

DECISION AID TOOL

Adjuvant Endocrine Therapy for Hormone Receptor-Positive Breast Cancer

This booklet is what is often called a decision aid. The goal of decision aids is to help patients better understand their treatment choices and to help them make the best medical decision possible for their situation.

This decision aid is for women who are post-menopausal and who have hormone receptor-positive (ER+ and/or PR+) breast cancer and are trying to decide whether or not to take adjuvant (after surgery) endocrine therapy and what type of endocrine therapy to take. The goal of this decision aid is to help patients and doctors talk to each other in order to make decisions about treatment. It is based on recommendations from the American Society of Clinical Oncology's updated Clinical Practice Guideline on adjuvant endocrine therapy. Use of this decision aid is voluntary.

The decision aid is divided into two sections:

1. Learning the risks and benefits of adjuvant endocrine therapy
2. Help for thinking through the decision

The first time you read this decision aid, your doctor should be present to help you understand the information, and any family members or friends you would like to include. You may also take this document home after reviewing it with your doctor.

This guide contains numbers or statistics which may predict the course of breast cancer. If you are not comfortable with this type of information, you may prefer not to use this decision aid.

What role do you prefer in making this choice?

- I prefer to share the decision with _____
- I prefer to decide myself after hearing the views of _____
- I prefer that someone else decides
- I prefer to decide on my own

If help is desired, from whom?

- Doctor Spouse/Partner Children Other family member(s)
- Other person _____

This decision aid tool is derived in part from recommendations in the American Society of Clinical Oncology Clinical Practice Guideline Update on Adjuvant Endocrine Therapy for Women with Hormone Receptor-Positive Breast Cancer. This decision aid tool is a practice tool based on ASCO® practice guidelines and is not intended to substitute for the independent professional judgment of the treating physician. Practice guidelines do not account for individual variation among patients. This tool does not purport to suggest any particular course of medical treatment. Use of the practice guidelines and this decision aid tool are voluntary. The practice guidelines and additional information are available at <http://www.asco.org/guidelines/endocrinebreast>. Copyright © 2010 by the American Society of Clinical Oncology. All rights reserved.

Weighing Your Options section adapted from the Ottawa Personal Decision Guide Copyright O'Connor, Stacey, Jacobsen 2004

This guide is for women who have already gone through menopause. Sometimes it can be difficult to know whether you have really gone through menopause. You cannot assume you have gone through menopause even if you have not had a period for a year. Cancer treatment can interfere with menstruation. If you are not sure, talk to your doctor.

If you have not gone through menopause, then this decision aid is not for you. The treatments for women who have gone through menopause are different than those treatments for women who have not.

If you menstruated before cancer treatment, you should speak with your doctor about your menopausal status. For women who have not definitively gone through menopause, you should take tamoxifen, but not an aromatase inhibitor.

If you had a treatment that causes menopause (called “ovarian ablation,” which can be either medications or surgery), your doctor can discuss whether or not you can take an aromatase inhibitor.

Women using this guide should also be sure their breast cancer was hormone receptor-positive (often referred to as ER+ and/or PR+). If you are unsure if your cancer was hormone receptor-positive, please talk to your doctor.

If your cancer was ER+ and/or PR+, your treatment options include taking medicines that can reduce the chance that your breast cancer will return. These medicines include an aromatase inhibitor, tamoxifen, or both sequentially (or taking one and then the second).

For men with breast cancer, only tamoxifen is recommended.

Adjuvant Endocrine Therapy

After you have surgery, radiation, and/or chemotherapy, you should think about whether or not to take adjuvant endocrine therapy. Adjuvant endocrine therapy is medicine only for women with ER+ and/or PR+ breast cancer. There are two basic types of adjuvant endocrine therapy: tamoxifen and aromatase inhibitors. Tamoxifen has been proven to lower the chance of breast cancer returning and helps women with early-stage breast cancer live longer. Tamoxifen is a pill that is taken every day. Aromatase inhibitors lower the amount of estrogen in the body. There are three different aromatase inhibitor medicines: anastrozole, letrozole, exemestane; but they all work the same way. Aromatase inhibitors are also pills that are taken every day.

Who can and cannot take adjuvant endocrine therapy?

Women who are postmenopausal and who have ER+ and/or PR+ breast cancer can take either tamoxifen or one of the aromatase inhibitors.

For women who are premenopausal—or who are going through menopause, but it is not done—only tamoxifen is recommended. This includes women who have not gone through menopause, have working ovaries, or who no longer menstruate because of cancer treatment.

If you are taking one of a group of antidepressants, like Prozac (fluoxetine), Paxil (paroxetine), and Wellbutrin (bupropion), and considering an adjuvant endocrine treatment, you should tell your doctors that you are taking this medicine.

How long should women take adjuvant endocrine therapy?

Women may take either an aromatase inhibitor for 5 years

OR, Women may take tamoxifen for 5 years

OR, Women can start tamoxifen, take it for 2 or 3 years and then switch to an aromatase inhibitor

OR Women can start tamoxifen, take it for 5 years and then switch to an aromatase inhibitor

Women should not take an aromatase inhibitor for more than 5 years

RISKS AND BENEFITS OF ADJUVANT ENDOCRINE THERAPY

Introduction to benefits and risks

The information described in this decision aid is from one study called the BIG 1-98 trial. This study included almost 5000 women who were postmenopausal. Women were followed for over 6 years. One group of the women took tamoxifen, a second group took letrozole (an aromatase inhibitor), and a third group took tamoxifen for 2 years and then switched to the aromatase inhibitor for 3 more years.¹ All the women were instructed to take their medicine for 5 years.

The numbers in this decision aid show the risk and benefits, on average, for the women who were postmenopausal with hormone receptor positive breast cancer (in this study).

What is the main benefit of taking one of these medicines?

The benefit of taking either tamoxifen or an aromatase inhibitor is to lower the chance of your breast cancer returning. These medicines also lower the chance of cancer developing in the other breast.

How would taking an aromatase inhibitor or tamoxifen change the chances of having breast cancer coming back?

The risk of your cancer coming back depends on many things, including the stage of the cancer (the tumor size and whether or not it was in your lymph nodes) and the benefits you may get from adjuvant endocrine treatment.

This Decision Aid includes pictographs to show the differences between the drugs. Each pictograph contains 100 squares. Each square is equal to 1 person.

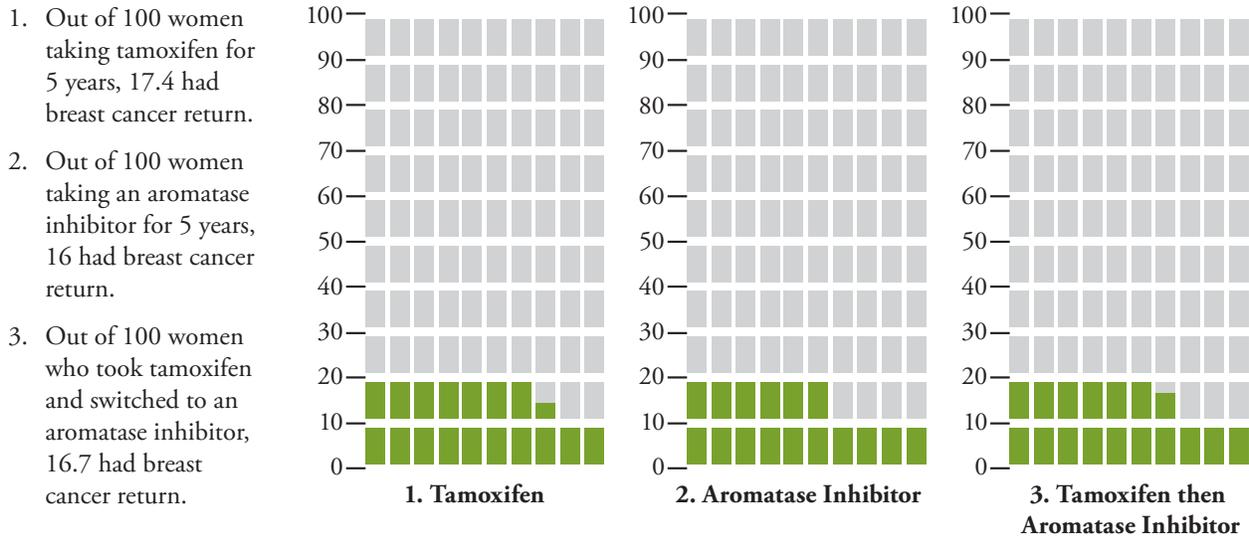
The numbers in these charts reflect an average risk of breast cancer diagnosis; the chance of it coming back in you may be either higher or lower, based on the stage of the cancer and other clinical factors. If an ER+ and/or PR + breast cancer is going to come back, it usually happens within the first 5 or 10 years.

1. There was a fourth group of women who first took letrozole for two years and then switched to tamoxifen. This Decision Aid does not discuss that option.

BENEFITS

The first set of pictographs, below, show the chances of breast cancer coming back in the same breast in 5 years.

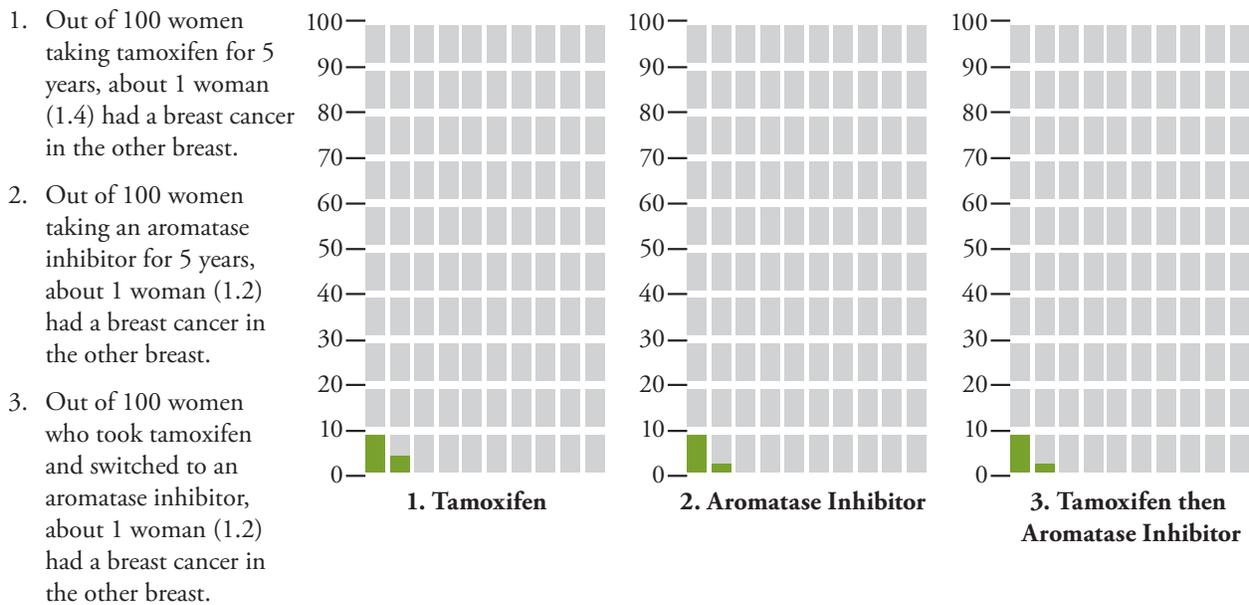
Chances of breast cancer coming back (in the same breast your cancer was in)



Therefore, the number of women who had breast cancer come back was quite similar with all three treatments. There were small differences favoring the use of an aromatase inhibitor as either first treatment, or after tamoxifen.

This set of pictographs show the chances of getting breast cancer in the other breast within 5 years.

Chance of getting breast cancer in the other breast



Therefore, there was no difference in the number of women who had breast cancer return with any of the three treatments.

RISKS

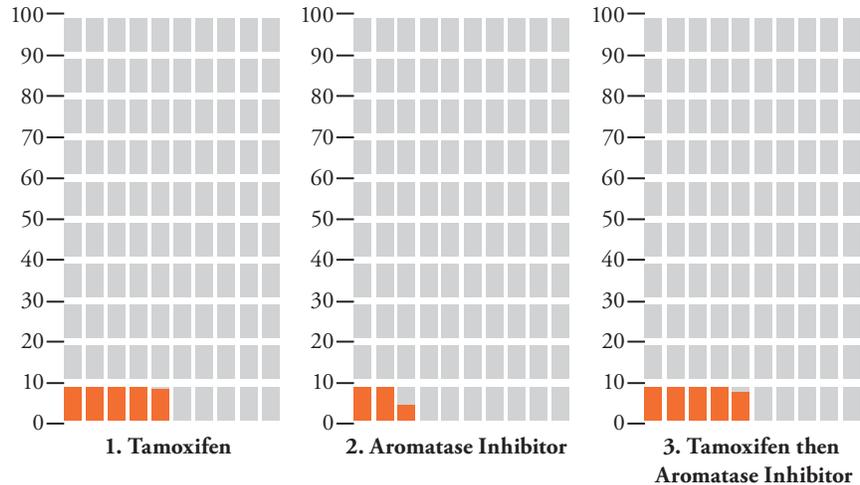
Like all medicines, tamoxifen and aromatase inhibitors have side effects. The pictographs below show the chance of having some of the more serious or more common side effects.

Blood clots (Venous Thromboembolism)

When blood forms clots, they block blood flow and this can be dangerous. For example, it can lead to a life-threatening lung problem (called pulmonary embolism), heart attack, or stroke. There are medicines and other treatments for blood clots, if you should get a blood clot.

Chance of getting a blood clot in 5 years

1. Out of 100 women taking tamoxifen for 5 years, about 5 women (4.9) got blood clots.
2. Out of 100 women taking an aromatase inhibitor for 5 years, about 2 women (2.4) got blood clots.
3. Out of 100 women who took tamoxifen and switched to an aromatase inhibitor, about 5 women (4.8) got blood clots.



Therefore, about 2 1/2 fewer women (2.4-2.5) taking an aromatase inhibitor had a blood clot, compared to those taking tamoxifen or tamoxifen followed by an aromatase inhibitor.

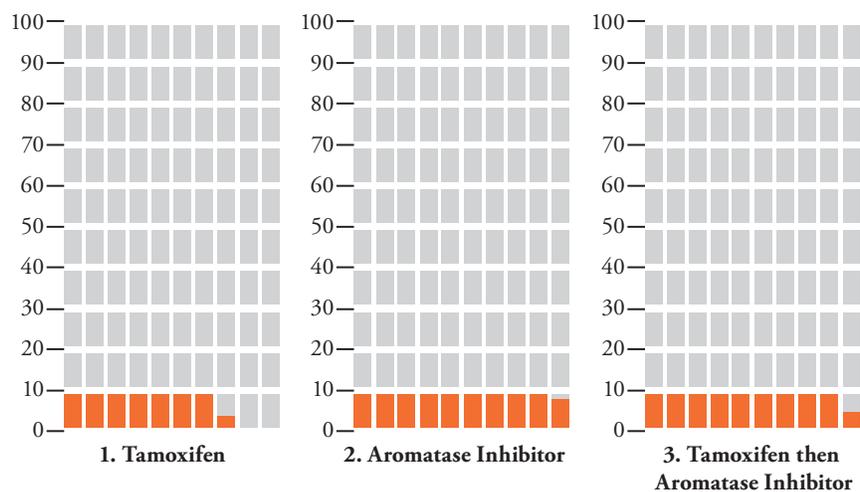
Bone fracture

After menopause, a woman can lose bone and her bones may be more likely to break. Aromatase inhibitors may slightly increase the chances of a bone break compared to tamoxifen.

In a woman who is postmenopausal, tamoxifen may help prevent osteoporosis [fragile bones].

Chance of getting a bone fracture in 5 years

1. Out of 100 women taking tamoxifen for 5 years, about 7 women (7.3) had a bone fracture.
2. Out of 100 women taking an aromatase inhibitor for 5 years, about 10 women (9.8) had a bone fracture.
3. Out of 100 women who took tamoxifen and switched to an aromatase inhibitor, about 10 women (9.4) had a bone fracture.



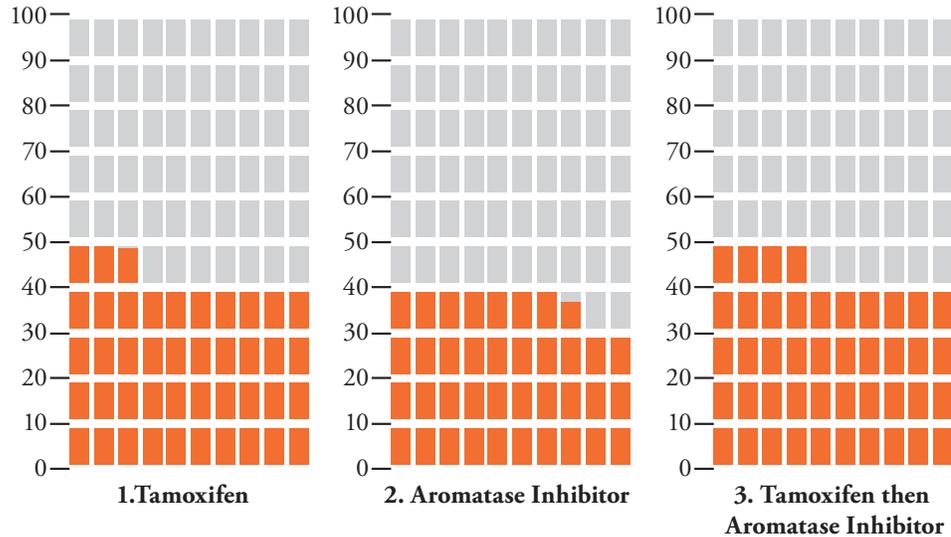
Therefore, about 2 to 3 fewer women (2.1-2.5) taking tamoxifen had a bone fracture, compared to those taking an aromatase inhibitor.

Hot flashes

Hot flashes are sudden feelings of being hot and sweaty.

Chance of having hot flashes over the next 5 years

1. Out of 100 women taking tamoxifen for 5 years, about 43 women got hot flashes.
2. Out of 100 women taking an aromatase inhibitor for 5 years, about 38 women (37.7) got hot flashes.
3. Out of 100 women who took tamoxifen and switched to an aromatase inhibitor, 44 got hot flashes.



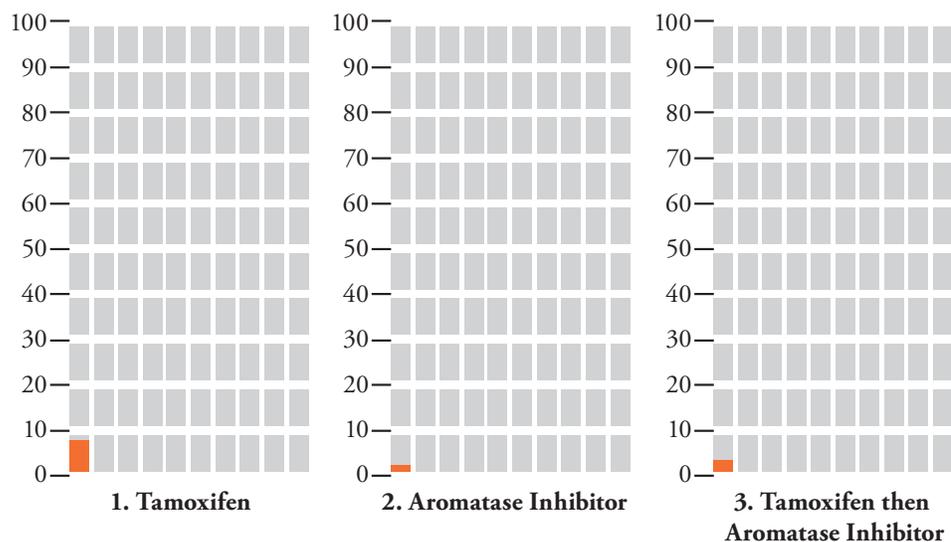
Therefore, 5 to 6 more women taking tamoxifen had hot flashes, compared to those who took an aromatase inhibitor.

Endometrial cancer

Endometrial cancer is a cancer of the lining of the uterus or womb. Postmenopausal bleeding can be a warning sign that there is an abnormality in the uterus. Not all bleeding that happens when you are postmenopausal is endometrial cancer, but you need to tell your doctor if it happens. Endometrial cancer is highly curable.

Chance of getting endometrial cancer in the next 5 years

1. Out of 100 women taking tamoxifen for 5 years, less than 1 woman (0.84) got endometrial cancer.
2. Out of 100 women taking an aromatase inhibitor for 5 years, less than 1 woman (0.13) got endometrial cancer.
3. Out of 100 women who took tamoxifen and switched to an aromatase inhibitor, less than 1 woman (0.26) got endometrial cancer.



There is a slightly greater chance of getting endometrial cancer with tamoxifen than with an aromatase inhibitor or tamoxifen followed by an aromatase inhibitor.

Additional side effects

Some women have other side effects. They can include vaginal dryness, joint pain, and osteoporosis. You can ask your doctor more about these side effects.

WEIGHING YOUR OPTIONS

The following pages are to help you think about what type of adjuvant therapy (for hormone receptor-positive (ER+ and/or PR+) breast cancer) to have after you have talked to your doctor. You may want to do this on your own or with someone else (for example, family, friends, or other caregivers outside of the doctor's office).

Your treatment options include:

- Taking tamoxifen or
- Taking an aromatase inhibitor or
- Taking tamoxifen first and then changing to an aromatase inhibitor.

The next two pages include three steps:

1. What decision do you need to make?
2. What information and help do you need to make the decision?
3. What are the next steps?

1. What decision do you need to make?

How soon do you want to make a choice? _____

2a. What information do you need to make the decision?

Do you have enough support and advice from other people to make a choice? _____

If not, who do you want to talk with before making your decision? _____

Are you choosing your treatment option without pressure from others? _____

Do you have enough facts to make a choice? _____

If not, what more would you like to know? _____

Do you know the benefits and risks of each option? _____

If not, what information do you need? _____

2b. Which benefits and risks matter most to you (please see table below)?

In the following table, use the numbers to show how important each benefit and risk is to you.

If you circle the number five, then the risk or benefit matters most. If you circle zero, then the risk or benefit matters least.

Finally, make a star or asterisk (*) in the column next to the benefit and/or risk(s) that you think are most likely to happen or are most worried about.

	How much does this matter? Please circle a #: [0 (none) —5 (a lot)]	How likely is this to happen to you? [0 (none) —5 (a lot)]
BENEFITS:		
Lowering the chances of breast cancer coming back	0 1 2 3 4 5	0 1 2 3 4 5
Lowering the chances of getting breast cancer in the other breast	0 1 2 3 4 5	0 1 2 3 4 5
<i>You can add another benefit here:</i>	0 1 2 3 4 5	0 1 2 3 4 5
RISKS:		
Blood clots	0 1 2 3 4 5	0 1 2 3 4 5
Bone fracture	0 1 2 3 4 5	0 1 2 3 4 5
Endometrial cancer	0 1 2 3 4 5	0 1 2 3 4 5
Hot flashes	0 1 2 3 4 5	0 1 2 3 4 5
<i>You can add other concerns here and below:</i>	0 1 2 3 4 5	0 1 2 3 4 5
	0 1 2 3 4 5	0 1 2 3 4 5
	0 1 2 3 4 5	0 1 2 3 4 5

3. In the following space, write down any additional other concerns and/or issues that you think are important to your decision (for example, other health issues, your age, money issues, family, etc.):

4. Plan the next steps

Consider planning your next steps based on your needs:

- a. If you feel you do not have enough support and/or if you feel pressure from others—you may want to look for other support. Your doctor, hospital, or clinic may be able to refer you to others who could help you find additional support.
- b. If you feel you do not have enough facts about adjuvant endocrine medicines, you may want to get more. For example, you could visit cancer.net (www.cancer.net).

Please use the space below or another page to write any questions or concerns you have:
