

Image-guided radiofrequency excision biopsy of breast lesions

Interventional procedures guidance

Published: 22 July 2009

www.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, and specifically any special arrangements relating to the introduction of new interventional procedures. 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.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the [Yellow Card Scheme](#).

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. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

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 the public 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 radiofrequency (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.

2.3 Efficacy

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](#).

- 2.3.1 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 out of 34) of these results were false negatives; the lesions were subsequently diagnosed as either DCIS or IDC. Similarly, 5% (6 out of 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 out of 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 out of 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 out of 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).

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the [overview](#).

Information for patients

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

ISBN: 978-1-4731-6316-4

Endorsing organisation

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