NICE National Institute for Health and Care Excellence

Decision aid

Intrabeam radiotherapy for treating early breast cancer

Information to help people with breast cancer, people close to them, and their health professionals discuss the options

What are the options?

Many people with early breast cancer are offered breast-conserving surgery (often called lumpectomy) as an alternative to mastectomy. If you have a lumpectomy you will usually be offered radiotherapy as well, to help prevent the cancer coming back in the breast (known as local recurrence). The well-established way to do this in the NHS is by **external radiotherapy**. In this type of radiotherapy, radiation is beamed at the breast from outside the body. It is given as a number of treatments, each of which lasts a few minutes. Most people have 1 treatment a day, 5 days a week for 3 weeks starting after the surgical wound has healed. You have to travel to the treatment centre for each of these treatments, but you can normally go home again afterwards. You can find out more about external radiotherapy at NHS Choices. **Intrabeam** is an alternative kind of radiotherapy. It gives the radiation just once, directly to the tissue that surrounded the tumour, during the lumpectomy operation. Some people need to have external radiotherapy as well as Intrabeam.

What does NICE recommend?

After looking carefully at the evidence, NICE has said **it is not yet possible to know for sure if Intrabeam is as good as external radiotherapy at preventing breast cancer coming back.**

NICE has said that Intrabeam should not be used in every hospital in the NHS, and can only be used in hospitals that already have Intrabeam machines. There will be special arrangements for collecting information about the long-term effects of Intrabeam to help future decisions about whether the NHS should make it more widely available.

NICE recommends that you should be offered Intrabeam only if a team made up of a wide range of breast cancer experts involved in your care think it is a suitable **option** for you to think about. Their recommendation will take into account things like the kind of breast cancer you have and how likely it is to come back.

The choice for you

For some people in whom the chance of cancer coming back is very low, the first choice is between having radiotherapy or no radiotherapy. Also, external radiotherapy may not be suitable for some people. This decision aid is not written for people in these situations.

If external radiotherapy or Intrabeam are both options for you, **you can choose which one to have**. This decision aid can help you and your cancer team decide together what is best for you. **There are pros and cons to having either option**.

Information about how this decision aid was produced and the evidence on which it is based is available on the NICE website.

How do the benefits and drawbacks of external radiotherapy and Intrabeam compare?

There is a large amount of evidence for external radiotherapy. One study has compared Intrabeam with external radiotherapy in nearly 2,300 women with breast cancer. **NICE said that it is difficult to be sure how Intrabeam compares with external radiotherapy, especially in the longer term**, because:

- The study lasted 5 years but for about half the women in it, the available information comes from about 2½ years of follow-up or less. Results were published in 2014 but full details of what happened to the women in the longer term are not yet available.
- The average dose of external radiotherapy in the study was higher and given over a longer period than would be normal in the UK. It was also given to the whole breast. Radiotherapy techniques are constantly being refined, and some people for whom Intrabeam is an option would now be offered partial-breast external radiotherapy.

The table on the next few pages is based on the study results. It summarises things most people are likely to think about when choosing between external radiotherapy and Intrabeam. You can use the table on page 6 to note down what you think about them. There may also be other things that are important to you. Talk to your breast cancer team about all these things.

It is not possible to know in advance what will happen to any individual person.

	External radiotherapy (ERT)	Intrabeam
How long is the radiotherapy treatment? *See also the diagram on page 7*	ERT is usually given as 1 treatment a day, 5 days a week for 3 weeks starting after the surgical wound has healed. Each treatment lasts a few minutes. People who have ERT have to come to the treatment centre each day for treatment, but normally they can go home again afterwards.	Intrabeam treatment is given once, during the lumpectomy operation. Most people who have Intrabeam don't have to come to the treatment centre for more radiotherapy after their operation. Some people need to have ERT as well as Intrabeam. This depends on the pathology report after the operation is over. **It is not possible to know in advance if you will need ERT after Intrabeam**. For every 100 women in the study, on average 22 women who had Intrabeam also needed ERT, and 78 women did not.
How good is the treatment at preventing the cancer coming back? *See also the diagrams on page 8*	In the study, for every 100 women who had whole-breast ERT alone, over 5 years, on average: • 1 woman had local recurrence • 99 women did not have local recurrence.	In the study, for every 100 women who had Intrabeam (with or without additional ERT), over 5 years, on average: • 2 women had local recurrence • 98 women did not have local recurrence.
	NICE thought that the rates of local recurrence in both groups of women were low. There is uncertainty about the precise numbers because of the low rate of recurrences and the length of time the women were followed up. It could be that the different rates of local recurrence seen in the study were due to chance, and that recurrence is actually no more or less likely with either treatment. But it could be that there truly is a difference, which could also be greater than that seen in the study. It is not yet possible to know for sure either way. **NICE said that Intrabeam (with or without additional ERT) has not been shown to be as good as ERT alone at preventing local recurrence**.	

	External radiotherapy (ERT)	Intrabeam
What would my options be if I have local recurrence of my cancer?	If you have ERT alone and then later on you have local recurrence, you would usually be offered a mastectomy. Breast-conserving treatment might be suitable for some people but not everyone.	If you have Intrabeam and don't need ERT as well, breast-conserving surgery (plus ERT) might be an option if you have local recurrence. However, a mastectomy might still be advised.
What is the chance of dying from breast cancer or other causes? *See also the diagrams on page 9*	In the study, for every 100 women who had whole-breast ERT alone, over 5 years, on average: • 3 women died from breast cancer • 4 women died from other causes • 93 women did not die.	In the study, for every 100 women who had Intrabeam (with or without additional ERT), over 5 years, on average: • 3 women died from breast cancer • 1 woman died from other causes • 96 women did not die.
	NICE said that it is not possible to be sure that people given Intrabeam (with or without additional ERT) are truly less likely to die overall than people who have ERT alone. This is because not enough information is available about the women who took part in the study.	
How likely is the radiotherapy to damage other parts of my body?	Radiotherapy can sometimes damage the heart, the ribs and the lungs. In ERT the beam of radiation can usually be targeted to avoid these problems, but they could still happen. In theory the risk would be less with Intrabeam because the dose of radiation is only given once, directly to where the tumour was. But there is no reliable information about how ERT and Intrabeam compare for this. Also, some people need ERT after Intrabeam (see page 3).	
How likely am I to get fatigue?	Radiotherapy can cause extreme tiredness and lack of energy, known as fatigue. This can last for weeks or months. Not everyone gets fatigue and, if they do, some people find it bothers them more or less than other people. Surgery and chemotherapy can also cause fatigue. In theory Intrabeam would cause less fatigue than ERT because the dose of radiation is given only once, but there is no reliable information about how they compare for this. Also, some people need ERT after Intrabeam (see page 3).	

<table>
<tr><th></th><th colspan="2">External radiotherapy (ERT) Intrabeam</th></tr>
<tr><td>How likely am I to get short-term skin reactions?</td><td colspan="2">Radiotherapy can sometimes cause short-term skin problems on the treated breast, but not everyone gets them. They are usually mild but can sometimes be more serious, when the skin becomes sore and raw and weeps. In theory the risk would be less with Intrabeam because the dose of radiation is given only once, directly to where the tumour was, rather than externally to the breast. Some evidence from the study supports this, but the actual numbers of people likely to be affected are uncertain. Also, some people need ERT after Intrabeam (see page 3).</td></tr>
<tr><td rowspan="3">How likely am I to get longer-term changes to my breast?
See also the diagrams on page 10</td><td colspan="2">Information about longer-term problems is only available from 1 small part of the study (a sub-study). Some people need ERT after Intrabeam (see page 3). Fibrosis (thickening and stiffening of the breast tissue) is the only longer-term problem for which information is available comparing whole-breast ERT, Intrabeam alone, and Intrabeam plus ERT.</td></tr>
<tr><td>The sub-study suggests that, over 3 years, on average:
in every 100 women who have whole-breast ERT alone, 18 women would get fibrosis and 82 women would not.</td><td>The sub-study suggests that, over 3 years, on average:
in every 100 women who have Intrabeam alone, 6 women would get fibrosis and 94 women would not.
in every 100 women who have Intrabeam plus ERT, 38 women would get fibrosis and 62 women would not.</td></tr>
<tr><td colspan="2">There is uncertainty about the numbers because of the small size of the study and the length of time the women were followed up. It could be that the different rates of fibrosis seen in women who had whole-breast ERT alone and those who had Intrabeam alone were due to chance, and that fibrosis is actually no more or less likely with either of these treatments. But it could be that there truly is a difference, which could also be greater than that seen in the study. It is not possible to know for sure either way. NICE thinks that you are more likely to get fibrosis if you have Intrabeam plus ERT than if you have Intrabeam alone, but the actual numbers of people likely to be affected are uncertain.</td></tr>
</table>

Other things to think about

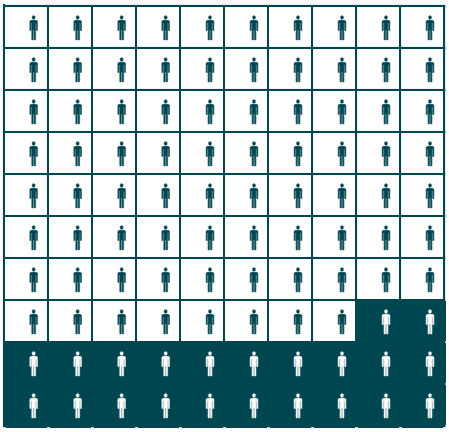
If you decide to have Intrabeam, extra information will be collected about what happens to you, including whether your cancer comes back and your quality of life. This will help find out more about how Intrabeam compares with external radiotherapy. It will be collected in a confidential way and shared with researchers, but no-one will be able to identify you.

How you feel about the options

Issue	How important is this to me?			
	Very important	Important	Not important	Not at all important
Knowing that external radiotherapy is the well-established NHS approach				
Having to travel to the treatment centre for 3 weeks of external radiotherapy				
The possibility that I might still need external radiotherapy if I have Intrabeam				
The chance of my cancer returning in the breast (local recurrence)				
Options if I get local recurrence				
The chance of dying from breast cancer or other causes				
The possibility of getting fatigue				
The possibility of getting shorter-term skin reactions				
The possibility of longer-term changes to my breast				
Having extra information collected about me if I choose Intrabeam				
Other things I want to talk about:				

Diagrams to help explain the numbers in the decision aid

People who had Intrabeam who turned out to need external radiotherapy (ERT) as well



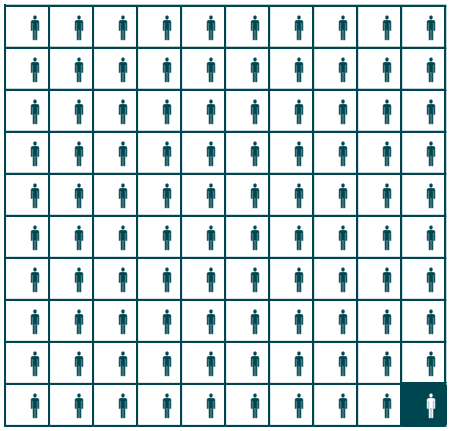
In the study, in every 100 women who had Intrabeam, **on average**:

- 78 women did not need ERT as well
- 22 women needed ERT as well

It is not possible to know in advance what will happen to any individual person

Local recurrence of breast cancer over 5 years

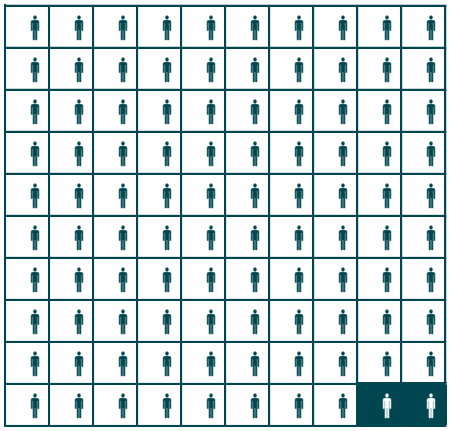
Local recurrence in women who had whole-breast external radiotherapy (ERT) alone



In the study, in every 100 women who had ERT alone, over 5 years **on average**:

- 99 women did not have local recurrence of their cancer
- 1 woman had local recurrence of her cancer

Local recurrence in women who had Intrabeam, with or without additional external radiotherapy (ERT)



In the study, in every 100 women who had Intrabeam with or without additional ERT, over 5 years **on average**:

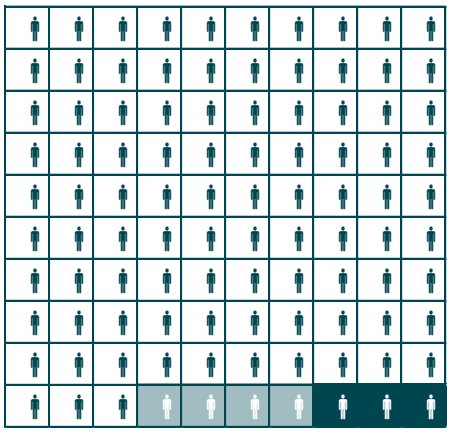
- 98 women did not have local recurrence of their cancer
- 2 women had local recurrence of their cancer

There is uncertainty about the precise numbers because of the low rate of recurrence and the length of time the women were followed up. **NICE said that Intrabeam (with or without additional external radiotherapy) has not been shown to be as good as external radiotherapy alone at preventing local recurrence**.

It is not possible to know in advance what will happen to any individual person

Chance of dying over 5 years

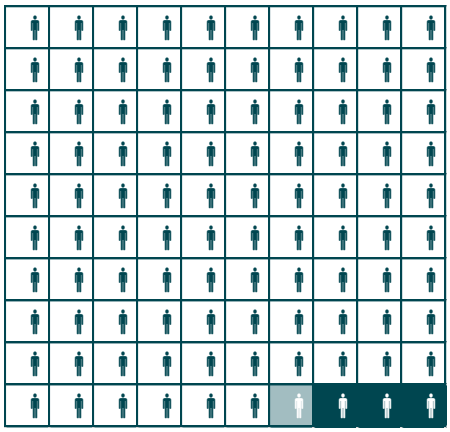
Deaths in women who had whole-breast external radiotherapy (ERT) alone



In the study, in every 100 women who had ERT alone, over 5 years **on average**:

- 93 women did not die
- 3 women died from breast cancer
- 4 women died from other causes

Deaths in women who had Intrabeam, with or without additional external radiotherapy (ERT)



In the study, in every 100 women who had Intrabeam with or without additional ERT, over 5 years **on average**:

- 96 women did not die
- 3 women died from breast cancer
- 1 woman died from other causes

NICE said that it is not possible to be sure that people given Intrabeam (with or without additional external radiotherapy) are truly less likely to die overall than people who have external radiotherapy alone. This is because not enough information is available about the women who took part in the study.

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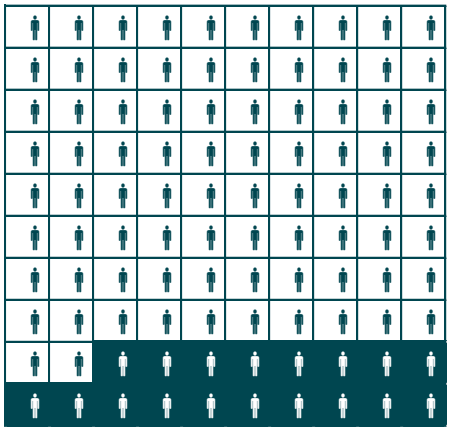
Chance of breast fibrosis over 3 years

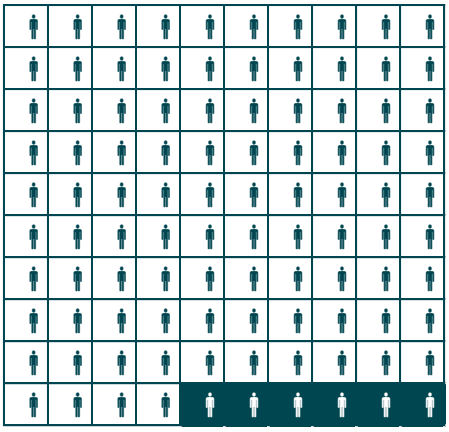
Breast fibrosis in women who had whole-breast external radiotherapy (ERT) alone



The sub-study suggests that, in every 100 women who have ERT alone, over 3 years **on average**:

- 82 women would not get breast fibrosis
- 18 women would get breast fibrosis

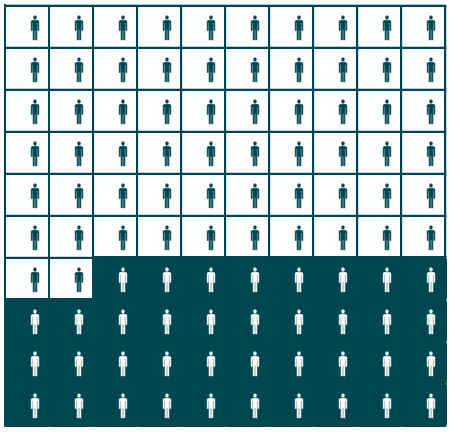
Breast fibrosis in women who had Intrabeam alone



The sub-study suggests that, in every 100 women who have Intrabeam alone, over 3 years **on average**:

- 94 women would not get breast fibrosis
- 6 women would get breast fibrosis

Breast fibrosis in women who had Intrabeam plus whole-breast external radiotherapy (ERT)



The sub-study suggests that, in every 100 women who have Intrabeam plus ERT, over 3 years **on average**:

- 62 women would not get breast fibrosis
- 38 women would get breast fibrosis

It is not possible to know in advance what will happen to any individual person