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Understanding NICE guidance

Information for people who use NHS services

National Institute for Health and Clinical Excellence

Using a radiofrequency cutting probe to take a sample to test for breast cancer

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

This leaflet is about when and how a radiofrequency cutting probe can be used in the NHS to take a sample to test for breast cancer in people with breast lumps. It explains guidance (advice) from NICE (the National Institute for Health and Clinical Excellence).

This HealthTech 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 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 lumps 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 page 7.

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What has NICE said?

There is not much good evidence about how well this procedure works or how safe it is. There are also worries about the possibility of test results incorrectly showing that the patient does not have breast cancer.

If a doctor wants to use a radiofrequency cutting probe for taking a sample from a person with a breast lump, they should make sure that extra steps are taken to explain the uncertainty about how well it works, as well as the uncertainty surrounding potential risks of the procedure. This should happen before the patient agrees (or doesn't agree) to the procedure. The patient should be given this leaflet and other written information as part of the discussion. There should also be special arrangements for monitoring what happens to the patient after the procedure.

NICE has encouraged further research into radiofrequency cutting probes and may review the procedure if more evidence becomes available.

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Radiofrequency cutting probes to take samples to test for breast cancer

This procedure may not be the only possible method for taking a sample from a breast lump. Your healthcare team should talk to you about whether it is suitable for you and about any other options available.

The medical name for this procedure is 'image-guided radiofrequency excision biopsy'. The procedure is not described in detail here – please talk to your doctor for a full description.

A lump or mass found in the breast may need to be tested for cancer. A radiofrequency cutting probe can be used to remove some or all of the lump and a small amount of tissue around it. A local anaesthetic is given and a small cut (of about 6 to 8 mm) made in the breast to insert the probe. The probe has a cutting tip that uses radiofrequency energy to cut out the lump. The lump can then be removed and tested to find out whether it is cancerous or not.

What does this mean for me?

If your doctor has offered you radiofrequency probe sampling to test for breast cancer, he or she should tell you that NICE has decided that the benefits and risks are uncertain, and there is the possibility of an incorrect test result. This does not mean that the procedure should not be done, but that your doctor should fully explain what is involved in having the procedure and discuss the possible benefits and risks with you. You should only be asked if you want to agree to this procedure after this discussion has taken place. You should be given written information, including this leaflet, and have the opportunity to discuss it with your doctor before making your decision.

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 procedure?
- What happens if something goes wrong?
- What may happen if I don't have the procedure?

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Summary of possible benefits and risks

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

Some of the benefits and risks seen in the studies considered by NICE are briefly described below. NICE looked at 2 studies on this procedure.

How well does the procedure work?

In a study that looked at 742 breast lumps, 34 were thought to be noncancerous (also known as benign) after sampling using a radiofrequency cutting probe. The patients then had surgery to remove and further examine the lumps. Three of these lumps were found to have been diagnosed incorrectly and were, in fact, cancerous. In the same study, 119 lumps were thought to have very early stage cancerous cells present (called ductal carcinoma in situ or DCIS) following removal using a radiofrequency cutting probe. However, 6 of these were later found to have a more serious type of invasive cancer cell present (called invasive ductal carcinoma or IDC).

In a study of 100 patients with 106 breast lumps that were thought to be noncancerous following an imaging scan, and then removed using a radiofrequency cutting probe, 93% showed no sign (either by examination or by scanning) of any lump remaining between 4 and 6 months later.

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 aim of this procedure, when used for noncancerous lumps, is completely removing the lump and ensuring that the appearance of the breast after removal is satisfactory to the patient. They also said that the success factors of the procedure, when used in patients with suspected early breast cancer, were removal of an adequate sample for testing, survival rate and whether the breast cancer returns.

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Risks and possible problems

In the study of 742 lumps removed by radiofrequency cutting probe, only 1 patient developed an infection. The infection was cleared up with antibiotic tablets.

In the study of 100 patients, most said that the level of pain felt during the procedure was low, giving it a score of less than 1 point on a scale from 0 for no pain to 10 for severe pain. Of these procedures, only 2 out of 106 lumps removed caused bleeding.

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 bruising, infection, skin burns and failing to get a sample are possible complications. In theory, other problems could include spreading (or 'seeding') tumour cells along the path of the probe, bleeding, temporary pain and damage to fat cells due to heat.

More information about breast lumps

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. This 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 'Image-guided radiofrequency excision biopsy of breast lesions'. This leaflet and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/HTG198

You can order printed copies of this leaflet from NICE publications (phone 0845 003 7783 or email publications@nice.org.uk and quote reference N1909). 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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