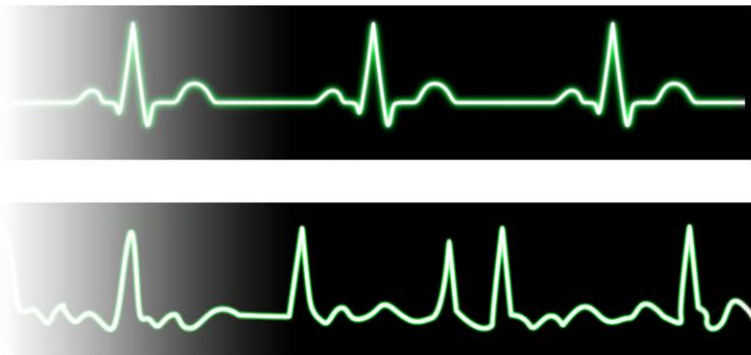
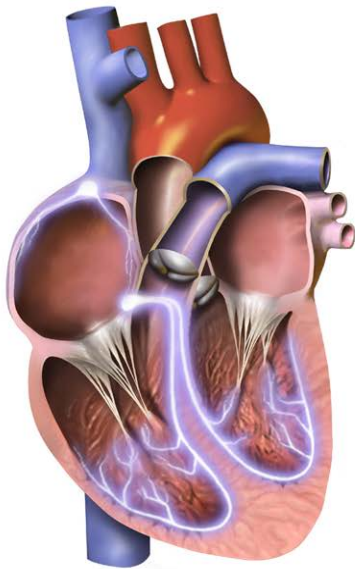


# A Patient Decision Aid for Choosing Among Anticoagulants for Atrial Fibrillation



# **What is Shared Decision-Making?**

Most of us want to be informed about our health conditions and treatment options. This information can be useful as it helps us to participate with our physicians when making decisions about our health care.

This booklet will help you to understand more about atrial fibrillation and the anticoagulant treatment options that are available to reduce the risk of stroke.

We will read through this booklet together. Feel free to stop and ask questions at any time.

# Introduction

Recently, you were diagnosed with a heart condition called **atrial fibrillation**. This is a common abnormality causing an irregular heartbeat. It can sometimes cause a fluttering feeling or shortness of breath.

In people with atrial fibrillation, blood can pool in the heart and form a blood clot. This blood clot can break off and travel through the bloodstream to the brain or other body part. If the clot lodges in the brain, this will result in a stroke.

Many people with atrial fibrillation will not have a stroke. But for those who do, they may have a **minor stroke**, which may result in some disability, but will allow the person to continue to live independently. Some people will experience a **major stroke**, which will leave them dependent upon others, or lead to death.

It is not possible to know exactly who will have a stroke. However, it is known that the risk is higher in those with atrial fibrillation who are also **older**, have **high blood pressure, diabetes** or have had a **previous stroke**. Based on these factors,

doctors use rules to predict a person's risk of stroke and bleeding. These prediction rules are referred to as CHA<sub>2</sub>DS<sub>2</sub>-VASc and HAS-BLED.

Taking no treatment will put people with atrial fibrillation at a high risk of stroke. However, if their CHA<sub>2</sub>DS<sub>2</sub>-VASc score is low, the risk of stroke is not high.

Taking aspirin has been thought to reduce the risk of stroke in people with atrial fibrillation for a long time and can be taken by people with a low risk CHA<sub>2</sub>DS<sub>2</sub>-VASc score. Research has found that although it does lower the risk of stroke, aspirin is not as effective as anticoagulants drugs. Aspirin increases the risk of bleeding compared to no treatment but less so than anticoagulants.

Using a blood thinning drug (anticoagulant) is the most effective way to reduce the risk of stroke in people with atrial fibrillation. There are four blood thinner drugs available to decrease your risk of having a stroke. The four drugs are:

**Warfarin** or one of the new oral anticoagulants (NOACs): **Dabigatran** or **Rivaroxaban** or **Apixaban**

Each of these drugs can cause side effects. The main side effect is **bleeding**. Some of the bleeding episodes can be severe. Other side effects such as heart attack and indigestion are less common and are described in the summary comparison table at the end of the decision aid.

It is not possible to know exactly who will have bleeding. However, the risk is higher in those who are older, have severe kidney or liver disease, previous stroke or bleed, or who use alcohol or other blood thinning drugs such as aspirin or anti-inflammatories.

We are now going to give you information to help you choose between warfarin, dabigatran, rivaroxaban and apixaban.

# What Do I Need to Know about Atrial Fibrillation and Blood Thinner Drugs?

The important **benefit** of taking either warfarin or any of the new anticoagulants for atrial fibrillation is decreasing the risk of **stroke**.

## What is a **Stroke**?

A stroke can be: **Minor** or **Major**

The main difference between minor and major stroke is that patients who experience a **minor stroke (50% of all strokes)** will improve, and will be able to take care of themselves. Patients who experience a **major stroke (50% of all strokes)** will need to be cared for by others for the rest of their lives, or may die.

### In a **Minor Stroke (50% of all strokes)**:

You may suddenly notice that you cannot move your arm or leg on one side as well as before, or you lose feeling in the arm or leg on the same side.

You may lose your ability to fully understand what people are saying to you. When you try to speak, you may have trouble finding words or your speech may be slurred. You may not be able to swallow properly initially or fully control your bladder or bowels.

You may be brought into the hospital for a short time for treatment and tests. Your condition will improve over the next few days. You may recover completely, or you may still have some difficulty dressing, bathing, walking or feeding yourself but you will be able to live at home.

You are now at increased risk of having another stroke.

**In a Major Stroke (50% of all strokes):**

You may suddenly become dizzy or experience a black out. You are brought to the hospital. The doctors cannot understand what you say to them or you cannot understand what they say to you. Your arm and leg on one side are numb and you cannot move them. You may not be able to swallow food or liquids or control your bladder or bowels.

About one in five people who experience a major stroke will die within 6 months. If you survive, you will receive fluids into a vein, and undergo physiotherapy and tests. You stay in the same condition for one week and then slowly improve. You cannot dress, bathe, or feed yourself, and cannot walk. You may also have trouble with blurred or unclear vision.

The nurses sit you in a chair for 1 hour, 3 times a day. You need help with feeding yourself and you may only be allowed pureed food. You likely still have trouble understanding what people are saying or being able to speak clearly, but you can understand simple questions such as “Are you in pain?”. You sleep during the day much more than you did before the stroke and may feel depressed.

After one month of some improvement, your condition stabilizes. You will need help from others for your daily activities for the rest of your life.

You are now at increased risk of having another stroke.

\*\*\*\*\*



The important **harm** of taking blood thinners (warfarin, dabigatran, rivaroxaban or apixaban) is bleeding. We will now describe a bleed.

## What is a **Bleed**?

A bleed can be: **Minor** or **Major**

The main difference between minor and major bleed is that patients who experience a **minor bleed** will not need to stay in hospital as the bleed does not threaten life or limb. Patients who experience a **major bleed** have a chance of dying and need to go to the hospital.

## What is a **Minor Bleed**?

A minor bleed occurs once in a while, but usually can be stopped with pressure or will stop on its own.

Minor bleeds include cuts, bleeding in your gums, or nosebleeds. You might also notice that your skin bruises more easily, but the bruises generally heal and disappear after a few days.

## What is a **Major Bleed**?

The severity of major bleeding varies according to the location and extent of the bleeding. The two main sites of major bleeding are:

### Gut or Brain

There is an important difference between a major bleed in the gut versus the brain. A **bleed in the gut (35-60% of all major bleeds)** may occur in the esophagus, stomach or intestines. Most will improve and return back to their usual self, but 5 to 10% of people will die of a gut bleed. Patients who experience a **bleed in the brain (10-20% of all major bleeds)** have a high risk of dying and if they survive, are very likely to need to be cared for by others for the rest of their lives.

When you have a **bleed into the Gut (35-60% of all major bleeds):**

you may notice mild pain in your stomach area for a day or two. You then may vomit blood and feel very weak. You are taken to the hospital where you will receive blood transfusions.

Approximately, 5 to 10% of patients with stomach bleeds will die.

You stay in the hospital for 3 to 5 days receiving intravenous medication. A doctor puts a tube (endoscope) through your mouth into your stomach to see where you are bleeding from, and may be able to stop the bleeding. When you are sent home, you feel better. However, you may be worried about having another bleed. You will need to take pills to protect the stomach from more bleeding.

**When you have a bleed into the Brain (10-20% of all major bleeds):**

you will have a major stroke. This type of stroke from a bleed is usually more severe than strokes caused by clots. Approximately 50% of patients with a bleeding stroke die, and most of those who survive require a lot of help for the rest of their life.

We will now compare **warfarin** and each of the three NOACs (**dabigatran, rivaroxaban, apixaban**) to help you choose between them.

# Warfarin

Warfarin has been used as a blood thinner for the past 60 years. Because it has been used for so long, we know a lot about it and have a lot of experience using it.

If you are on warfarin, you take a pill once a day and you must remember to take it. You will have to have blood tests done regularly, eventually every 1 to 3 months. These tests are done to lower your risk of stroke and bleeding. Your doctor may need to see you, or phone you to adjust the dose of warfarin.

Your alcohol intake should be no more than one drink per day. You should not engage in activities that might be likely to cause major bruising or bleeding, for example contact sports. You should check with your doctor or pharmacist before taking other medications. This is because certain medications may interact with warfarin and cause problems.

You have to tell your doctor, dentist, or other caregiver that you are taking warfarin. You will be encouraged to wear a medical alert bracelet.

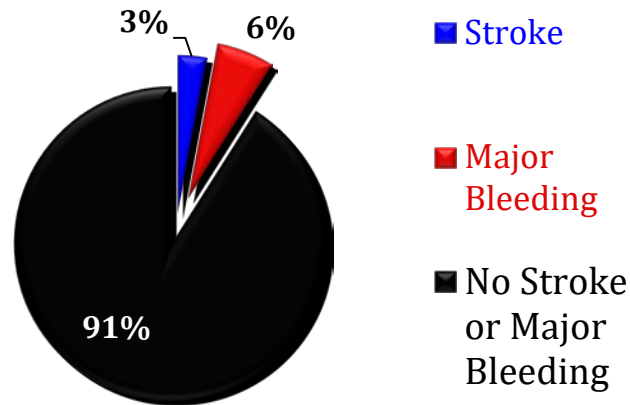
For atrial fibrillation patients taking warfarin, there is a **3% (3 out of 100 people)** chance of having a **stroke** 😞 every two years. This risk may differ for you, depending on your own stroke risk factors.

Most people taking warfarin have easy bruising and increased bleeding from cuts. Many will have an occasional nosebleed or pass blood in their urine. This type of bleeding is minor.

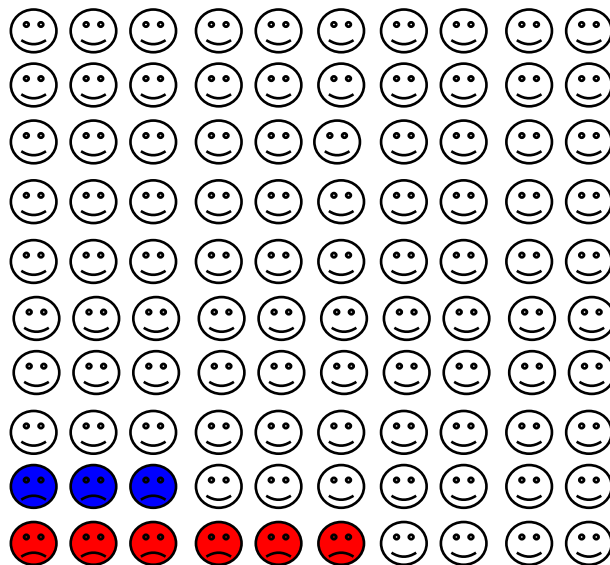
**Major bleeding** 😞 occurs in **6% (6 out of 100 people)** of patients every two years.

However, **91% of people (91 out of 100 people)** with atrial fibrillation taking warfarin will **not have a stroke or major bleeding** 😊 over the next two years.

# Warfarin Demonstration



This pictogram represents a group of 100 people.



In 2 years:

 **Stroke (3 out of 100 people)**

 **Major Bleeding (6 in 100 people)**

 **No Stroke or Major Bleeding (91 in 100 people)**

## **NOACs – New Oral Anticoagulants**

New oral anticoagulants (NOACs) include **dabigatran, rivaroxaban** and **apixaban**, and are three new “blood thinners”. Our knowledge and experience is limited currently but we will learn more about their effectiveness and potential side effects over time.

If you are on dabigatran or apixaban, you take a pill twice a day and you must remember to take it. If you are on rivaroxaban, you must take a pill once a day. There are no blood tests that can monitor how thin your blood is for any of these 3 drugs, but you will need to have kidney function tested at least once per year.

Your alcohol intake should be no more than one drink per day. You should not engage in activities that might be likely to cause major bruising or bleeding, for example contact sports. You should check with your doctor or pharmacist before taking other medications. This is because certain medications may interact with one of the NOACs and cause problems; many of these interactions are not yet known.

You have to tell your doctor, dentist, or other caregiver that you are taking one of the new oral anticoagulants. You will be encouraged to wear a medical alert bracelet.

Most people taking one of the new oral anticoagulants have easy bruising and increased bleeding from cuts. Many will have an occasional nosebleed or pass blood in their urine. This type of bleeding is minor.

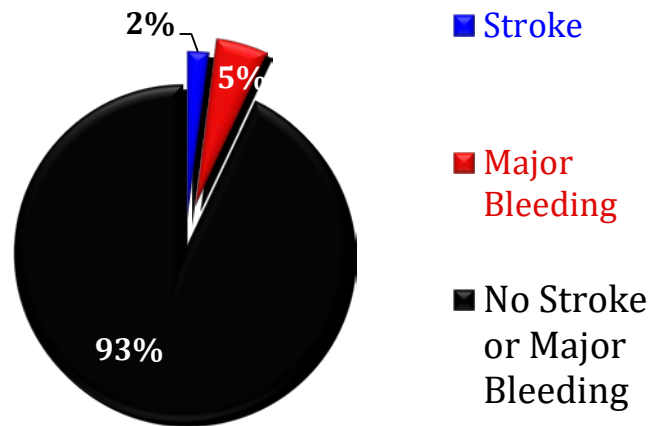
In atrial fibrillation patients taking any of the three new oral anticoagulants, there is a **2% (2 out of 100 people)** chance of having a **stroke** 😞 every two years. This risk may differ for you, depending on your own risk factors for stroke.

**Major bleeding** 😞 occurs in **5% (5 out of 100 people)** of patients every two years.

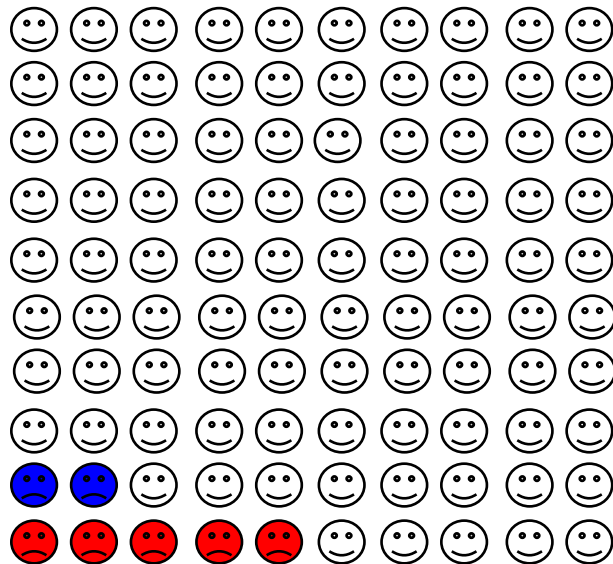
However, **93% of people (93 out of 100 people)** with atrial fibrillation taking the new oral anticoagulants will **neither have a stroke nor major bleeding** 😊 over the next two years.



# New Oral Anticoagulants Demonstration



This pictogram represents a group of 100 people.



In 2 years:

 **Stroke (2 out of 100 people)**

 **Major Bleeding (5 in 100 people)**

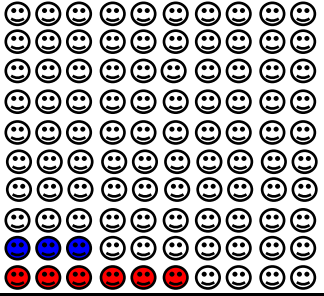
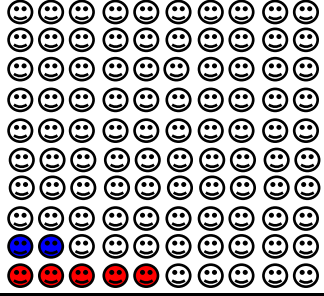
 **No Stroke or Major Bleeding (93 in 100 people)**

# Summary Comparison Charts

## Step #1: Anticoagulants versus Alternatives

Issue	No Treatment	Aspirin	Anticoagulants (Warfarin or NOAC)
Stroke (over 2 years )	11.4%	9.2%	2.7%
Major Bleeding (over 2 years ), which includes: - Intracranial bleed (MOST harmful) - Gastrointestinal bleed	0.5% 0.2% 0.1%	1.1% 0.5% 0.5%	5.3% 0.9% 1.9%
No stroke or major bleeding (over 2 years)	88%	90%	92%
● Stroke ☹ Major Bleeding 😊 No Stroke or Major Bleeding (over 2 years)			
Other Adverse Effects requiring stopping drug (over 2 years)	0%	7.6%	7.8%
Heart Attack (over 2 years)	3.3%	1.5%	1.3%
Death (over 2 years)	12%	10.5%	6.1%

## Step #2: Warfarin versus NOAC

Issue	Warfarin (Coumadin)	New Oral Anticoagulants (NOACs)
<b>Stroke</b> (over 2 years )	<b>3%</b>	<b>2.4%</b>
<b>Major Bleeding</b> (over 2 years ), which includes: - Intracranial bleed (MOST harmful) - Gastrointestinal bleed	<b>5.6%</b> 1.3% 1.3%	<b>5%</b> 0.6% 2.3%
<b>No stroke or major bleeding</b> (over 2 years)	91%	93%
<p>☹️ <b>Stroke</b></p> <p>☹️ <b>Major Bleeding</b></p> <p>😊 <b>No Stroke or Major Bleeding</b> (over 2 years)</p>		
<b>Other Adverse Effects</b> requiring stopping drug (over 2 yrs)	8.4%	7.3%
<b>Heart Attack</b> (over 2 years)	1.3%	1.3%
<b>Death</b> (over 2 years)	6.3%	6%
<b>Pill Taking</b>	You MUST remember to take a pill ONCE a day	You MUST remember to take a pill ONCE or TWICE a day
<b>Blood Tests</b>	Yes, to monitor how thin is your blood - initially every week then every month or less often	No tests to monitor blood thinning but you will need kidney blood testing at least every year*
<b>Activity Restrictions</b>	Limit alcohol and injury	Limit alcohol and injury
<b>Antidote</b> (if you bleed, are there treatments that can stop the bleeding?)	Yes, there are specific drugs that stop the bleeding	No, you will need blood transfusions until the drug wears off
<b>Special Diet?</b>	No, but we would advise you not to vary your diet much	No
<b>Taking Other Drugs</b>	Certain drugs interact with warfarin to increase risk, especially other blood thinners	A few drugs interact with NOACs to increase risk, especially other blood thinners
<b>Drug Cost</b>	Approximately \$9 per month (covered by ODB)**	Approximately \$104 per month (restricted coverage by ODB)**

\*you cannot take dabigatran, rivaroxaban, or apixaban if you have poor kidney function or have a mechanical heart valve; \*\* ODB = Ontario Drug Benefit (government drug plan)

### Step #3: If Choosing NOAC, Which NOAC to Take?

Issue	Dabigatran 110mg (Pradaxa)	Dabigatran 150mg (Pradaxa)	Rivaroxaban 20mg (Xarelto)	Apixaban 5mg (Eliquis)
<p>We present comparisons with <b>Warfarin</b> as Relative Risk (RR):</p> <p>If the relative risk (RR) is less than 1, then the outcome is <i>less common</i> with the NOAC compared to warfarin.</p> <p>If the relative risk (RR) is greater than 1, then the outcome is <i>more common</i> with the NOAC compared to warfarin.</p>				
<b>Stroke</b> (over 2 years )	No Difference	RR 0.7	No Difference	RR 0.8
<b>Major Bleeding</b> (over 2 years ), which includes:	RR 0.8	No Difference	No Difference	RR 0.7
- Intracranial bleed (MOST harmful)	RR 0.3	RR 0.4	RR 0.7	RR 0.4
- Gastrointestinal bleed	No Difference	1.4	1.6	No Difference
<b>Other Adverse Effects</b> requiring stopping drug (over 2 yrs)	1.6	1.6	No Difference	0.9
<b>Heart Attack</b> (over 2 years)	No Difference	No Difference	No Difference	No Difference
<b>Death</b> (over 2 years)	No Difference	No Difference	No Difference	RR 0.9
<b>Pill Taking</b>	You MUST remember to take 1 pill TWICE a day	You MUST remember to take 1 pill TWICE a day	You MUST remember to take 1 pill ONCE a day	You MUST remember to take 1 pill TWICE a day
<b>Blood Tests</b>	No tests to monitor blood thinning but you will need kidney blood testing at least every year*			
<b>Activity Restrictions</b>	Limit alcohol and injury			
<b>Antidote</b> (if you bleed, are there treatments that can stop the bleeding?)	No, you will need blood transfusions until the drug wears off			
<b>Special Diet?</b>	No			
<b>Taking Other Drugs</b>	A few drugs interact with dabigatran, rivaroxaban and apixaban to increase risk, especially other blood thinners.			
<b>Drug Cost</b>	Approximately \$104 per month (restricted coverage by ODB)**	Approximately \$104 per month (restricted coverage by ODB)**	Approximately \$92 per month (restricted coverage by ODB)**	Approximately \$103 per month (restricted coverage by ODB)**

\* You cannot take dabigatran, rivaroxaban, or apixaban if you have poor kidney function or have a mechanical heart valve; \*\* ODB = Ontario Drug Benefit (government drug plan)

This completes our presentation  
on anticoagulants for atrial fibrillation.

Please complete the required  
questionnaires once you have an  
understanding of the material.

Thank you for participating in our study.