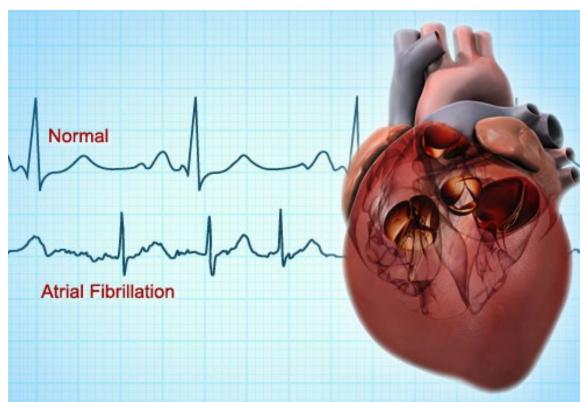
Warfarin or Dabigatran for Atrial Fibrillation?



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What are my choices?

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What is Shared Decision-Making?

Most of us want to be better 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 functional disability, but will allow the patient to continue to function 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 <u>risk is higher</u> in those with atrial fibrillation who are also **older**, have **high blood pressure**, **diabetes** or have had a **previous stroke**.

Blood thinning drugs (anticoagulants) are the most effective way to reduce the risk of stroke in people with atrial fibrillation. One of two blood thinner drugs can be used to <u>decrease your risk</u> of having a stroke. The two drugs are:

Warfarin or Dabigatran

However, these drugs can sometimes 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.

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

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

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

We will now describe what it would be like to experience a stroke.

What is a <mark>Stroke</mark>?

A stroke can be:

<u>Minor</u> or <u>Major</u>

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 <u>major</u> **stroke (50% of all strokes)** will need to be cared for by others for the rest of their lives, or may die.

In a <u>Minor Stroke (50% of all strokes)</u>:

you will suddenly notice that you cannot move your arm or leg on one side as well as before. You notice that you have lost 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 foods or liquids or 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 <u>Major Stroke (50% of all strokes)</u>:

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 cannot swallow food or liquids or control your bladder or bowels.

About one in five people who experience a major stroke will die. 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 to be cared for by others for the rest of your life.

You are now at increased risk of having another stroke.

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

What is a <mark>Bleed</mark>?

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 go to the hospital as the bleed is slight and only lasts for a few minutes. Patients who experience a **major bleed** have a chance of dying and will need to go to the hospital.

What is a **Minor Bleed**?

A minor bleed occurs once in while, but only lasts for a few minutes.

Minor bleeds happen when you have a small cut, but it only takes a few minutes to stop bleeding. You might have some bleeding in your gums when you are brushing your teeth or have an occasional nosebleed. However, the bleeding will stop very quickly. You might also notice that your skin bruises very quickly after being hit, but the bruise will 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:

Stomach or **Brain**

There is an important difference between a major bleed in the stomach versus the brain. Patients who experience a **bleed in the stomach (35-60% of all major bleeds)** will improve, and more than 90% of patients will return back to their usual self. 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 <u>Stomach</u>** (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 <u>Brain</u> (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 **dabigatran**, 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.

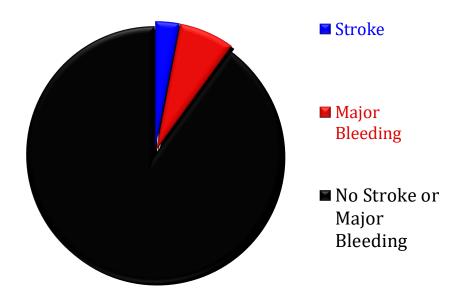
You have to tell your doctor, dentist, or other caregiver that you are taking warfarin. You will be encouraged to wear a medical alert bracelet. For atrial fibrillation patients taking warfarin, there is a **3% (3 out of 100 people)** chance of having a **stroke** ⁽³⁾ every two years.

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 ⁽²⁾ occurs in 7% (7 out of 100 people) of patients every two years.

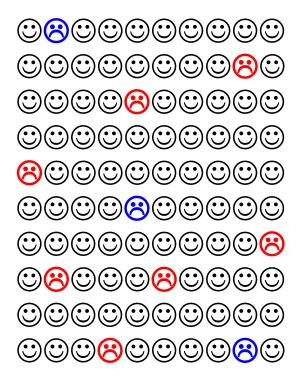
However, **90% of people (90 out of 100 people)** with atrial fibrillation taking warfarin will **not have a stroke or major bleeding** ⁽²⁾ over the next two years.

Other important details are in a table below.



Warfarin Demonstration

This pictogram represents a group of 100 people.



In 2 years: Stroke (3 out of 100 people) Major Bleeding (7 in 100 people) No Stroke or Major Bleeding (90 in 100 people)

Dabigatran

Dabigatran is a brand new "blood thinner". Our knowledge and experience is limited currently but we will learn more about its effectiveness and potential side effects over time.

If you are on dabigatran, you take a pill twice a day and you must remember to take it. There are no blood tests that can monitor how thin your blood is, but you will need to have kidney function tested every 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 dabigatran and cause problems; many of these interactions are not yet known.

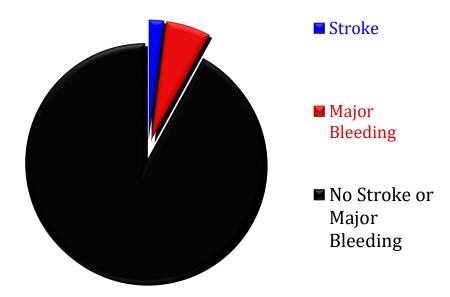
You have to tell your doctor, dentist, or other caregiver that you are taking dabigatran. You will be encouraged to wear a medical alert bracelet. In atrial fibrillation patients taking dabigatran, there is a **2% (2 out of 100 people)** chance of having a **stroke** $\ensuremath{\mathfrak{S}}$ every two years.

Most people taking dabigatran 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 \otimes occurs in **6% (6 out of 100 people)** of patients every two years.

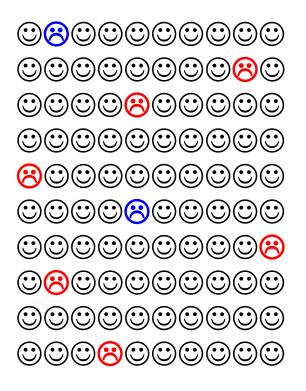
However, **92% of people (92 out of 100 people)** with atrial fibrillation taking dabigatran will **neither have a stroke nor major bleeding** over the next two years.

Other important details are in a table below.



Dabigatran Demonstration

This pictogram represents a group of 100 people.



In 2 years: Stroke (2 out of 100 people) Major Bleeding (6 in 100 people) No Stroke or Major Bleeding (92 in 100 people)

Issue	Warfarin	Dabigatran
		150mg
Stroke (over 2 years)	3%	2%
	(30 in 1000 people)	(20 in 1000 people)
Major Bleeding (over 2	7% (70 in 1000 people)	6% (60 in 1000 people)
years) including: - Intracranial bleed	1.4% (14 in 1000)	0.9% (9 in 1000)
- Gastrointestinal bleed	2.0% (20 in 1000)	3.0% (30 in 1000)
No stroke or major	90%	92%
bleeding (over 2 years)		
	08000000000000000000000000000000000000	08000000000000000000000000000000000000
😕 Stroke	000000000000000000000000000000000000000	000000000000000000000000000000000000000
[®] Major Bleeding	00000000000000000	00000000000000000
🕲 No Stroke or Major	000000000000000000000000000000000000000	000000000000000000000000000000000000000
Bleeding	<u>8000000000000000000000000000000000000</u>	000000000000000000000000000000000000000
(over 2 years)	00000	00000
Other Adverse effect	3.2% (32 in 1000)	5.4% (54 in 1000)
requiring stopping drug		
(over 2 years)		
Heart attack (over 2	0.64% (about 6 in 1000)	0.81% (8 in 1000)
years)		
Pill Taking	You MUST remember to	You MUST remember to
	take a pill once a day	take a pill twice a day
Blood Tests	Yes, to monitor how thin	No tests to monitor blood
	is your blood - initially	thinning but you will
	every week then every	need kidney blood
	month or less often	testing every year*
Activity Restrictions	Limit alcohol and injury	Limit alcohol and injury
Antidote (if you bleed,	Yes, there are specific	No, you will need blood
are there treatments	drugs that stop the	transfusions until the
that can stop the	bleeding	drug wears off
bleeding?)	0	
Special diet?	No, but we would advise	No
-	you not to vary your diet	
	much	
Drug Cost	Approximately \$10 per	Approximately \$100 per
-	month (covered by	month (not covered by
	ODB)**	ODB)**

Warfarin – Dabigatran Summary Comparison

*you cannot take dabigatran if you have poor kidney function; ** 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.