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Guidelines from the European Society of Breast Imaging for diagnostic interventional breast procedures

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Abstract The aim of the breast team is to obtain a definitive, nonoperative diagnosis of all potential breast abnormalities in a timely and cost-effective way. Percutaneous needle biopsy with its high sensitivity and specificity should now be standard practice, removing the need for open surgical biopsy or frozen section. For patients with cancer, needle biopsy provides a cost-effective and rapid way of providing not only a definitive diagnosis but prognostic information, allowing prompt discussion of treatment options, be they surgical or medical. Early removal of uncertainty

also allows better psychosocial adjustment to the disease. Patients with benign conditions found either by themselves or as a result of population or opportunistic screening can be promptly reassured and discharged, removing the health care and psychological costs of surgical biopsy or repeated follow-up. Radiologists involved in breast imaging should ensure that they have the necessary skills to carry out core biopsy and/or fine-needle aspiration (FNA) under all forms of image guidance. This paper provides guidelines on best practice for diagnostic interventional breast procedures and standards, against which all practitioners should audit themselves, from the European Society of Breast Imaging.

Keywords Breast cancer · Diagnostic imaging · Needle biopsy · Guidelines

Introduction

The aim of the breast team is to obtain a definitive, nonoperative diagnosis of all potential breast abnormalities in a timely and most cost-effective way. Women with no significant breast problems should be reassured as quickly

as possible, and women with cancer should be diagnosed without delay.

The highest levels of diagnostic accuracy in the nonoperative diagnosis of breast disease are achieved by using a triple approach [1], which combines the results of clinical examination and imaging with fine-needle aspira-

tion cytology (FNAC) and/or core biopsy (both wide bore and vacuum-assisted) of significant breast abnormalities [2, 3]. When the results of all three modalities agree, the level of diagnostic accuracy exceeds 99% [4]. It is of interest to note that similar levels of accuracy have been obtained in the case of impalpable lesions, in which clinical examination is noncontributory [5].

Percutaneous needle biopsy with its high sensitivity and specificity should now be standard practice, removing the need for open surgical biopsy or frozen section [6–9]. For patients with cancer, needle biopsy provides a cost-effective and rapid way of providing not only a definitive diagnosis but prognostic information, allowing prompt discussion of treatment options, be they surgical or medical. Early removal of uncertainty also allows better psychosocial adjustment to the disease. It is not the goal of percutaneous biopsy to completely excise cancer.

Benign conditions found either by the patient themselves or as a result of population or opportunistic screening can be promptly reassured and discharged, removing the health care and psychological costs of surgical biopsy [10, 11]. The role of needle biopsy versus short-term follow up in the management of probably benign lesions is less clear cut. The American literature, where annual examinations are routine, suggests that there is no difference in the levels of stress or intention to reattend [12, 13]. On the other hand, in the UK NHS Breast Screening Programme, early recall is considered more stressful both in the short- and long-term than needle biopsy [14, 15]. Early follow-up is said to be

cheaper, but this might depend on individual health care economies and clinic organisation [16, 17]. The two options should be discussed with the patient, and if the triple approach confirms benignity, then the lesion can be reclassified as benign and the patient discharged. Radiologists involved in breast imaging should ensure that they have the necessary skills to carry out core biopsy and/or FNAC under stereotactic, ultrasound (US) and magnetic resonance imaging (MRI) control.

The aim of this paper is to provide guidelines for diagnostic interventional breast procedures by the European Society of Breast Imaging.

Standards and objectives

Tables 1 and 2 provide a list of both outcome and process standards for interventional breast biopsy against which all individual practitioners and their multidisciplinary teams should audit themselves.

Standard 1

This standard applies to all carcinomas (invasive and in situ) and applies to diagnoses made by FNAC and/or core biopsy vacuum-assisted biopsy. Only definitive diagnoses of malignancy should be included. Open surgical biopsy is not included.

Table 1 Quality indicators (standards) for breast interventional procedures

Objective	Criteria	Acceptable standard	Desirable target
1 To ensure that the majority of cancers, both palpable and impalpable, receive a nonoperative tissue diagnosis of cancer	The percentage of women who have a nonoperative diagnosis of cancer by cytology or needle histology	>70%	>80%
2 To minimise the number of visits necessary to achieve a definitive diagnosis	The number of visits for interventional procedures	No more than 2	No more than 1
3 To minimise the number of unnecessary operative procedures	Ratio of benign:malignant biopsies	≤1:1	≤0.5:1
4 To achieve optimum aspiration technique and minimise the number of repeat needle biopsy procedures	Inadequate rate of NAC (all)	<25%	<15%
5 To maximise the nonoperative diagnosis rate and minimise the number of repeat needle biopsy procedures	Inadequate rate of FNAC from cancer	<10%	<5%
6 To maximise the nonoperative diagnosis rate and minimise the number of repeat needle biopsy procedures	Miss rate on core breast biopsy from cancer	<5%	<2%
7 To minimise understaging of invasive breast cancer	Percent of noninvasive core breast biopsies that are invasive at final surgery	<15%	<5%
8 To minimise understaging of breast cancer	Percent of high-risk core breast biopsies that are malignant at surgery	<25%	<10%

NAC needle aspiration cytology, FNAC fine-needle aspiration cytology

Table 2 Quality indicators (standards) for breast interventional procedures (population screening)

Objective	Criteria	Acceptable standard	Desirable target
9 To minimise the number of unnecessary operative procedures	The rate of benign biopsies (when population screening)	Prevalent screen <3.6 per 1,000; incident screen <2.0 per 1,000	Prevalent screen <1.8 per 1,000; incident screen <1.0 per 1,000

Standard 2

There is a risk that, in an attempt to drive up the nonoperative diagnostic rate, repeated attendances for needle biopsy during a single clinical episode are likely to be associated with unnecessary anxiety. A definitive diagnosis should be achieved in the minimum number of visits wherever possible.

To date, these standards and objectives have been laid down for screening programmes [18, 19] and, to a lesser extent, for referral (symptomatic) practice [20], but we have pulled them together and updated them. Each objective defines the purpose of the standard and has an accompanying criteria, which defines how the standard should be measured. The acceptable standard is a minimum that all teams should achieve. The desirable target is aspirational. We are aware that long-established teams and countries with population screening can comfortably attain these targets and, indeed, have national targets set at higher levels [18], but this only comes with considerable experience and the repeated use of audit [21]. We are confident that in a few years, we will be able to revisit and reset both the acceptable standard and the desirable target.

Before interventional procedures

All patients should undergo a thorough workup including clinical examination and imaging prior to FNAC and/or core biopsy. The imaging characteristics of suspicious lesions are demonstrated using special views, including fine-focus magnification views for microcalcifications and spot compression views and US examination for mass lesions, focal asymmetry or architectural distortion. Imaging features of mammographically and/or US-detected abnormalities are assessed to determine the probability of malignancy, and this should be indicated in the radiological report. The radiologist must be certain that the abnormality seen on US is the same as the abnormality seen on mammography and, where relevant, that this corresponds to the palpable lesion. There should be written local protocols clearly defining the indications for FNAC, automated core biopsy and other needle biopsy techniques [2]. The procedure should be explained to the patient, with a brief explanation of risks and benefits. It should be standard practice to provide the patient with written information about complications.

Teaching and experience

Training standards have been set out by the European Association of Radiology in the European Training Charter for Clinical Radiology (<http://www.eur-online.org>) [22]. We suggest that a minimum of 20 interventional procedures are undertaken under supervision (with histological verification) before commencing independent practice and then a minimum of 25 per year to maintain competence [23, 24].

Choice of sampling technique

Current evidence suggests that, firstly, vacuum-assisted core biopsy (VACB) properly carried out provides better sensitivity and specificity than either 14-gauge core biopsy or FNAC for microcalcifications and architectural distortion. Secondly 14-gauge core biopsy provides better sensitivity and specificity than FNAC for other types of lesions [8, 9, 25, 26]. Core biopsy also facilitates definitive diagnosis of benign lesions [10, 11]. This has to be balanced against the cost and the fact that unless one uses imprint cytology [27, 28] or fast-track biopsy techniques [29] it is not possible to provide an answer immediately. Finally, core biopsy provides information on invasion, grade, hormone receptor status and other immunological and genetic markers. These can be used to assist in management decisions and aid in monitoring of the effects of neoadjuvant treatment [30]. In expert hands, remarkable results can be obtained on cytological specimens [31, 32].

FNAC may be preferred in some centres for sampling mass lesions and obvious carcinoma, but only where a satisfactory standard of excellence of both sampling and cytology interpretation has been achieved [8, 9, 33–35]. The main advantages of FNAC are cost [20, 33, 36] as one only requires 18- to 23-gauge disposable needles attached to a plastic syringe. Additional equipment includes glass slides with alcohol fixative for unsmear tissue samples [37]. Another advantage is the ability to provide immediate reporting, either on adequacy by a technician or a full diagnosis when a cytopathologist is available [25, 33, 38, 39]. While this is considered to be very beneficial for women with benign disease, it is less clear cut for patients with malignancy who need longer to come to terms with their diagnosis. The combination of the two techniques has been shown to be beneficial [40], particularly for cancer, as

FNAC allows for rapid diagnosis, which is subsequently confirmed by histology (core biopsy). This avoids the risk of a false positive diagnosis and obtains prognostic information for treatment decisions.

Needle size is important, with clear evidence that, when comparing 14-, 16- and 18-gauge needles, accuracy rises with needles of increasing size [41]. Long-throw needles used with a fully automated biopsy gun produce the best specimens [42–44]. Current best practice is to use a long-throw (2-cm) 14-gauge needle with biopsy gun (integral or separate).

VACB (from 8 to 11 gauge) can be used with either standard upright or prone stereotactic apparatus and under US guidance. Published evidence shows that the use of VACB is associated with higher rates of calcium retrieval and lower rates of underdiagnosis of both ductal carcinoma in situ (DCIS) and invasive tumour [25, 45, 46]. Where available, VACB may be considered the sampling method of choice for:

- Indeterminate cluster of microcalcifications
- Obviously malignant cluster of microcalcifications, to increase to the chance of detection of invasive foci
- Discordant results after 14-gauge core biopsy
- Architectural distortion
- Diagnostic excision of papillary lesions diagnosed at core biopsy

Guidance

High proportions of mammographically detected lesions are impalpable and require image guidance for FNAC or core biopsy sampling. In addition, image guidance, particularly US, can have advantages over freehand procedures when sampling palpable lesions to ensure accurate and safe sampling [47, 48]. The choice of radiological guidance must be the method that (a) allows the best visualisation of the lesion, (b) offers the best chance of successful and adequate lesion sampling and (c) is the simplest and cheapest.

If a diagnostic MRI of the breast identifies a suspicious lesion, every effort should be made to reidentify the lesion on conventional modalities such as mammography or US [49]. If a lesion can be clearly identified on mammography or US, biopsy should be performed using one of these guiding modalities. However, second-look US fails to identify a sonographic correlate in up to 77% of MRI-detected lesions referred for biopsy [50, 51]. Where possible, MRI procedure should be undertaken with the same sequences used for the diagnostic study and, if time permits, in the second week of the menstrual cycle [52].

A clip should be placed at the end of the procedure to allow for mammographic marking if subsequent surgical intervention is indicated. Two orthogonal mammographic views are required to document the position of the clip.

Complications

Complications from both FNAC and core biopsy are rare. However, the following have been reported:

- Pain
- Haematoma
- Fainting
- Pneumothorax [54]
- Infection [55]
- Seeding of tumour [56, 57, 60] (this does not appear to be of clinical significance)
- Removal of lesion by the core. (It is not the objective of the diagnostic biopsy to remove the lesion in its entirety; however, this will happen in the case of small lesions, and it is good practice to take a stereo film at 0° to check how much remains and, if needed, deploy a marker clip.)
- Dislocation of clip placement [53, 58]

Adequacy of sampling

FNAC sample

An adequate FNAC sample should contain at least five clusters of epithelial cells, each of which should contain five or more cells [2].

Core biopsy

Generally, it is not appropriate to be dogmatic about the number of specimens taken when undertaking core biopsy, particularly when using US. The important thing is to achieve the targets set out above. Liberman [59, 60] suggests that a minimum of five passes are required. With experience, mass lesions can be diagnosed with a couple of passes [61]. However, it is necessary to obtain a representative sample adapted to lesion size and tissue consistency and document this. There should be radiological and pathological correlation before discussing the result with the patient. There are two specific lesion types in which more definitive evidence based guidance can be provided: microcalcification and architectural distortion.

Microcalcifications

Representative microcalcification must be demonstrated in the core specimens on specimen radiography [45]. Identification of microcalcification on histology alone is not a reliable indicator of adequate sampling (histological microcalcification is a common incidental finding and can be present when there is no calcification visible on mammography) [62]. The literature is divided on how to

ensure optimal diagnostic accuracy: the minimalist approach of counting calcification on the specimen radiographs verses counting the number of cores or the volume removed. Bagnall [63] recommends that at least three flecks of calcification be seen in at least two cores. Ideally, five flecks or more should be seen in three cores. This requirement is obviously lessened in lesions with fewer than ten flecks of calcification. In these circumstances, a comparison before and after the procedure (scouts 0°) to evaluate the percentage of microcalcifications retrieved by the biopsies is indicated. Biopsies that retrieve more than 50% of the cluster can be considered as representative of the lesion [64]. On the other hand, Lomschitz [65] considers that when using 11-gauge VACB, 12 specimens (harvested by two rotations) gives maximum diagnostic yield.

If sampling is not adequate and/or in discordant radiohistological results, the procedure should be repeated or localisation surgical biopsy performed [46]. Surgical biopsy is not required when histology shows a definitively benign cause for calcifications in core specimens confirmed by specimen radiography to contain calcifications clearly representative of those considered suspicious on mammography.

Specificity and absolute sensitivity for sampling microcalcifications is significantly higher with the use of larger-bore biopsy devices, such as VACB, and such devices may be considered where there is diagnostic uncertainty [66, 67]. Surgical open biopsy is normally required to exclude frank malignant change in the adjacent tissues when histology shows indeterminate changes (e.g. hyperplasia with atypia) [45, 63], as even with large volume sampling, underestimation of disease will take place, i.e. hyperplasia on core is a harbinger of noninvasive disease, and some noninvasive core biopsies will turn out to be invasive on surgical treatment.

It is not the goal of percutaneous biopsy to completely excise cancer [64].

Architectural distortion

Management of architectural distortion is still controversial, as 20–50% of cases of architectural distortion are due to malignancy [68]. Traditional teaching is that all these lesions should be removed. However, data from several published series now show that image-guided core biopsy is accurate in distinguishing malignant lesions from benign causes, e.g. radial scar, providing targeting is accurate and sufficient material is obtained [69–72]. A recent series has shown that the most accurate results are obtained by taking more than 12 11-gauge samples using a VACB device [73]. Recommendations for the management of architectural distortion depends on the local availability of vacuum-assisted mammotomy. If VACB is not available, it is recommended that conventional core biopsy is performed

as the initial diagnostic procedure on all distortions not due to surgical scarring [26]. If this shows malignant change, therapeutic surgery should be performed (a minimum of three cores targeted to sample different areas of the imaging abnormality). For all other diagnoses, diagnostic surgical open biopsy should be performed.

If VACB is available, it is recommended that initial diagnosis is carried out using conventional automated core biopsy. Again, a malignant result should be managed by therapeutic surgery. However if a result is benign or shows radial scar with no evidence of epithelial atypia, a choice of either open surgical excision or excision with VAB may be offered. VAB can be performed under US or stereotactic X-ray guidance, and a minimum of 12 11-gauge cores should be obtained. Where VAB is chosen and histology again shows either benign changes or radial scar with no evidence of epithelial atypia, then further excision is not required.

In all cases, management should be discussed prospectively by the multidisciplinary team. If there is doubt regarding concordance of the imaging/histology findings, diagnostic surgical excision should be recommended.

Staging of the axilla

Sentinel lymph node biopsy (SLNB) has become rapidly accepted as an alternative to axillary sampling or clearance [74, 75]. Seven-year follow-up from Veronesi et al. suggests that this is a safe procedure [76]. Variable surgical and pathological practice indicates that there are still outstanding questions [75, 77]. Axillary node US with either FNAC or core biopsy can identify between 30% and 40% axillas with macroscopic disease [78–82] and according to Deurloo can reduce the number of SLNBs by up to 14% [80].

Documentation

Images should be taken to document accurate needle placement. A written report to both the referring team and the reporting pathologist should include:

- Nature of lesion biopsied
- Radiological opinion and classification
- Details of procedure undertaken (including needle calibre)
- Adequacy of targeting
- Quantity of material sampled
- Presence or absence of microcalcification on specimen radiographs
- Changes (or not) of the lesion after biopsy (e.g. mass decreasing in size)
- Placement of a clip marker and description of its position

- Pathology centre where the specimen is being processed
- Complications (if any)

After interventional procedures

Communication and discussion of result

Clinical examination, together with the result of imaging, must be considered with the results of needle biopsy to ensure clinico-radio-pathological concordance before management decisions are made. It is good practice that this occurs in a multidisciplinary fashion, preferably as part of a regular multidisciplinary meeting where full notes are taken or a written report is produced.

In addition to routine quality control tests, to ensure equipment safety and performance during imaging and interventional procedures, outcome data on the procedures should be collected. This data should be prospectively collected and summarised for each facility and physician who performs the procedures and by the reporting pathologist. In addition to data required to monitor performance against the standards outlined in the early part of the document, the number of complications, and the number of lesions requiring repeat biopsy and the reason should be recorded. A number of accreditation schemes are available [20, 81, 82].

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