

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

Interventional procedures guidance

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Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

1 Guidance

- 1.1 Current evidence on the safety and efficacy of image-guided vacuum-assisted excision biopsy of benign breast lesions appears adequate to support the use of this procedure, provided that the normal arrangements are in place for consent, audit and clinical governance.
- 1.2 Clinicians wishing to perform this procedure should undergo training as recommended by the Royal College of Radiologists in '[Ultrasound training recommendations for medical and surgical specialties](#)'.

2 The procedure

2.1 Indications

- 2.1.1 Image-guided vacuum-assisted core biopsy has been regularly used for gathering samples of tissue in women with breast lesions suspicious of breast cancer, or when histological evidence of a benign lesion is required. This procedure can also be used to remove benign breast lesions such as fibroadenomas. This can reduce the need for open surgical biopsy or excision.
- 2.1.2 Diagnosis of benign breast disease is usually done by clinical examination, imaging and fine needle biopsy; this is known as the triple test. Women who have negative results for malignancy in all three tests may choose to have benign lumps removed.

2.2 Outline of the procedure

- 2.2.1 The procedure involves the use of a needle probe device with vacuum suction to remove breast tissue under imaging guidance (commonly ultrasound). The aim of the procedure is to continue using the biopsy device until the lesion visible on imaging has been removed. A small incision is made in the breast and an 8- or 11-gauge probe is inserted through the lesion. Small amounts of tissue are aspirated and the probe is withdrawn further into the lesion and the process repeated. When the device has been removed the site of incision is compressed for a short time. The procedure takes between 13 and 60 minutes, depending on the size of lesion being removed. The procedure can be performed on an

outpatient basis under local anaesthesia.

2.3 Efficacy

- 2.3.1 Complete removal was achieved in between 22% (21/95) and 98% (121/124) of lesions. The success rate may depend on the gauge of the probe used and the size of the lesion to be removed (these are often dependent variables). The accuracy of determining complete removal may depend on the quality of the imaging technique used.
- 2.3.2 In one case series, 23% (3/13) of patients with incompletely excised lesions after vacuum-assisted biopsy had subsequent open surgery excision. For more details, refer to the Sources of evidence.

2.4 Safety

- 2.4.1 The most frequent complication of this procedure was haematoma. This complication was recorded in 13% (24/186) of patients in one case series, but none of these haematomas were classified as serious. In another study of 20 patients, no clinically problematic haematomas were reported.
- 2.4.2 In one large case series, 39% (73/186) of patients complained of mild postoperative pain, and 4% (8/186) of moderate pain. No patients reported severe pain.
- 2.4.3 Bleeding during the procedure occurred in 4% (2/56) of patients in one case series, and in 2% (3/186) in another. However, all three latter cases resolved with little or no intervention. For more details, refer to the Sources of evidence.
- 2.4.4 The Specialist Advisors noted that complications include haemorrhage, haematoma formation, vasovagal episodes and failure to excise the correct area. In addition, wound infection is a possible problem.

2.5 Other comments

- 2.5.1 It was noted that, despite prior biopsy, patients may occasionally be found to have a malignant cancer.

- 2.5.2 It was noted that benign lesions such as fibroadenomas may sometimes recur after this procedure.

3 Further information

- 3.1 The NHS Breast Screening Programme has produced guidelines entitled '[Clinical guidelines for breast cancer screening assessment](#)'.

Andrew Dillon
Chief Executive
February 2006

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the following document.

['Interventional procedure overview of image-guided vacuum-assisted excision biopsy of benign breast lesions'](#), February 2005.

Information for patients

NICE has produced [information on this procedure for patients and carers](#). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

4 About this guidance

NICE interventional procedure guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.

This guidance was developed using the NICE [interventional procedure guidance](#) process.

We have produced a [summary of this guidance for patients and carers](#). Information about the

evidence it is based on is also [available](#).

Changes since publication

20 January 2012: minor maintenance.

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Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).