NICE guidance

Image-guided radiofrequency excision biopsy of breast lesions

Interventional procedures guidance
Published: 22 July 2009
nice.org.uk/guidance/ipg308

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 radiofrequency (RF) excision biopsy of breast lesions is inadequate in quantity and quality, and there are concerns about the possibility of false-negative biopsy results.

Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.

1.2 Clinicians wishing to undertake image-guided RF excision biopsy of breast lesions should take the following actions.

- Inform the clinical governance leads in their Trusts.
- Ensure that patients and their carers understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. In addition, the use of NICE's information for patients ('Understanding NICE guidance') is recommended.
- Audit and review clinical outcomes of all patients having image-guided RF excision biopsy of breast lesions (see section 3.1).

1.3 NICE encourages further research into image-guided RF excision biopsy of breast lesions. Research should be in the form of diagnostic studies aimed at quantifying the risk of false-negative results associated with the procedure. NICE may review the procedure on publication of further evidence.

2 The procedure

2.1 Indications and current treatments

2.1.1 Breast abnormalities may be benign or malignant. Diagnosis is based on clinical findings, imaging and tissue sampling. Tissue sampling is usually by fine needle aspiration for cytology, or by needle core biopsy for histology. Histology allows for differentiation between benign tumours such as fibroadenomas (typically between 1 cm and 3 cm in size), and others such as non-invasive ductal carcinoma in situ (DCIS) and invasive ductal carcinoma (IDC). Open surgical biopsy or image-guided vacuum-assisted core biopsy may also be used to establish tumour type and grade.

2.1.2 Breast cancer is the most common cancer in women in the UK. If cancer is diagnosed, treatment depends on the type, stage and grade of the tumour.

2.1.3 In general terms, the more tissue retrieved with multiple core samples or larger tissue samples, the more accurate the diagnosis is likely to be. With this procedure, the whole lesion can be removed.

2.2 Outline of the procedure

2.2.1 Image-guided RF excision biopsy of breast lesions aims to achieve minimally invasive retrieval of an intact specimen for histological examination, while minimising the risk of bleeding and haematoma formation. This procedure is not indicated currently for the therapeutic removal of known cancers unless there are no surgical options.

2.2.2 The procedure is carried out with the patient under local anaesthesia. Using image guidance, a small incision is made in the breast. A probe with a unipolar RF cutting tip is advanced to the site of the lesion. Small wires and capturing arms are extended from the tip of the probe to surround the lesion, which is then dissected using the RF cutting tip. The sample is captured in the arms of the device and withdrawn.

2.2.3 Probes of various diameters and expandable RF cutting tips can be used, depending on the diameter of the sample to be captured.

> Sections 2.3 and 2.4 describe efficacy and safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the overview.

2.3 Efficacy

2.3.1 In a case series of 742 breast lesions (absolute number of patients not reported), 34 lesions were initially identified as atypical ductal hyperplasia (benign lesions) after RF excision biopsy. Following subsequent surgery and histological examination 9% (3/34) of these results were false negatives; the lesions were subsequently diagnosed as either DCIS or IDC. Similarly, 5% (6/119) of lesions initially diagnosed as DCIS following RF excision biopsy were subsequently diagnosed as IDC after surgical excision and biopsy.

2.3.2 In a case series of 100 patients (106 lesions) with breast lesions diagnosed as fibroadenomas based on imaging findings, who were subsequently managed by

RF excision biopsy, 93% (79/85) of patients showed no physical or imaging evidence of residual lesions at follow-ups of between 4 and 6 months.

2.3.3 The Specialist Advisers listed key efficacy outcomes for this procedure, when used for benign lesions, as intact removal of the lesion and patient acceptability/ cosmetic appearance. The Specialist Advisers listed additional efficacy outcomes, when used in early breast cancer, as delivery of an evaluable lesion for histology, and both local recurrence and survival.

2.4 Safety

2.4.1 The case series of 742 lesions (absolute number of patients not stated) reported that infection (not otherwise defined) occurred in less than 1% (1/742) of biopsies (resolved with oral antibiotics) (follow-up not stated). The case series of 100 patients (106 lesions) recorded a mean pain score during the procedure of less than 1 point (using a visual analogue scale from 0 [no pain] to 10 [severe pain]).

2.4.2 In the case series of 100 patients (106 lesions), bleeding occurred in 2% (2/106) of excision procedures but this was controlled by 'conservative measures' (not otherwise defined).

2.4.3 The Specialist Advisers listed adverse events reported in the literature as haematoma, infection, skin burns and failure to deliver an adequate sample. They considered theoretical adverse events to include seeding of tumour cells along the biopsy tract, haemorrhage, pain (temporary) and fat necrosis due to thermal damage.

3 Further information

3.1 This guidance requires that clinicians undertaking the procedure make special arrangements for audit. NICE has identified relevant audit criteria and has developed audit support (which is for use at local discretion).

3.2 For related NICE guidance see our website.

Information for patients

NICE has produced information on this procedure for patients and carers ('Understanding NICE guidance'). 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.

It has been incorporated into the NICE pathway on early and locally advanced breast cancer, along with other related guidance and products.

We have produced a summary of this guidance for patients and carers. Tools to help you put the guidance into practice and information about the evidence it is based on are also available.

Changes since publication

6 January 2012: minor maintenance.

Your responsibility

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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.

Accreditation