

Understanding NICE guidance

Information for people who use NHS services

Using brachytherapy as the only type of radiotherapy following breast cancer surgery

NICE 'interventional procedures guidance' advises the NHS on when and how new procedures can be used in clinical practice.

This leaflet is about when and how brachytherapy can be used in the NHS to treat people following surgery for breast cancer. It explains guidance (advice) from NICE (the National Institute for Health and Clinical Excellence).

Interventional procedures guidance makes recommendations on the safety of a procedure and how well it works. An interventional procedure is a test, treatment or surgery that involves a cut or puncture of the skin, or an endoscope to look inside the body, or energy sources such as X-rays, heat or ultrasound. The guidance does not cover whether or not the NHS should fund a procedure. Decisions about funding are taken by local NHS bodies (primary care trusts and hospital trusts) after considering how well the procedure works and whether it represents value for money for the NHS.

NICE has produced this guidance because the procedure is quite new. This means that there is not a lot of information yet about how well it works, how safe it is and which patients will benefit most from it.

This leaflet is written to help people who have been offered this procedure to decide whether to agree (consent) to it or not. It does not describe breast cancer or the procedure in detail – a member of your healthcare team should also give you full information and advice about these. The leaflet includes some questions you may want to ask your doctor to help you reach a decision. Some sources of further information and support are on the back page.

What has NICE said?

The evidence shows that there are no major safety worries about this procedure. However, there is not a lot of evidence about how well the procedure works and there is very little information about results in the long term (5 years or more).

For these reasons, NICE has said that this procedure should only be carried out as part of a research study (also called a clinical trial). The research should look at how well the procedure works for a minimum period of 5 years after the procedure.

Other comments from NICE

It is very important that any procedure to treat early breast cancer should be supported by a lot of good quality evidence from large numbers of patients.

This procedure may not be the only possible treatment for breast cancer. Your healthcare team should talk to you about whether it is suitable for you and about any other treatment options available.

Using brachytherapy as the only type of radiotherapy following breast cancer surgery

The medical name for this procedure is 'Brachytherapy as the sole method of adjuvant radiotherapy for breast cancer after local excision'.

The procedure is not described in detail here – please talk to your specialist for a full description.

Treatment for breast cancer usually involves surgery to remove the tumour and part of the surrounding breast (local excision) or the entire breast (mastectomy). This is sometimes followed by radiotherapy, particularly if only part of the breast has been removed. This radiotherapy (traditional radiotherapy) is usually delivered by shining a beam of radiation at the breast tissue (external beam irradiation).

Brachytherapy is the medical word for internal radiotherapy in which the source of radiation is placed inside the body. It can be used as an additional treatment (known as adjuvant) after surgery. Radioactive sources are inserted through wires or fine tubes (sometimes with a balloon device) into the space in the breast where tissue has been removed. The radioactive sources are usually in place for a few minutes or a few days, depending on the strength of the radioactivity being delivered. The aim of the procedure is to minimise the chance of the cancer recurring.

What does this mean for me?

Your doctor can only offer you this procedure as part of a research study. NICE has recommended that some details should be collected about every patient who has this procedure in the UK. Your doctor may ask you if details of your procedure can be used to help collect more information about this procedure. Your doctor will give you more information about this.

You may want to ask the questions below

- What does the procedure involve?
- What are the benefits I might get?
- How good are my chances of getting those benefits? Could having the procedure make me feel worse?
- Are there alternative procedures?
- What are the risks of the procedure?
- Are the risks minor or serious? How likely are they to happen?
- What care will I need after the operation?
- What happens if something goes wrong?
- What may happen if I don't have the procedure?

Summary of possible benefits and risks

Some of the benefits and risks seen in the studies considered by NICE are briefly described below. NICE looked at eight studies on this procedure.

How well does the procedure work?

The studies that NICE looked at all had similar results. In a study of 258 patients treated with either brachytherapy to the part of the breast from which the tumour has been removed or traditional radiotherapy, there were no significant differences between the two. The cancer came back in 6 out of 128 patients in the brachytherapy group and in 4 out of 130 patients in the traditional radiotherapy group. After 5 years there was still little difference between the groups, with 95% of the brachytherapy patients still alive, compared with 92% of the traditional radiotherapy group.

Another study of 398 patients had similar results. After 5 years the cancer had come back in 1% of patients in both groups. After 5 years 87% of the brachytherapy patients were still alive, compared with 93% of the traditional radiotherapy patients.

A third study of 144 patients followed their progress for 75 months. It showed that cancer came back in 4 out of 51 patients in the brachytherapy group, compared with 5 out of 94 patients in the traditional radiotherapy group. At the end of the 75 months, 88% of the brachytherapy patients were still alive, compared with 92% of the traditional radiotherapy patients.

You might decide to have this procedure, to have a different procedure, or not to have a procedure at all.

As well as looking at these studies, NICE also asked expert advisers for their views. These advisers are clinical specialists in this field of medicine. The advisers said that success factors are whether the cancer comes back, whether the patient dies from the cancer, cosmetic appearance and quality of life.

Risks and possible problems

The study of 103 patients showed that between 17% and 43% of patients developed skin redness after the procedure. Fibrous (scar) tissue developed in between 11% and 32% of patients. Damage to the fat cells (breakdown or death of cells) happened in between 7% and 12% of patients.

As well as looking at these studies, NICE also asked expert advisers for their views. These advisers are clinical specialists in this field of medicine. The advisers said that other complications include: breast swelling (oedema), breast pain, development of spider veins, fluid retention and changes to skin colour.

More information about breast cancer

NHS Direct online (www.nhsdirect.nhs.uk) may be a good starting point for finding out more. Your local Patient Advice and Liaison Service (PALS) may also be able to give you further advice and support.

About NICE

NICE produces guidance (advice) for the NHS about preventing, diagnosing and treating different medical conditions. The guidance is written by independent experts including healthcare professionals and people representing patients and carers. They consider how well an interventional procedure works and how safe it is, and ask the opinions of expert advisers. Interventional procedures guidance applies to the whole of the NHS in England, Wales, Scotland and Northern Ireland. Staff working in the NHS are expected to follow this guidance.

To find out more about NICE, its work and how it reaches decisions, see www.nice.org.uk/aboutguidance

This leaflet is about 'Brachytherapy as the sole method of adjuvant radiotherapy for breast cancer after local excision'. This leaflet and the full guidance aimed at healthcare professionals are also available at www.nice.org.uk/IPG268

You can order printed copies of this leaflet from NICE publications (phone 0845 003 7783 or email publications@nice.org.uk and quote reference N1629).

We encourage voluntary sector organisations, NHS organisations and clinicians to use text from this booklet in their own information about this procedure.