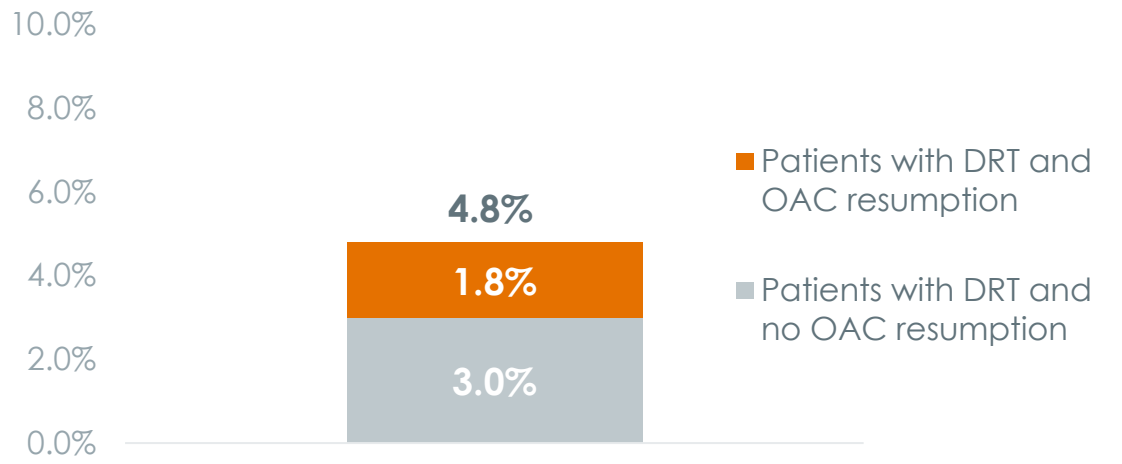
LAA Closure and Device-related Thrombus

Effective closure (≤3 mm) remained high (98.6%) at 4 months, while 1.8% of patients demonstrated clinically relevant device-related thrombus that resulted in resumption of anticoagulation.

Residual Leak	Post-procedure (n=1,111)	4 months (n=1,112)
Effective closure (≤3 mm)	1110 (99.9%)	998 (98.6%)
0 mm	990 (89.1%)	793 (78.4%)
>0 mm to ≤3 mm	120 (10.8%)	205 (20.3%)
>3 mm to ≤5 mm	1 (0.1%)	14 (1.4%)
>5 mm	0 (0.0%)	0 (0.0%

Values are number of patients (%). Residual leak was assessed in individuals with imaging that is both available and able to be assessed for the measurement of interest.

Device-related Thrombus at 4 Months



Clinical Considerations	
Patients with DRT followed by stroke*	2 (0.2%)
Patients with stroke and no DRT**	43 (95.6%)

Values are number of patients (%).
*Denominator is all patients with core-lab assessed DRT imaging (n=1320)
**Denominator is ITT LAAC patients with ischemic stroke (n=45)

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In the first head-to-head trial of WATCHMAN FLX™ vs. NOACs in a broad AFib patient population:

01

PRIMARY EFFICACY ENDPOINT MET

WATCHMAN FLX demonstrated statistical non-inferiority to NOACs for cardiovascular death, all stroke, or systemic embolism at 36 months (5.7% vs. 4.8%; P<0.0001).

02

PRIMARY SAFETY ENDPOINT MET

WATCHMAN FLX showed statistical superiority to NOACs for ISTH non-procedural major bleeding and modified clinically relevant non-major bleeding at 36 months, (10.9% vs.19.0%; P<0.0001), including a significant 45% relative risk reduction.

03

LOW ANNUALIZED ISCHEMIC STROKE RATES

WATCHMAN FLX device demonstrated a 1.1% annualized ischemic stroke/SE rate, aligned with rates observed in prior, seminal clinical trials of NOACs.

04

SIGNIFICANTLY REDUCED BLEEDING (INCLUDING PROCEDURAL)

Reaffirming superiority of the primary safety endpoint, WATCHMAN FLX demonstrated a statistically significant 34% risk reduction in ISTH bleeding (including procedural) at 36 months.

05

SUPERIOR NET CLINICAL BENEFIT WITH WATCHMAN

WATCHMAN FLX showed statistical superiority to NOACs for the endpoint of cardiovascular death, stroke, systemic embolism, and non-procedural major and modified clinically-relevant non-major bleeding at 36 months (15.1% vs. 21.8%; P<0.0001).

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Study Caveats

Boulder Community Health

- In the trial, there were 83 major bleeds in the Watchman arm vs 87 in the NOAC arm (5.5% vs 5.8%; HR, 0.92; 95% CI, 0.68-1.24)
- This comparison was a secondary endpoint and declared "noninferior"
- The interpretation is also correct that the Watchman arm was not superior to NOACs in regards to major bleeding
- Stroke was higher (namely ischemic) in the Watchman arm
- There were 33 strokes in the NOAC group vs 50 in the Watchman arm (2.6% vs 3.3%; hazard ratio [HR], 1.46; 95% CI, 0.94-2.27)
- Ischemic stroke rates were 45 (watchman) vs 27 (DOAC) (HR, 1.61; 95% CI, 1.00-2.59)
- DRT rate was 4.8% in in the Watchman arm
- Simply stated: There were 17 more strokes in the Watchman arm and four fewer episodes of major bleeding

Takeaways

Boulder Community Health

- There is no "perfect" therapy to completely eliminate stroke risk.
- Decision to move forward with a Watchman implant should involve all major pros/cons of procedure vs medication.
- Balance of bleeding risk vs ischemic stroke is paramount in this discussion.
- There is more data being evaluated as we speak about post-Watchman regimens (Plavix/ASA vs NOAC vs ASA).
- I personally feel having a NOAC prescribed (even at a lower dose) may be preferable to Plavix/ASA to prevent DRT and potential ischemic strokes.

Thank You!

Boulder Community Health