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Image-guided vacuum-assisted excision biopsy of benign breast lesions

Understanding NICE guidance –
information for people considering
the procedure, and for the public



Ordering information

You can download the following documents from www.nice.org.uk/IPG156

- this booklet
- the full guidance on this procedure.

For printed copies of the full guidance or information for the public, phone the NHS Response Line on 0870 1555 455 and quote:

- N0983 (full guidance)
- N0984 (information for the public).

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About this information

The National Institute for Health and Clinical Excellence (NICE) is the independent organisation responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health. One of NICE's roles is to produce guidance (recommendations) on whether interventional procedures are safe enough and work well enough to be used routinely in the NHS in England, Wales and Scotland.

This information describes the guidance that NICE has issued on a procedure called image-guided vacuum-assisted excision biopsy of benign breast lesions. It is not a complete description of what is involved in the procedure – the patient's healthcare team should describe it in detail.

NICE has looked at whether image-guided vacuum-assisted excision biopsy is safe enough and works well enough for it to be used routinely for the removal of benign breast lesions.

To produce this guidance, NICE has:

- looked at the results of studies on the safety of image-guided vacuum-assisted excision biopsy of benign breast lesions and how well it works
- asked experts for their opinions
- asked the views of the organisations that speak for the healthcare professionals and the patients and carers who will be affected by this guidance.

This guidance is part of NICE's work on 'interventional procedures' (see 'Further information' on page 10).

About the procedure

Image-guided vacuum-assisted excision biopsy is a non-surgical procedure that can be used to remove benign (non-cancerous) lumps in the breast.

A small opening is made in the breast. A piece of equipment that has a needle attached to a suction device is then placed into the area of the lump. Small amounts of breast tissue are sucked away through the needle, and this is repeated until the lump appears to have gone. The doctor sees what is happening from ultrasound images of the area (sometimes other types of image are used). When the lump appears to have been removed, the needle device is taken out and the opening is pressed for a short time to help stop bleeding.

How well the procedure works

What the studies said

The number of breast lumps that were completely removed using the new procedure ranged from 21 out of 95 lumps (22%) in one study to 121 out of 124 lumps (98%) in another study. The likelihood of success may depend on the size of the needle device used and the size of the woman's lump. Also, the quality of the images used during the procedure may affect how easy it is to tell whether all the lump has been removed.

In one study that followed what happened in 13 women who had vacuum-assisted biopsy, 3 women (23%) needed surgery to remove parts of the lump that remained after the new procedure.

Risks and possible problems with the procedure

What the studies said

The most common problem affecting women in the studies was the formation of a blood-filled swelling called a haematoma. In one study, 24 out of 186 women (13%) had a haematoma following the procedure, but none of these was said to be serious. In another study, none of 20 women had a serious haematoma.

In the study that followed what happened in 186 women, 73 women (39%) had mild pain after the procedure, and 8 women (4%) said they had moderate pain. No one said they had severe pain.

Bleeding during the procedure happened in 2 out of 56 women (4%) in one study, and in 3 out of 186 women (2%) in another.

What the experts said

The experts said that problems during or following the procedure include haemorrhage (bleeding), haematoma formation and feelings of faintness. Doctors could miss parts of the lump, and the area could become infected.

What has NICE decided?

NICE has considered the evidence on image-guided vacuum-assisted excision biopsy. It has recommended that when doctors use this procedure for people with benign breast lesions, they should be sure that:

- the patient understands what is involved and agrees (consents) to the treatment, and
- the results of the procedure are monitored.

Doctors who want to carry out this procedure should have the training recommended by the Royal College of Radiologists in 'Ultrasound training recommendations for medical and surgical specialties' (which can be found at www.rcr.ac.uk/docs/radiology/pdf/ultrasound.pdf).

Other comments from NICE

Occasionally a woman might be found to have cancer after having the procedure even if a biopsy before the procedure showed that the lump was benign.

What the decision means for you

Your doctor may have offered you image-guided vacuum-assisted excision biopsy. NICE has considered this procedure because it is relatively new. NICE has decided that the procedure is safe enough and works well enough for use in the NHS. Nonetheless, you should understand the benefits and risks of image-guided vacuum-assisted excision biopsy before you agree to it. Your doctor should discuss the benefits and risks with you. Some of these may be described above.

Further information

You have the right to be fully informed and to share in decision-making about the treatment you receive. You may want to discuss this guidance with the doctors and nurses looking after you.

The NICE website (www.nice.org.uk) has further information about NICE, the Interventional Procedures Programme and the full guidance on image-guided vacuum-assisted excision biopsy of benign breast lesions that has been issued to the NHS. The evidence that NICE considered in developing this guidance is also available from the NICE website.

If you have access to the internet, you can find more information on breast lumps on the NHS Direct website (www.nhsdirect.nhs.uk). You can also phone NHS Direct on 0845 46 47.

The NHS Breast Screening Programme has produced guidelines for breast cancer screening assessment in the NHS, which can be found at www.cancerscreening.nhs.uk/breastscreen/publications/nhsbsp49.html

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