A DECISION AID FOR
AFIB STROKE PREVENTION
FOR PATIENTS WITH ATRIAL FIBRILLATION

CardioSmart
American College of Cardiology

For Patients with VERY HIGH RISK

You have **atrial fibrillation**, also known as AFib, which means you have an irregular heart beat. This is a very common heart rhythm problem.

People with AFib tend to have a higher chance of **stroke**. A stroke is where part of your brain dies. It can be very serious, causing permanent harm or death.

Irregular heart beats from AFib can cause blood to collect in the heart and form a **blood clot**. This clot may travel to the brain and could prevent blood flow, resulting in a **stroke**.

Each person's risk for stroke is different – patients can be at low, moderate or high risk for stroke. This booklet is for patients who are **high risk**, which means you likely want to consider some options available to help prevent stroke.

Perhaps you have a new diagnosis of AFib and are learning about the different options available. For most people, this means taking medicines commonly referred to as "**blood thinners**." Or, you may have been on warfarin for years and are now **considering alternatives**, such as a newer blood thinner or a procedure to place a device in the heart. This booklet will help you understand your options so that you can discuss them with your clinician and loved ones.

We know talking about strokes can be scary. But, knowing how you can help reduce your risk for stroke is important. And, understanding your options may help you decide **what is best for you, your health, and your lifestyle.**

YOUR STROKE RISK AND OPTIONS

You've been given this booklet because you have a **high risk** for stroke with your AFib. This is likely due to your age or other illnesses or conditions you may have.

- This means you **likely want to do something** to help reduce your risk for stroke.
- You may have several options for stroke prevention treatment. Let's first discuss what **no treatment** versus **treatment** looks like.
- Getting treatment will **reduce your risk for stroke**.

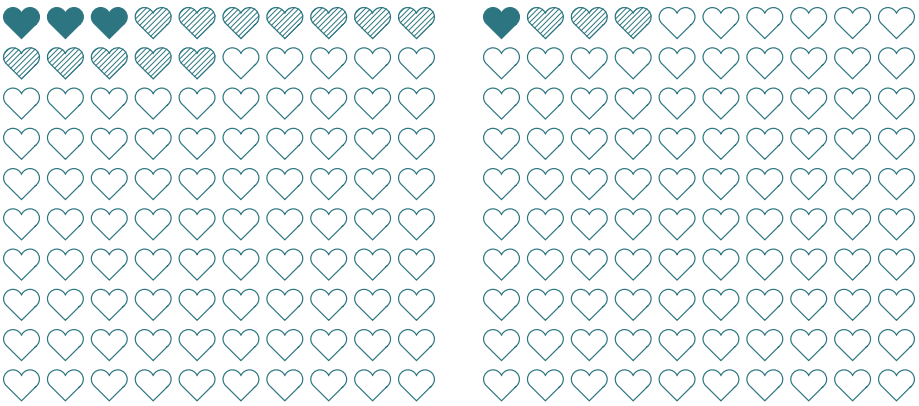
Stroke Risk per Year

WithOUT Treatment

Each year, between **3 to 15 out of 100** people like you (depending on your exact risk factors) will have a stroke.

WITH Treatment

Each year, between **1 to 4 out of 100** people like you (depending on your exact risk factors) will have a stroke.



= Minimum risk for stroke

= Potential additional risk

= Unaffected

For a more personalized risk estimate, ask your clinician.

Your stroke risk is at **least 3 out of 100 per year**, but may be higher and likely will increase over time. This is your stroke risk per year, which means this risk goes up with time. Compared to most people without AFib, this is a high risk of stroke.

Doing something for stroke prevention is almost **always recommended** by clinicians and usually worth the potential risks.

The numbers presented in this booklet are a summary of information from recent medical studies. However, no one can know what will happen to each individual person.

BLEEDING RISK

If you choose to get **treatment** for stroke prevention, you will most likely be put on a **blood thinner medicine**.

- Blood thinners, also called anticoagulants or anti-clotting medicines, help prevent clots from forming in the blood. This means that clots are less likely to form and cause a stroke. However, this also means that it is easier for your body to bleed.
- The most common side effect when taking a blood thinner medicine is the **increased risk of major bleeding**. Bleeding risk increases over time.
- A major bleed is bleeding that requires hospitalization and treatment. This can include bleeding in your head, stomach or intestines. These bleeds can lead to death
- Minor bleeds can also occur often because it is harder for your blood to clot. This could include severe nose bleeds or cuts that take a long time to stop bleeding. An increase in bruising is also likely.
- Some people have a higher risk of bleeding than others. It can be difficult to predict who will have a bleeding event and how serious that bleeding will be.

WEIGHING IMPORTANT CONSIDERATIONS

While blood thinners will increase the risk of major bleeding, they also lower the risk for stroke. In most cases, **strokes are much more serious than bleeding**, which is why clinicians recommend taking blood thinners.

Talk to your clinician about your individual bleeding risk.

You should carefully think about your options and consider what is a bigger concern for you:
lowering the risk for stroke or **limiting the risk of bleeding.**

COMPARING OPTIONS

For most people, **blood thinners medicines** are the best treatment option. There are several different blood thinners you could choose from. You may already be on one of the medicines below and considering different blood thinner options.

- **Warfarin (Coumadin)** is more common and has been used for a long time as the go-to therapy.
- **Direct oral anticoagulant (DOAC)** medicines (apixaban [Eliquis], dabigatran [Pradaxa], edoxaban [Savaysa], or rivaroxaban [Xarelto]) are newer medicines that help do the same thing as warfarin. Research studies now suggest that DOACs work just as well and, in some cases, better than warfarin for some people.

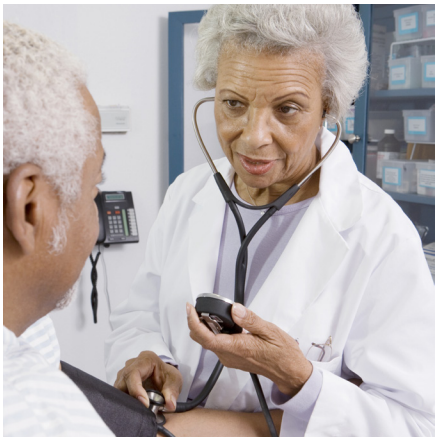
You should think about the **side effects and lifestyle changes** that come with taking blood thinners and the difference between warfarin and the DOACs.

	Warfarin (Coumadin)	**DOAC** (apixaban [Eliquis], dabigatran [Pradaxa], edoxaban [Savaysa], or rivaroxaban [Xarelto])
Side Effects	Increased risk of bleeding, so must avoid activities that could cause bleeding or bruising.	
	Compared to DOACs, warfarin appears to have a higher risk of major bleeding, including bleeding in the brain (which is rare).	Compared to Warfarin, DOACs appear to have a lower risk of major bleeding.
	Side effects include skin rash and anemia (low red blood cells).	Depending on which DOAC you take, side effects include skin rash, stomach upset or pain, or anemia (low red blood cells).
	Can cause severe and noticeable bruising.	
Medicine Details	Medicine must be taken daily – usually once or twice per day.	
	May interact with other medicines.	
Lifestyle	Requires regular blood testing to make sure it's working correctly.	Does NOT require regular blood testing.
	Once started, medicine should be taken for the rest of your life.	
	Requires changes to and monitoring of your diet.	Does NOT require change to your diet.
Cost	Low-cost, where a 1-year supply costs about $100. Follow-up blood testing may cost additional money or co-pays.	Cost varies depending on insurance. May be completely covered by your insurance, but if not, could cost as much as $3,500 for a 1-year supply.

If you choose to take a blood thinner, talk to your clinician about which one might be best for you.

OTHER TREATMENT OPTION: CLOSURE DEVICE

For those people with a high risk of stroke who have problems taking blood thinners long term, there may be another option: the **left atrial appendage closure device**. However, it's important to note that the closure device is **not for everyone and is not an appropriate option for many people**.



Getting the closure device is a decision that is dependent on your medical eligibility, your insurance status, and your personal goals.

WHAT IS THE CLOSURE DEVICE?

The closure device is **placed in part of the heart** to prevent the movement of blood clots from the heart to the rest of the body.

In order to be eligible for the closure device, you must:

- Have a high stroke risk
- Show that you have had or are likely to have problems taking blood thinners long term
- Discuss with your clinician whether the closure device is right for you

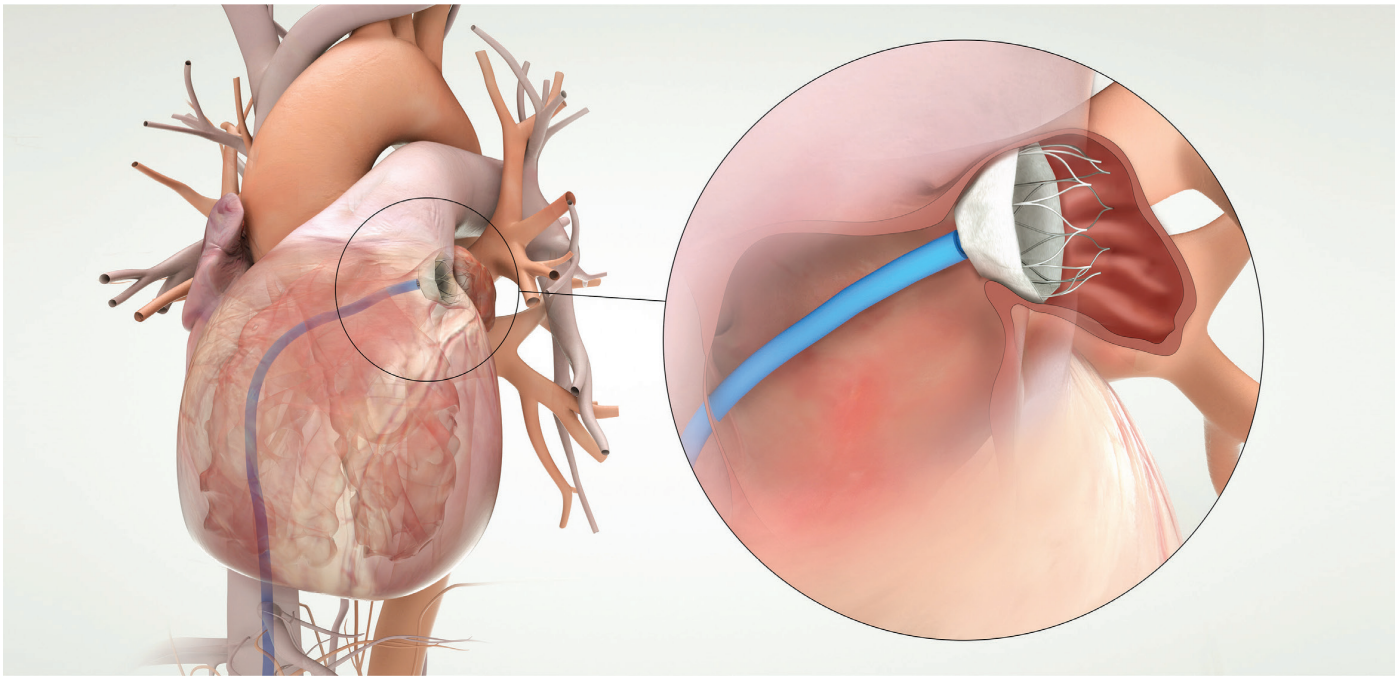
One of the benefits of the closure device is that 9 out of 10 people who get it can **stop taking blood thinner medicine** after a few months (but will need to continue on other medicines).

This can be helpful over time for patients who:

- Have a high risk of bleeding
- Have had problems with major bleeding in the past
- Are active and may worry about severe bleeding

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.



The device is **placed using a catheter**, or small tube, that is inserted into the upper leg and then guides the device to the heart.

- This is usually done using general anesthesia, where the patient is fully asleep.
- Recovery from the procedure usually requires a 24-hour stay in the hospital.

The main risk of the closure device is around the procedure to place it.

While the goal of the closure device is to not have to be on blood thinners long term, **patients must be able to be on blood thinners for a short period of time following the procedure** in order to be eligible for the device.

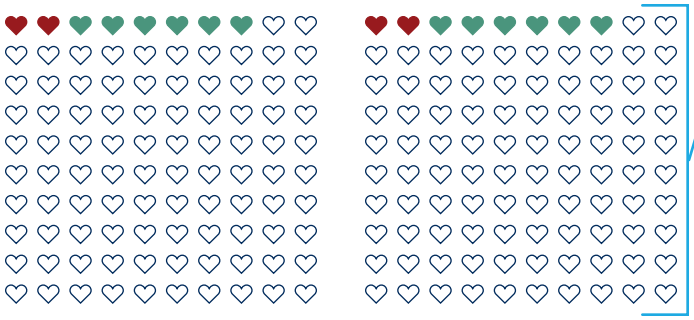
- Patients will have to take a blood thinner medicine for at least 45 days following the procedure, and sometimes longer.
- After 45 days, the doctor will determine whether the patient can stop taking blood thinners.

STROKE, BLEEDING, AND PROCEDURE RISKS

You should compare the stroke and other risks between blood thinners and the device.

Blood Thinners	Closure Device

Stroke Risk



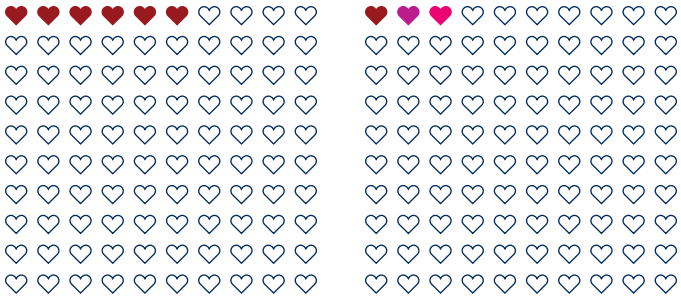
Each year, out of 100 people like you who take **blood thinners**, about:

- ♥ = 2 will have a stroke
- ♥ = 6 will be saved from a stroke

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

- ♥ = 2 will have a stroke
- ♥ = 6 will be saved from a stroke

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

What We Don't Know

Since the **closure device** is a **new treatment**, we have less understanding of how well it works to prevent stroke and the long term side effects.

- **Stroke Risk:** Studies show that the closure device reduces strokes in people with AFib about the same as blood thinners. However, the exact benefit is less certain.
- **Bleeding Risk**: Studies on the closure device have only compared its effectiveness to the warfarin blood thinner. Therefore, we do not know how it compares to the newer DOACs, which appear to have a lower bleeding risk than warfarin.
- **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.

SIDE EFFECTS AND LIFESTYLE CONSIDERATIONS

To compare, let's now look at the side effects and lifestyle changes that come with blood thinners versus the closure device.

	Blood Thinner (Coumadin, Eliquis, Pradaxa, Savaysa, Xarelto)	Closure Device (WATCHMAN)
Side Effects	Increased risk of bleeding, so must avoid activities that could cause bleeding or bruising.	Usually requires only short-term use of blood thinners, so there is a lower bleeding risk, which means you will not have to avoid activities.
	Bleeding in the brain or stomach is possible.	
	Depending on which blood thinner you take, side effects include skin rash, stomach upset or pain, or anemia (low red blood cells).	Since the device requires a procedure to place it in the heart, there are some risks during and after the procedure.
	Can also cause severe and noticeable bruising.	Less is known about long term side effects.
Medicine Details	Medicine must be taken daily – usually once or twice per day.	Blood thinners do not usually need to be taken after the first 45 days. Other medicines will still need to be taken.
	May interact with other medicines.	Device does NOT interact with other medicines.
	Can be used by patients with any type of AFib because it reduces risk of clotting throughout the heart.	Can be used as a long term therapy to prevent stroke only in non-valvular AFib patients because it reduces clotting in left atrial appendage.
Lifestyle	Depending on which blood thinner you take, it may require regular blood testing to make sure it's working correctly.	Requires clinic follow-up visits in the beginning and a follow-up echo procedure.
	Depending on which blood thinner you take, it may require changes to and monitoring of your diet.	Does NOT require change to your diet.
	Once started, medicine should be taken for the rest of your life.	One-time procedure where blood thinners can usually be stopped after the first 45 days.
Cost	Depending on which blood thinner you take and your insurance, the cost could be low (where a 1-year supply costs about $100) or high (where a 1-year supply can cost about $3,500 without insurance). Cost of follow-up blood testing may apply.	Depending on your insurance, the device could be covered. Medicare has strict rules on what type of patient can receive the device, so talk to a clinician to know if you would be covered.

TALK TO YOUR DOCTOR

Your treatment options should be considered very carefully and discussed with your clinician. You need to consider what matters most to you – think about your stroke risk, your bleeding risk, and the risks of the device procedure, but also have a discussion with your clinician to decide if you are even a good fit for the device.

You may be considering switching blood thinner types. You may be considering the non-medicine option of the closure device. The closure device may not be an option for everyone. **Talk to your clinician on what is possible for you and what may be the best choice.**

Now that you have considered your options, it's time to make a decision on how you want to manage your stroke risk while living with AFib.

- The first step is to **talk to your clinician** about whether you should be taking a blood thinner or getting the closure device, and which option would be best for you, your health status, and your lifestyle.
- This is **your decision to make**, so take time to think about what matters most to you, and write down your questions or concerns below.

THINK ABOUT...

Questions for a clinician

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Questions for your loved ones

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Updated: July 2017 (The DA will be reviewed annually) • **Funding by:** American College of Cardiology Foundation • **Authors:** Larry A Allen MD MHS; Jocelyn S Thompson MA; Amy Jenkins MS; Paul Varosy MD; Frederick Masoudi MD MSPH; Christopher Knoepke PhD LCSW; Colleen McIlvennan DNP ANP; Daniel D Matlock MD MPH • **Conflicts of Interest:** Allen: Novartis, Boston Scientific, Janssen; Thompson: None; Jenkins: None; Varosy: None; Masoudi: Contract with American College of Cardiology as Chief Science Officer of NCDR; Knoepke: None; McIlvennan: None; Matlock: Grant support from American College of Cardiology Foundation

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