

Understanding NICE guidance

Information for people who use NHS services

Keyhole surgery to remove breast tissue to treat breast cancer

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 keyhole surgery to remove breast tissue can be used in the NHS to treat people with 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?

Currently there is not enough evidence to be certain about how well this procedure works or how safe it is.

For this reason, 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 with different sizes and locations of cancer, breast size, whether enough tissue surrounding the cancer has been removed, appearance after the procedure, whether the cancer comes back or whether further surgery is needed, quality of life and survival. The research should be carried out in hospitals that specialise in the management of breast cancer, by surgeons trained in both breast cancer surgery and keyhole surgery.

NICE may look at this procedure again if more information becomes available.

Other comments from NICE

Most of the evidence available relates to studies carried out in East Asia in people with small breasts. The technique may have different results for women with larger breasts. The procedure has also been used for non-cancerous (benign) breast lumps.

For details of all NICE guidance on breast cancer and its treatments (both medical and surgical), visit our website at www.nice.org.uk/Guidance/Topic

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.

Keyhole surgery to remove breast tissue to treat breast cancer

The medical name for this procedure is 'endoscopic mastectomy and endoscopic wide local excision for breast cancer'.

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

Breast cancer is the most common cancer in women. It also occurs in men, but this is much rarer. Breast cancer is described as 'early' if it is only in the breast and the lymph nodes nearby (most often in the armpit), and has not spread to other parts of the body. The cancer is said to be 'advanced' if it has spread to other parts of the body or if it has grown directly into other tissues and cannot be completely removed by surgery. Treatment depends on the type of cancer, how far it has spread, how fast it is growing, the patient's health, and their wishes.

Surgery is often the first option for early breast cancer and may involve removing the whole breast (mastectomy) or part of the breast (wide local excision). Radiotherapy, chemotherapy or hormone therapy may also be offered.

This keyhole procedure is done with the patient under a general anaesthetic. Part of the breast tissue (endoscopic wide local excision) or all of the breast tissue (endoscopic mastectomy) is removed using special instruments inserted

through small skin incisions. The skin envelope of the breast and nipple are left intact, ready for an implant that can be inserted during the same operation.

What does this mean for me?

Your doctor can only offer you this procedure as part of a research study (also called a clinical trial).

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 nine studies on this procedure.

How well does the procedure work?

In a study of 551 patients who had keyhole mastectomy, after 66 months, 100% of patients with ductal carcinoma in situ (a very early form of non-invasive breast cancer, often shortened to DCIS), and over 91% of patients with early breast cancer were disease free. However after 38 months the cancer had come back in 23 (or 4%) patients. This study also reported that 366 patients (out of the 481 patients who responded to a questionnaire) thought the procedure had given them a 'good' result, 66 thought they had a 'fair' result and 49 patients thought they had a 'poor' result.

In a study of 46 patients (21 patients had the keyhole procedure and 25 had a traditional mastectomy), all patients were alive after an average of 19 months (ranging from 6 to 35 months). The study completed laboratory tests for cancer cells at the edge of tissues that had been removed. Some cancer cells were left behind in 2 patients in the keyhole group and 1 patient in the other group. The patients needed to have radiotherapy to

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

kill any remaining cancer cells. This also happened in 2 other patients in 2 more studies which involved a total of 26 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 aims of the procedure are long term survival, removing the cancer completely, the cancer not returning, patient satisfaction, pain control after the procedure, speed of return to work and length of hospital stay.

Risks and possible problems

In 2 studies involving a total of 584 patients, there were reports of tissue death (nipple, skin, fat or muscle) in 42 patients. In another 2 studies involving a total of 89 patients, 6 patients experienced burns. A study of 84 patients reported bleeding or bruising (haematoma) in 9 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 possible problems include serious damage to blood vessels or nerves, air in the chest cavity (causing the lung to collapse), problems with the skin flap and a longer operation time for the keyhole procedure.

More information about breast cancer

NHS Choices (www.nhs.uk) may be a good place to find out more. Your local patient advice and liaison service (usually known as PALS) may also be able to give you further information 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 'endoscopic mastectomy and endoscopic wide local excision for breast cancer'. This leaflet and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/IPG296

You can order printed copies of this leaflet from NICE publications (phone 0845 003 7783 or email publications@nice.org.uk and quote reference N1849). The NICE website has a screen reader service called Browsealoud, which allows you to listen to our guidance. Click on the Browsealoud logo on the NICE website to use this service.

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

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ISBN 1-84629-952-7
N1849 1P Apr 09