

# Choosing Between Alternative Therapies for NVAF and Cryptogenic Stroke with Patients: The Essence of Shared Decision Making

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# Disclosure Statement of Financial Interest

Within the past 12 months, I have had a financial interest/arrangement or affiliation with the organization(s) listed below.

## Affiliation/Financial Relationship

Grant/Research Support

Consulting Fees/Honoraria

Major Stock Shareholder/Equity

Royalty Income

Ownership/Founder

Intellectual Property Rights

Other Financial Benefit

## Company

Edwards LifeSciences, Boston Scientific

# Shared decision making in stroke prevention



**ESC**

European Society  
of Cardiology

European Heart Journal (2017) 0, 1–9

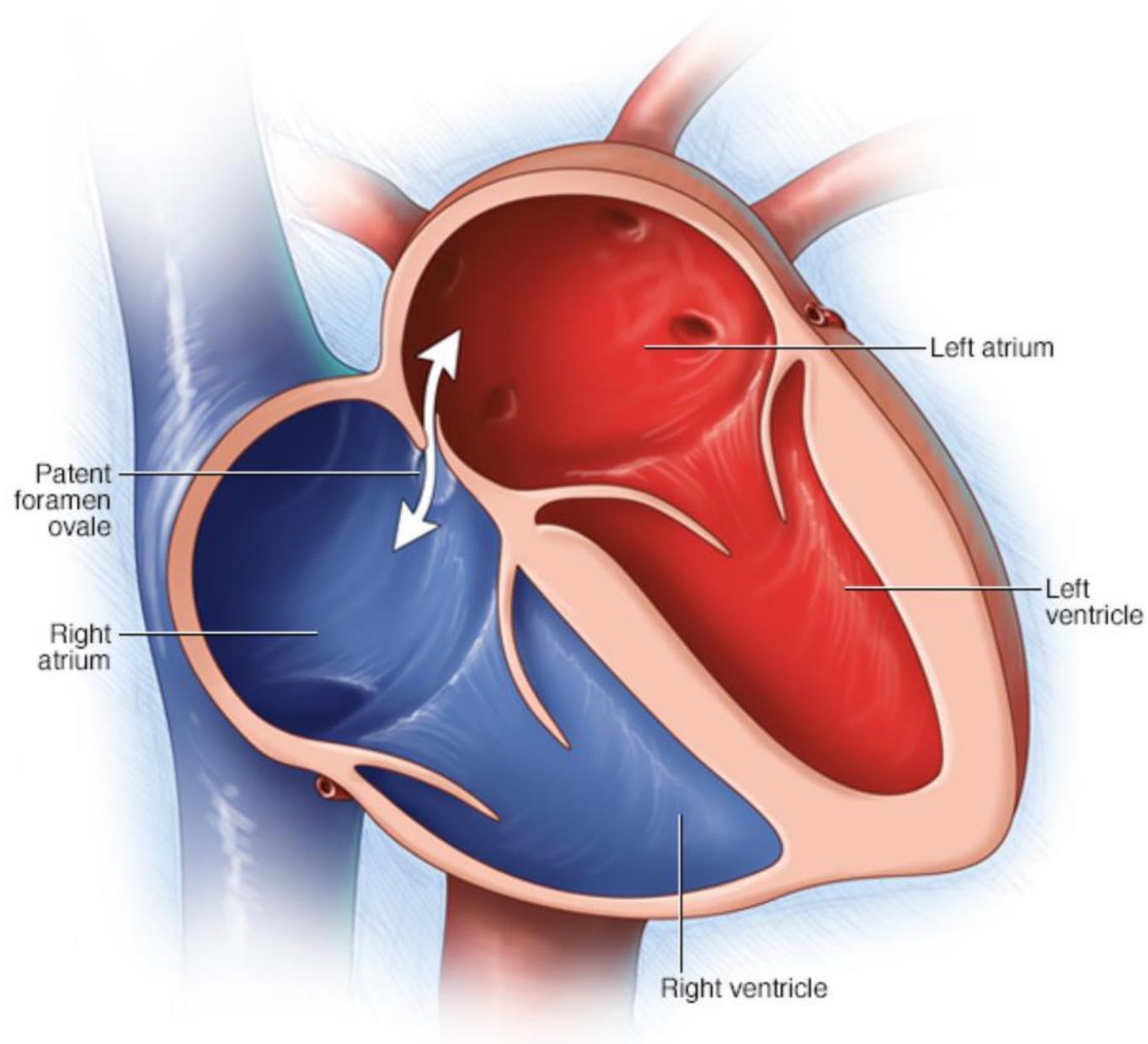
doi:10.1093/eurheartj/ehx478

**CURRENT OPINION**

## **The role of cardiologists in stroke prevention and treatment: position paper of the European Society of Cardiology Council on Stroke**

**Petr Widimsky<sup>1\*</sup>, Wolfram Doehner<sup>2,3</sup>, Hans Christoph Diener<sup>4</sup>,  
Isabelle C. Van Gelder<sup>5</sup>, Alison Halliday<sup>6</sup>, and Mikael Mazighi<sup>7</sup> on behalf of the ESC  
Council on Stroke**

Image source: Mayo Foundation.  
[https://www.mayoclinic.org/-/media/kcms/gbs/patient-consumer/images/2017/08/07/17/31/r7\\_patentforamenovale-8col.jpg](https://www.mayoclinic.org/-/media/kcms/gbs/patient-consumer/images/2017/08/07/17/31/r7_patentforamenovale-8col.jpg)



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# AMPLATZER™ PFO Occluder

## Instructions for Use

### Device Description

The AMPLATZER™ PFO Occluder (Figure 1) is a self-expandable, double-disc device made from a Nitinol wire mesh. The 2 discs are linked together by a short connecting waist. In order to increase its closing ability, the discs contain thin polyester fabric. The polyester fabric is securely sewn to each disc by a polyester thread.

The device has radiopaque marker bands on the distal and proximal ends of the device. The device contains an end screw on the proximal end to facilitate delivery and deployment. The device is sterilized with ethylene oxide.

### Figure 1. AMPLATZER™ PFO Occluder



# Shared decision making in PFO closure

- “(I)t is essential that we engage in shared decision making with neurologists...”
- “Team-based, multidisciplinary, Bayesian clinical judgment on an individual basis still remains the core of decision-making.”

Poulin and Kavinsky. *Cardiac Interventions Today*. May/June 2017; Pristipino et al. *Catheterization and Cardiovascular Interventions* 2013

# Amplatzer PFO Occluder IFU

## Patient Selection for Treatment

In considering the use of the AMPLATZER™ PFO Occluder, the rationale for seeking PFO closure and the safety and effectiveness of the procedure should be discussed with the patient and family. It is recommended that the medical team (neurologist and cardiologist) and the patient engage in a shared decision-making process...taking into account the patient's values and preferences.

It is recommended that the medical team (neurologist and cardiologist) and the patient engage in a shared decision-making process when considering the use of the AMPLATZER™ PFO Occluder. This process should take into account the patient's values and preferences.

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Guide and

Rates of new strokes in the RESPECT Trial. The results of the RESPECT Trial were analyzed at two time points. The first analysis, performed at a follow-up of about 1 year, showed that the rate of new strokes was about 50% less with the device compared to medication. The second analysis, performed at a follow-up of about 3 years, showed that the rate of new strokes was about 60% less with the AMPLATZER™ PFO Occluder plus blood-thinning medication alone. However, it is important to note that there were no deaths in either treatment group. The analysis suggested that about 6 of these patients would have a stroke after 1 year compared with about 12 out of 1000 patients treated with blood-thinning medication alone.

50% less strokes with the device compared to medication

The second analysis, performed at a follow-up of about 3 years, showed that the rate of new strokes was about 60% less with the device compared to medication.

Of 1000 people, there were 6 less strokes with the device compared to medication

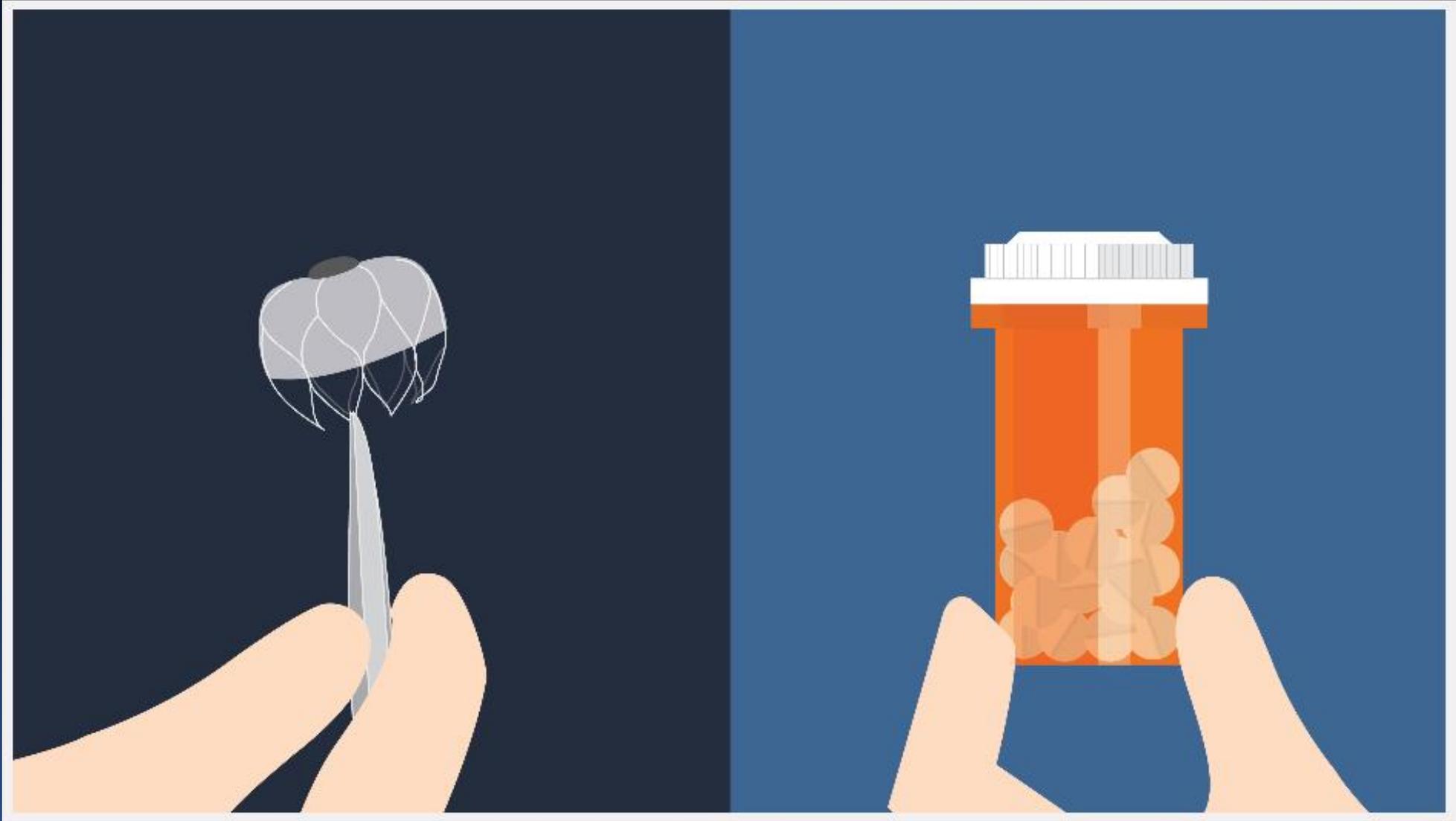


Image source: <https://healthblog.uofmhealth.org/heart-health/watchman-vs-blood-thinners-alternatives-for-patients-nonvalvular-atrial-fibrillation>; Michigan Health Franklin Cardiovascular Center



# Adherence and outcomes to direct oral anticoagulants among patients with atrial fibrillation: findings from the veterans health administration

Ryan T. Borne<sup>1\*</sup> , Colin O'Donnell<sup>2</sup>, Mintu P. Turakhia<sup>3,4</sup>, Paul D. Varosy<sup>1,2</sup>, Cynthia A. Jackevicius<sup>5</sup>, Lucas N. Marzec<sup>1</sup>, Frederick A. Masoudi<sup>1</sup>, Paul L. Hess<sup>1,2</sup>, Thomas M. Maddox<sup>6</sup> and P. Michael Ho<sup>1,2</sup>

## Abstract

**Background:** The direct oral anticoagulants (DOACs) reduce the risk of stroke in moderate to high-risk patients with non-valvular atrial fibrillation (AF). Yet, concerns remain regarding its routine use in real world practice. We sought to describe adherence patterns and the association between adherence and outcomes to the DOACs

# Medicare National Coverage Decision: LAAO



## I. Decision

*A formal shared decision making interaction  
(on anticoagulation choices)*

*with an independent,  
non-interventional physician*

*using an evidence-based decision tool*

- Continues to perform  $\geq 25$  interventional cardiac procedures that involve transeptal puncture through an intact septum, or which at least 12 are LAAC, over a two year period.

# Medicare National Coverage Decision: ICD

 Decision Memo for Implantable Cardioverter Defibrillators (CAG-00157R4)

Need a PDF? 

*A formal shared decision encounter must occur between the patient and a physician*

*or a qualified non-physician practitioner (PA, NP, clinical nurse specialist)*

• Additional Patient Criteria

*using an evidence-based decision tool*

Shared decision-making...can help to  
ensure adherence to  
management and empower patients...

2016 ESC Guidelines for the  
Management of Atrial Fibrillation

# Decision aids vs. usual care

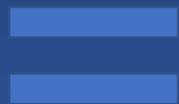
Systematic review of 105 RCTs (31,043 patients)



Patient involvement and knowledge  
Visit time by 2.5 min



Decisional conflict  
Proportion of patients undecided



Inconsistent effect on choice, adherence,  
costs

# Even while “on” DOACs, consistent use is low

ORIGINAL RESEARCH



Effect of Adherence to Oral Anticoagulants on Risk of Stroke and Major Bleeding Among Patients With Atrial Fibrillation

*Less than half of patients on a DOAC took their medication more than 80% of the time*

translate to improved adherence and whether adherence is associated with improved outcomes in patients with atrial fibrillation.

Yao, Noseworthy, et al. *J Am Heart Assoc* 2016





Eligibility Data Assessment **Decision** Library Patient Info Chart Note Credits

### Decision: Choose treatment to lower Stroke or Clot risk? INFO (Click on an option to see clinical impact)

- no medicine**
- aspirin
- warfarin
- apixaban
- dabigatran
- rivaroxaban
- edoxaban
- Watchman

Treatment frequency: **No pills**      Blood tests needed: **None**  
 Interactions with medications: **None**      Interactions with food: **None**



Population

Years

For 100 men age 82 taking no medicine for 1 year:

- > **Strokes or Clots** - CHA<sub>2</sub>DS<sub>2</sub>-VASC score of 6. INFO
- > **19** Have a Stroke or Clot INFO
- > **79** Have no Stroke, Clot or Major Bleed.
- > **2 Major Bleeds** based on HAS-BLED Score of 2. INFO
- > **2** Bleeds with no treatments

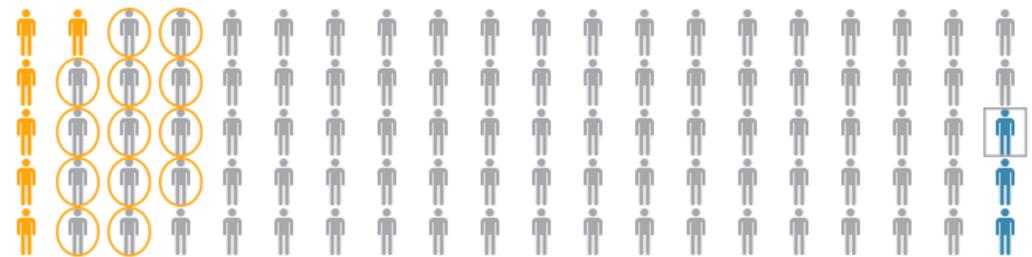
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Decision: Choose treatment to lower Stroke or Clot risk? INFO (Click on an option to see clinical impact)

- no medicine
- aspirin
- warfarin
- apixaban
- dabigatran
- rivaroxaban**
- edoxaban
- Watchman

Treatment frequency : **1 pill/day** Blood tests needed: **Yearly**  
 Interactions with medications: **Uncommon** Interactions with food: **Uncommon**



Population  
 100  1000

Years  
 1  5  10

For 100 men age 82 taking rivaroxaban for 1 year:

> **Strokes or Clots** - CHA<sub>2</sub>DS<sub>2</sub>-VASc score of 6. INFO

- 6 Have a Stroke/Clot
- 13 (of 19) Save a Stroke/Clot
- + 91 have no Stroke, Clot or Major Bleed.

> **3 Major Bleeds** based on HAS-BLED Score of 2. INFO

- 2 Bleeds with no treatments
- 1 More bleed from rivaroxaban

Continue

Decision: Choose treatment to lower Stroke or Clot risk? INFO (Click on an option to see clinical impact)

no medicine aspirin warfarin apixaban dabigatran rivaroxaban edoxaban **Watchman**

Watchman is a device placed in the heart during a minimally invasive procedure. Anticoagulants are used for the first 45 days, followed by anti-platelet medications for at least 6 months after the procedure.



Population

Years

For 100 men age 82 taking Watchman for 1 year:

**Strokes or Clots** - CHA<sub>2</sub>DS<sub>2</sub>-VASc score of 6. INFO

- 7 Have a Stroke/Clot
- 13 (of 20) Save a Stroke/Clot
- + 89 have no Stroke, Clot or Major Bleed.

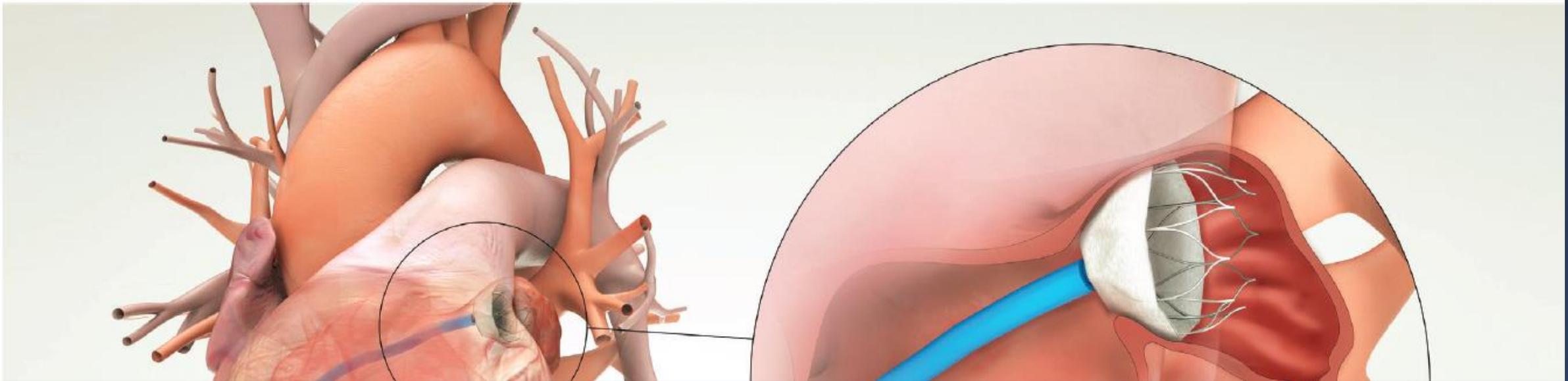
**2 Major Bleeds** based on HAS-BLED Score of 2. INFO

- 2 Bleeds with no treatments
- <1 More bleeds from Watchman
- 2 Procedural complications

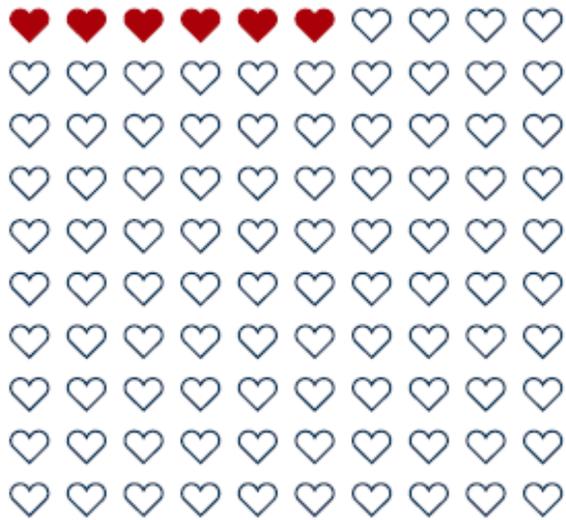
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## CLOSURE DEVICE

During a procedure, the closure device is placed in the left atrial appendage, the part of the heart where the majority of blood clots form in patients with AFib. The placement of the device closes off this area to help stop blood clots from moving to the rest of the body. It's important to note that the **closure device helps prevent strokes that start in the left atrial appendage only**. The closure device does not stop strokes that come from other places in the body.

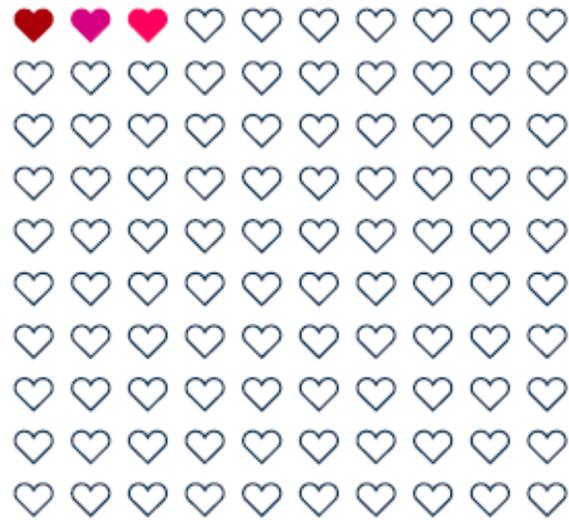


## Other Risk



Each year, out of 100 people like you who take **blood thinners**, about:

♥ = 6 will have major bleeding



Each year, out of 100 people like you who get a **closure device**, about:

♥ = 1 will have major bleeding

♥ = 1 will have a procedure-related stroke

♥ = 1 will have procedure-related damage to the heart

▶ **Procedure Risks:** The procedure risks of the device are different from center to center. The risks are improving and occur less among doctors who have done the procedure many times.

▶ **Long Term Risks:** We have less understanding of the long term risks and side effects of the device or what living with the device looks like over several years.

HealthDecision

Decision: Take a medication to lower Stroke or Systemic Embolism (SE) risk? **INPD**

Medication: aspirin

Treatment frequency: 1 pill/day

Interactions with medication: Uncommon

Population: 100, 1000

Years: 5, 10

Aspirin: 0x20, 10x10

For 100 men age 70 living alone for 1 year:

Stroke or Systemic Embolism (SE) (O-44, D6, VADs = 7)  
Stroke includes both thromboembolic and embolic.

17 HAVE a Stroke or SE (16.6%)

4 (of 21) HAVE a Stroke or SE (19%)

77 have no Stroke, SE or Major Bleed

Major Bleed (based on HAS-BLED Score = 3)  
Major Bleed does not include hemorrhagic stroke.

4 (of 9) Bleeds or 4.4% (4.6%)

2 (of 9) Major Bleeds from aspirin (22%)

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