

Practicalities of Shared-Decision Making for Stroke Prevention: Relevance to PFO Closure and LAA Occlusion

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Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner 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

Company Name(s)

W.L. Gore

Company Name(s)

Company Name(s)

Company Name(s)

Company Name(s)

Company Name(s)

Three take home points

- Shared decision making is an exchange of information between patients and their clinicians
- Shared decision making is not for all medical decisions
- Left atrial appendage closure is a preference-sensitive decision and decision aids are available for your practice



ESC

European Society
of Cardiology

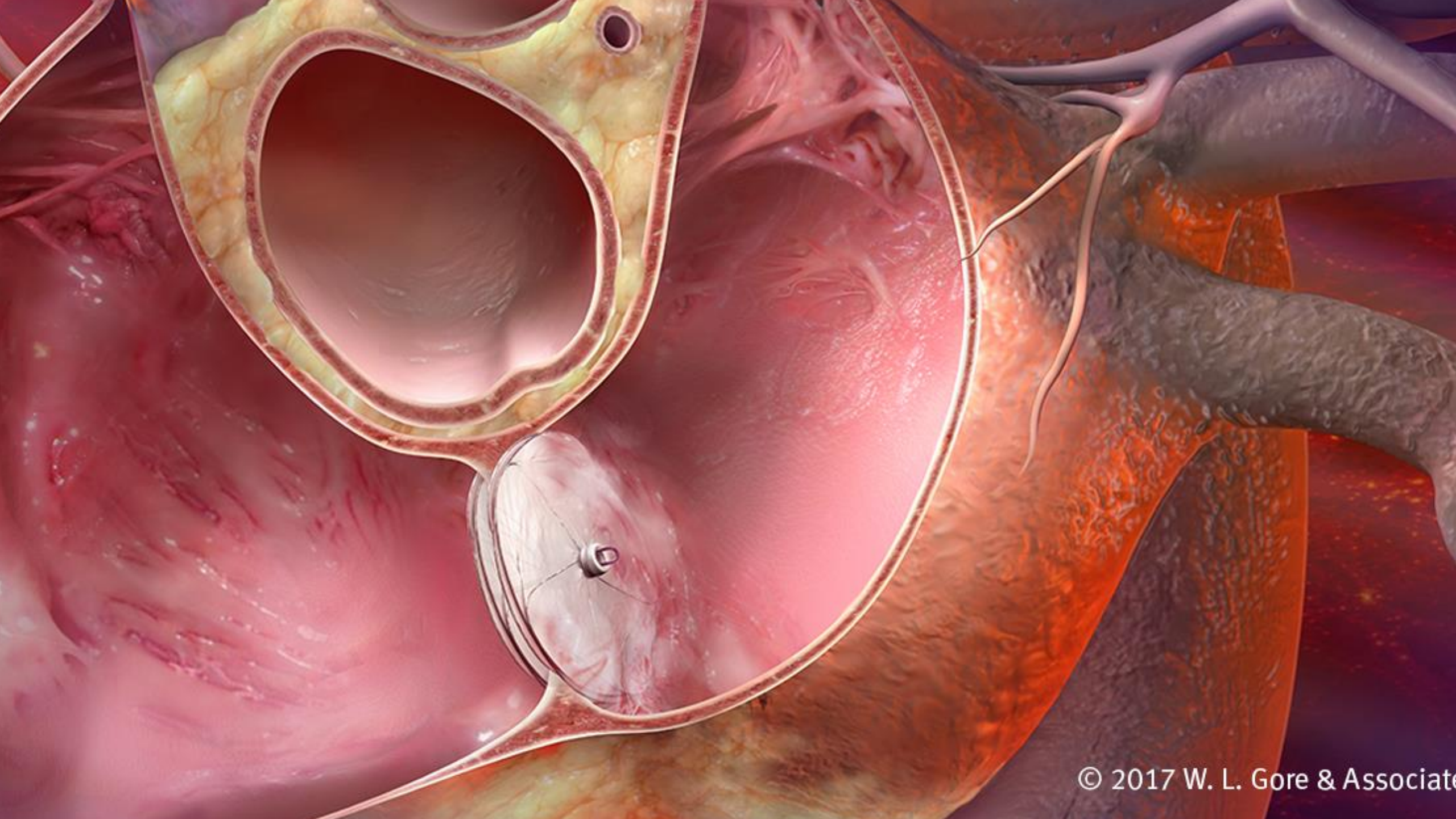
European Heart Journal (2017) **0**, 1–9

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^{1*}, Wolfram Doehner^{2,3}, Hans Christoph Diener⁴,
Isabelle C. Van Gelder⁵, Alison Halliday⁶, and Mikael Mazighi⁷ on behalf of the ESC
Council on Stroke**



AMPLATZER™

PFO Occluder

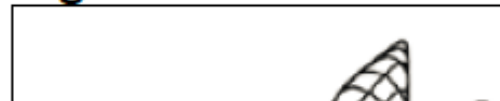
Instructions for Use

Device Description

The AMPLATZER™ PFO Occluder (Figure 1) is a self-expandable, double-disc device made from a Nitinol wire. The discs are linked together by a short connecting waist. In order to increase its closing ability, the discs contain 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 internal suture at the proximal end to facilitate delivery and deployment. The device is sterilized with ethylene oxide.

Figure 1. AMPLATZER™ PFO Occluder



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 the patient's family to ensure a shared decision-making process.

AMPLATZER™ PFO Occluder should be used in patients who meet the following criteria. Additional information is provided in the Clinical Practice Guidelines for the AMPLATZER™ PFO Occluder.

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.

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It is recommended that the medical team (neurologist and cardiologist) and the patient engage in a shared decision-making process when taking into account the patient's values and preferences in the Clinical Practice Guidelines for the AMPLATZER™ PFO Occluder.

making
sed while
Guide and

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

Shared Decision Making is a process by which

a **patient** and a **clinician**

work together,

have a **conversation**,

partner with each other

to identify the **best course of action**,

the best treatment or test

at this point in time.

Not just
throwing
numbers!

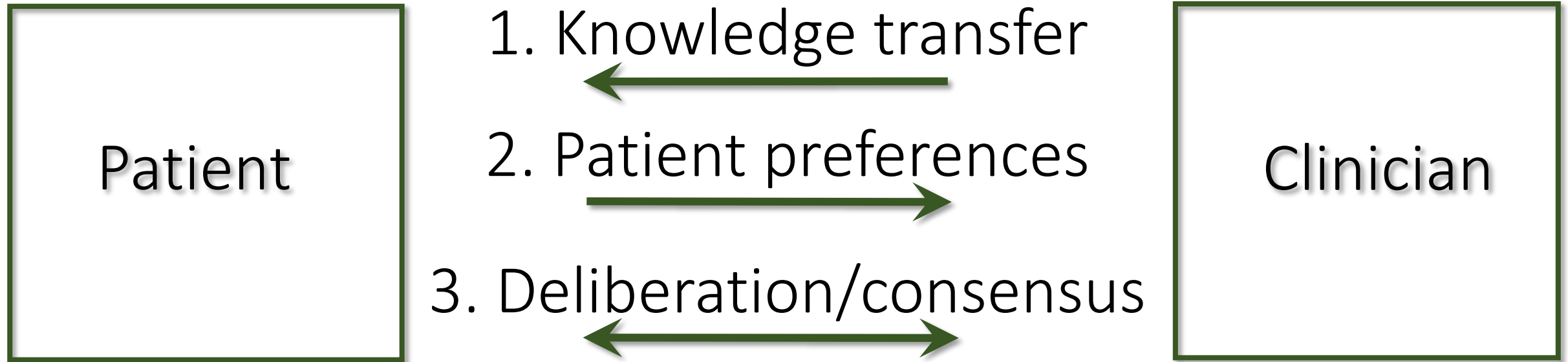
It is— about **sharing what matters**

Clinicians share information about the alternatives, benefits, harms

Patients share prior experience, goals, expectations, values.

[www.magicproject.org/
share-it](http://www.magicproject.org/share-it)

Shared decision making is *not* patient education or informed consent





Charles, Whelan, et al. *Soc Sci Med* 1999;

Spatz ES, Spertus JA. *Circ Cardiovasc Qual Outcomes* 2012.



GRADE

Strong recommendations

1. Clear balance 
 - benefits clearly outweigh risks/hassle/cost
 - risk/hassle/cost clearly outweighs benefits
2. Sufficient confidence in estimates (high or moderate) 
3. Patients values & preferences:
 - almost all **same** choice



Weak recommendations

1. Close balance 
 - Close call between benefits and risks/hassle/cost
 - Therefore more preference-sensitive
2. Low confidence in estimates 
3. Patients values & preferences
 - choice **varies** appreciably (or is very uncertain)




<https://bestpractice.bmj.com/info/us/toolkit/learn-ebm/what-is-grade/>



GRADE

Strong recommendations

1. Clear balance 
 - benefits clearly outweigh risks/burden/cost
 - risk/hassle/cost clearly


Just do it

2.

3. Patients values & preferences:
 - almost all **same** choice



Weak recommendations

1. Close balance 
 - Close call between benefits and risks/burden/cost
 - Therefore more

Shared decision making

2.

3. Patients values & preferences:
 - choice **varies** appreciably (or is very uncertain)



<https://bestpractice.bmj.com/info/us/toolkit/learn-ebm/what-is-grade/>



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 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 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 60% less with the device compared to medication. The analysis suggested that about 6 of these patients would have a stroke after 1 year compared with about 10 out of 1000 patients treated with blood-thinning medication alone.

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

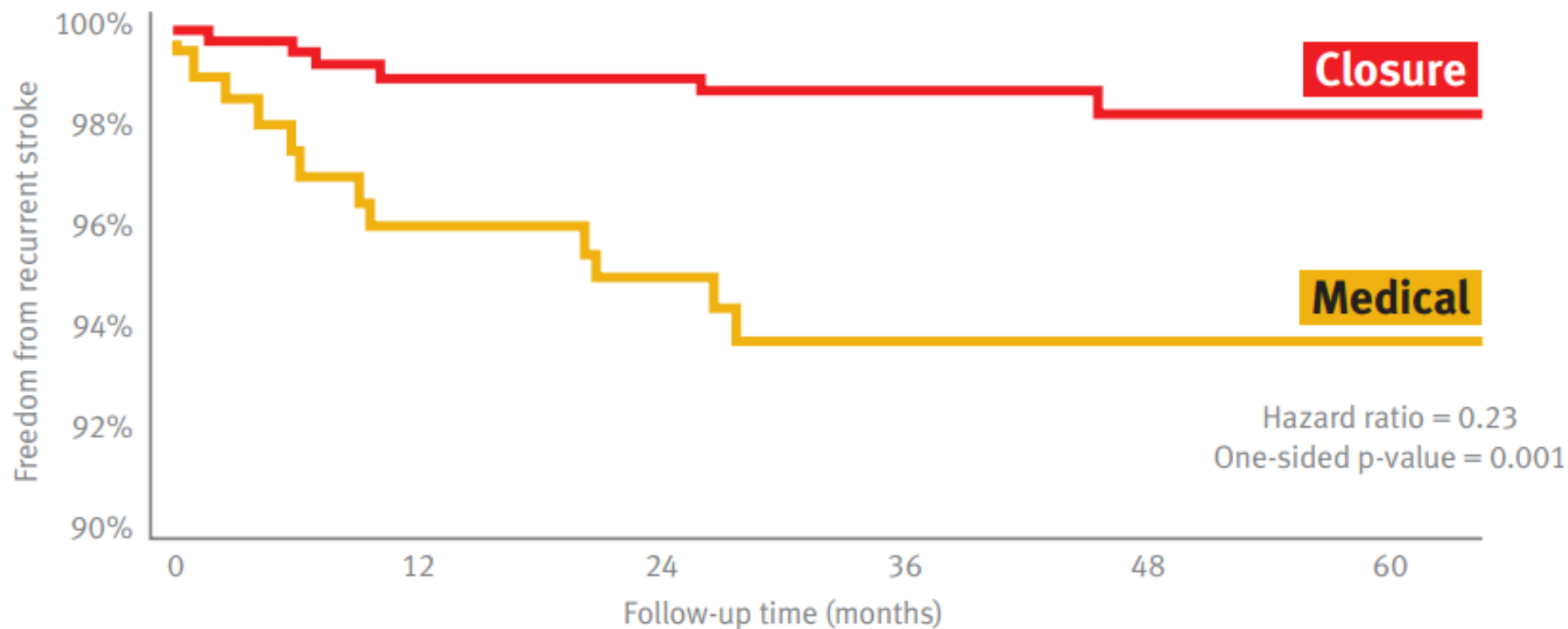
**Gore REDUCE Clinical Study: As published in
New England Journal of Medicine.⁷**

Sondergaard L et al. 2017 *NEJM*

77%

Relative stroke reduction

with PFO CLOSURE + medical therapy vs.
medical therapy alone.^{*,7}



PFO closure

Percutaneous closure of PFO followed by antiplatelet therapy



+ APL

PFO closure

Strong

Weak

Weak

Strong

More details



We recommend PFO closure followed by antiplatelet therapy over antiplatelet therapy alone.

Comparison of benefits and harms

Favours PFO closure

No important difference

Favours antiplatelets

Within 5 years

Events per 1000 people

Evidence quality

100

★★★★ Moderate

More

Important difference

3

★★★★ Moderate

More

Important difference

14

★★★★ Moderate

More

per 1000 people

Evidence quality

18 fewer

5

★★★★ Moderate

More

36 fewer

0

★★★★ High

More

MAGIC app

See patient decision aids

MAGIC app

Preferences and values

The panel felt that many patients would not want the long-term bleeding risk from anticoagulation therapy, which will usually outweigh the probable risk of procedure or device related events and persistent atrial fibrillation with PFO closure

<https://app.magicapp.org/app#/guideline/2649>

Practical issues

Antiplatelets

No key practical issues



<https://healthblog.uofmhealth.org/heart-health/watchman-vs-blood-thinners-alternatives-for-patients-nonvalvular-atrial-fibrillation>

Less than half of high-risk patients with afib are prescribed oral anticoagulation

Research

Original Investigation

Oral Anticoagulant Therapy Prescription in Patients With Atrial Fibrillation Across the Spectrum of Stroke Risk Insights From the NCDR PINNACLE Registry

Jonathan C. Hsu, MD, MAS; Thomas M. Maddox, MD, MSc; Kevin F. Kennedy, MS; David F. Katz, MD; Lucas N. Marzec, MD; Steven A. Lubitz, MD, MPH; Anil K. Gehi, MD; Mintu P. Turakhia, MD, MAS; Gregory M. Marcus, MD, MAS

Current state of patient preference: discontinuation high

- Prior studies: **20-50% discontinuation** rates (ATRIA study, General Practice Research Database)
- Orbit AF: **17% warfarin discontinuation**
- VA: NOACs better?
 - At one year, **37% NOAC, 61% warfarin**



Medicare National Coverage Determination: LAAO

I. Decision

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

*with an independent,
non-interventional physician*

using an evidence-based decision tool

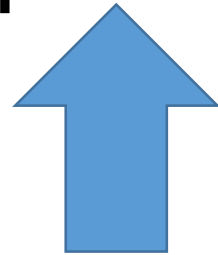
◦ Continues to perform ≥ 25 interventional cardiac procedures that involve transeptal puncture through an intact septum, or which at least 12 are LAAC, over a two year period.

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

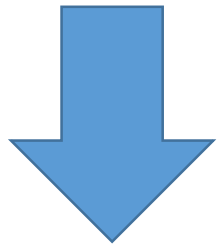
2016 ESC Guidelines for the management of
atrial fibrillation

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

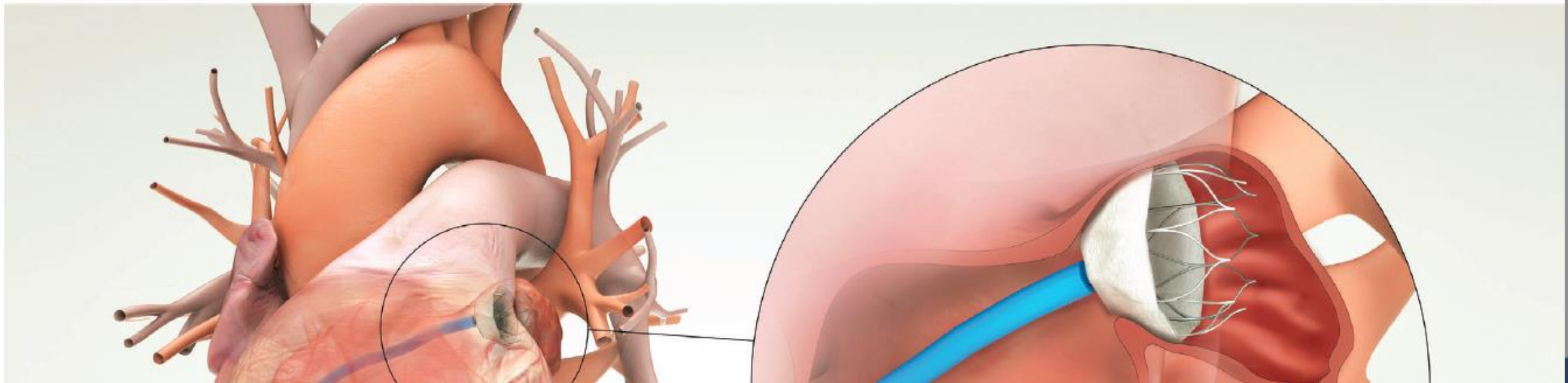


Inconsistent effect on choice, adherence,
costs

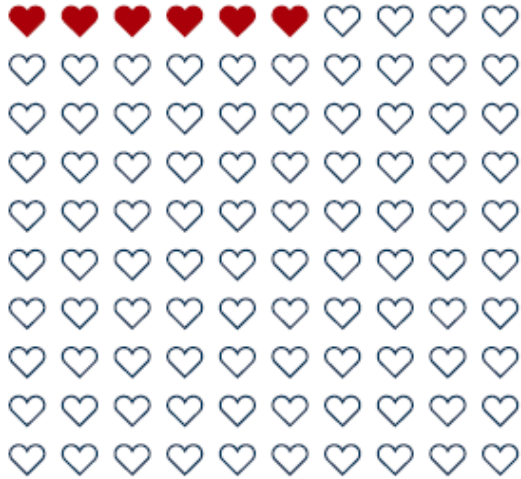
CLOSURE DEVICE

Search: “cardiosmart decision aids”

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.

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 - CHA₂DS₂-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** - CHA₂DS₂-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

Continue

Take home

- Shared decision making is an *exchange* of information between patients and their clinicians
- Shared decision making *is not* for all medical decisions
- Left atrial appendage closure is a preference-sensitive decision and decision aids *are available* for your practice

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