Purpose and Goal of the Task Force

Technologic advances in medicine have enabled physicians to perform less invasive procedures on their patients. A good example is stereotactic core-needle biopsy of the breast for nonpalpable mammographic lesions considered sufficiently suspicious for carcinoma to warrant biopsy. Ultrasound-guided and image-directed open surgical biopsies continue to be important approaches to the diagnosis of breast disease but are not the focus of this report.

Diagnostic radiologists, surgeons, and surgical pathologists must work together to achieve optimum patient outcome. Accordingly, a national task force

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was convened consisting of representa-
tives from the American College of Radi-
ology (ACR), the American College of
Surgeons, and the College of American
Pathologists to examine the issues sur-
rounding the technique of stereotactic
core-needle biopsy for occult mammo-
graphic lesions. A body of data suggests
the efficacy of this procedure. However,
the indications for diagnostic biopsy,
based on a careful assessment of level of
mammographic suspicion, should not be
altered simply because new technology is
available.

The task force submits the following
report, which includes a description of
the ACR Breast Imaging Reporting and
Data System (BI-RADS) as an introduc-
tion to the standardized terminology used
throughout the document. The report is
based on a comprehensive review of the
medical literature for the use of stereo-
tactic core-needle biopsy, including indi-
cations and contraindications, informed
consent, specimen handling, and manage-
ment of indeterminate, atypical, or dis-
cordant lesions. Also included are guide-
lines on the communication of results,
management and follow-up, quality as-
surance and quality improvement for
those involved in the performance of the
procedures, and proper equipment moni-
toring. It is anticipated that this report
will serve as an educational format for
both patients and physicians and promote
quality care.

| Category | Assessment                  | Description, Recommendation                                      |
|----------|-----------------------------|------------------------------------------------------------------|
| 1        | Negative                    | There is nothing to comment on. Routine screening.               |
| 2        | Benign finding              | A negative mammogram, but the interpreter may wish to describe a finding. Routine screening. |
| 3        | Probably benign finding     | A very high probability of benignity. Short interval follow-up suggested to establish stability. |
| 4        | Suspicious abnormality      | Not characteristic, but a definite probability of malignancy. Biopsy should be considered. |
| 5        | Highly suggestive of malignancy | A high probability of malignancy. Appropriate action should be taken. |

Adapted with permission from the American College of Radiology.
Breast Imaging Reporting and Data System

The American College of Radiology BI-RADS\(^1\) is the product of a collaborative effort among members of various committees of the American College of Radiology with the cooperation of the National Cancer Institute, the Centers for Disease Control and Prevention, the US Food and Drug Administration, the American Medical Association, the American College of Surgeons, and the College of American Pathologists. This standardized system will be used in this report to describe and categorize mammographic findings. In the past, a lack of uniformity in mammography terminology and reporting sometimes led to confusion as to whether lesions were likely to be benign or malignant and what the exact recommendations were for management. BI-RADS employs a standardized lexicon to bring uniformity to the description of mammographic findings. The examination is then categorized into one of five final assessment categories, and each of these categories is associated with one specific management recommendation (Table 1). These categories facilitate the tracking of patients to ensure that appropriate recommendations are carried out; the categorization also facilitates outcome analyses, such as the medical audit.

Summary of Relevant Literature

Screening mammography, performed at regular intervals, is the best method for early detection of breast cancer. Routine screening has reduced mortality from breast cancer. Unfortunately, the costs of the excisional biopsies generated during breast cancer screening projects may exceed the costs of the actual screening, and the majority of the biopsies yield benign results.\(^2\) The positive predictive value, defined here as the biopsy yield for malignancy, for biopsies generated by mammography in this country has been reported to range from 10 to 40%.\(^3,5\) A recent study of 50 community mammography facilities found an average biopsy yield for mammographic abnormalities of 21%.\(^6\) It has been estimated that 500,000 to 1,000,000 excisional breast biopsies are performed each year, which would translate to between 300,000 and 900,000 benign breast biopsies.\(^5\) Excessive biopsies for benign lesions have adverse effects on society and on the women who undergo them because they increase the costs of screening, cause morbidity and anxiety, and add to the barriers that keep women from using a potentially life-saving procedure.\(^7\)

In some institutions, particularly in Europe, fine-needle aspiration cytology (FNAC) has largely replaced excisional biopsy for the evaluation of mammographic abnormalities.\(^8\) In the United States, several problems have blocked the acceptance of FNAC for the evaluation of mammographically detected abnormalities, including the fact that it requires a skilled cytopathologist, the variability in the reported accuracy of the procedure, the high rates of insufficient sampling, and the medicolegal environment.\(^9,10\) The reported sensitivity of FNAC ranges from 68 to 100%, the specificity from 82 to 100%, and the rates of insufficient specimens from 2 to 36%.\(^10,11\) Even if sufficient specimens are obtained, a definitive diagnosis is not always possible.\(^12\) Another limitation of FNAC is its inabili-
Stereotactically guided core-needle biopsy (CNB) of the breast, which uses a large-bore needle, offers several advantages over FNAC. First, the interpretation can be rendered by pathologists who do not have special training in cytopathology. Next, it is rare for specimens to be insufficient. Third, it can usually differentiate intraductal from invasive carcinoma. Finally, CNB can characterize lesions more completely.

Imaging-guided CNB can be performed under stereotactic mammographic or ultrasonographic guidance. The method chosen to guide the biopsy depends on which modality best depicts the abnormality, the location of the abnormality within the breast, and the operator's experience.

Many reports in the medical literature document the sensitivity and specificity of stereotactically guided CNB (Table 2). Discrepancies in the published results may be caused by several factors, including basic definitions and methodology, case selection, gauge of the core biopsy needle used, and the number of specimens obtained. In general, better results have been reported when 14-gauge needles are used rather than smaller bore needles. Recent investigations have shown that five specimens reported with a 14-gauge needle achieve a 99% accuracy for masses, but it has been reported that 10 or more specimens may be required for stereotactically guided CNB of calcifications. Specimen radiography should be performed routinely for stereotactically guided CNBs of breast microcalcifications to determine whether calcifications have indeed been obtained and to direct the pathologist's evaluation of the tissue specimens.

One problem with stereotactically

| Year | Reference | Number of Cases | Number of Cancers | Sensitivity (%) | Specificity (%) |
|------|-----------|----------------|-------------------|----------------|----------------|
| 1991 | Dowlatshahi | 250            | 63                | 71             | 96             |
| 1992 | Dronkers  | 70             | 45                | 91             | 100            |
| 1993 | Elvecrog  | 100            | 36                | 97             | 100            |
| 1994 | Gisvold   | 160            | 67                | 85             | 100            |
| 1994 | Jackman   | 450            | 135               | 93             | 99             |
| 1994 | Mikhail   | 416            | 33                | 100            | 100            |
| 1994 | Janes     | 300            | 37                | 100            | 98             |
| 1991 | Parker    | 102            | 23                | 96             | 100            |
| 1996 | Brenner   | 230            | 143               | 96             | 96             |
| 1995 | Doyle     | 150            | 26                | 100            | 98             |
| 1995 | Israel    | 500            | 94                | 98             | 85             |
| 1996 | Meyer     | 388            | 62                | 98             | 100            |
guided CNB is that cancers may be missed during core-needle sampling, leading to a false-negative diagnosis. In one multi-institutional study, 5.4% of women who were diagnosed with a benign lesion by stereotactically guided CNB were found to have carcinoma at follow-up. Proponents of stereotactically guided CNB have argued that, although lesions are sometimes missed by stereotactically guided CNB, up to 20% of nonpalpable lesions can also be missed at the time of image-directed excisional biopsy. However, radiologists and surgeons experienced in excisional biopsies guided by needle-wire localization have reported that only 0.2 to 0.3% of lesions are missed. Furthermore, radiography of the excised specimen identifies the “misses” immediately so that they can be managed appropriately. On the other hand, the actual false-negative rate for stereotactically guided CNB is not known because most studies in the literature have not provided the rigorous long-term follow-up (at least 2 to 3 years) required to identify all false-negative diagnoses. In fact, the long-term follow-up of women diagnosed with a benign lesion is often an arduous process. One group of investigators reported that at 1 year after abnormal mammograms, only 71% of women complied with a recommendation for short-term follow-up.

Other problems with stereotactically guided CNB include the variability of results with the type of lesion being targeted, lack of standardized definitions and methods for study design, failure to identify invasion in approximately 20% of cases with a CNB diagnosis of ductal carcinoma in situ, and concern about displacement of epithelium and seeding of the needle track with tumor cells.

Cost-effectiveness issues have also been addressed in publications on stereotactically guided CNB of the breast. One article reported that a 50% reduction in the costs of biopsies for nonpalpable breast abnormalities had been achieved by the incorporation of stereotactically guided CNB into the authors’ practice. However, such cost savings can be achieved only if the threshold for biopsy of mammographic abnormalities is not significantly lowered with the use of stereotactically guided CNB. Lowering the threshold for recommending a biopsy increases the number of biopsies performed, and this could actually increase overall costs without detecting additional cancers. Several investigators have expressed concern that use of stereotactically guided CNB for probable benign findings, that is, those appropriately managed by 6-month follow-up mammography, could eradicate potential cost savings from the use of stereotactically guided CNB.

**Indications and Contraindications for Stereotactically Guided Core-Needle Breast Biopsy**

The indications and relative contraindications for stereotactically guided CNB depend on practice variations and the experience of the physician performing the biopsy. Stereotactically guided CNB can be performed on most nonpalpable, mammographically suspicious abnormal-
ities or on those highly suggestive of malignancy, for which open biopsy would be considered. Assessment of lesion characteristics such as size, radiographic density, multifocality, and precise location within the breast are important issues in planning the biopsy. The decision to perform needle biopsy, however, should not be made until a thorough imaging work-up has been completed and a breast physical examination has been performed. High-quality mammographic studies (including additional projections, spot compression, or magnification mammography) are essential for evaluation of nonpalpable breast abnormalities. Stereotactically guided CNB should not be a substitute for poor or inadequate imaging work-up. It is not uncommon for a patient to be referred for stereotactic needle biopsy of an abnormality “seen in one view only.” In almost every case, the abnormality can be

| Table 3 Abnormalities That Are Candidates for Stereotactically Guided Core-Needle Breast Biopsy |
| --- |
| 1. A solid, nonpalpable mass associated with: |
| (a) Irregular shape |
| (b) Spiculated or ill-defined margins |
| (c) Microlobulations |
| (d) Suspicious calcifications |
| (e) Associated findings, such as: |
| Focal skin thickening |
| Focal solitary dilated duct |
| 2. Microcalcifications with the following features: |
| (a) Morphology: varying size or shape (pleomorphic), fine linear, branching, or granular |
| (b) Distribution: clustered (grouped), linear, or regional |
| 3. An area of suspicious architectural distortion in a known prior biopsy site that demonstrates a suspicious interval change since a prior mammogram |
| 4. Asymmetry associated with suspicious calcifications, architectural distortion, a noncystic mass, a solitary dilated duct, or focal skin thickening |
| 5. Solid, circumscribed mass that is dominant (usually larger than 1 cm) or shows interval growth since a prior mammogram |
imaged on orthogonal views after careful mammographic evaluation. Likewise, an ultrasound evaluation is indicated for mass lesions that may represent breast cysts rather than solid abnormalities.

**Selection of Abnormalities**

Most significant mammographic abnormalities are suitable for needle biopsy (Table 3), with a few exceptions. Significant mammographic abnormalities can be divided into three basic categories: probably benign findings, suspicious abnormality, and highly suggestive of malignancy.

**Probably Benign Finding**

(Category 3)

The mammographic appearance of abnormalities in this category (see Table 1) suggests, but is not pathognomonic for, benignity. For the majority of findings in this category no prior mammogram exists for comparison. Therefore, for a high percentage of probably benign breast findings, a 6-month follow-up mammography is adequate. Stereotactically guided CNB may be indicated if the patient is anxious or has a strong family history of breast carcinoma, or when compliance with a recommendation for 6-month follow-up is unlikely.43,44

**Suspicious Abnormality**

(Category 4)

This is the category (see Table 1) in which stereotactically guided CNB is most useful. Stereotactically guided CNB of appropriate abnormalities in this category can differentiate those patients requiring

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**Table 4**

**Contraindications to Stereotactically Guided Core-Needle Biopsy**

| I. Lesions in the benign or probably benign category, such as: |
|---------------------------------------------------------------|
| A. Masses that:                                               |
| (1) Are circumscribed, of low density, and smaller than 1 cm unless changed since the prior mammogram |
| (2) Contain intralesional fat of a density that is pathognomonic for a lymph node, oil cyst, or hamartoma |
| (3) Are multiple, noncalcified, and circumscribed              |
| B. Microcalcifications that are:                              |
| (1) Tiny, round or oval, uniform, and in a localized cluster   |
| (2) In a discrete cluster (or clusters) suggestive of milk of calcium, secretory disease, or sclerosing adenosis |
| (3) Diffuse, nonclustered, and suggestive of milk of calcium, secretory disease, or sclerosing adenosis |

II. Unequivocal, palpable masses

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surgical management from those who can be managed using clinical and mammographic follow-up.

**HIGHLY SUGGESTIVE OF MALIGNANCY (CATEGORY 5)**

For patients with abnormalities in this category (see Table 1), stereotactically guided CNB can be used preoperatively to confirm diagnosis and expedite surgical planning and therapy.45,46 In some patients with abnormalities in this category, image-directed, open surgical biopsy is an appropriate option.

The mammographic abnormalities summarized in Table 3 represent lesions for which stereotactically guided CNB can be considered. These do not represent absolute indications; a physician’s judgement is also required.

**RELATIVE CONTRAINDICATIONS TO STEREOTACTICALLY GUIDED CORE-NEEDLE BIOPSY OF THE BREAST**

Not all patients with nonpalpable breast abnormalities are candidates for stereotactic biopsy (Table 4). Some patients may be too large to be accommodated by the stereotactic system, and the weight limit of a particular unit is an important consideration. The thickness of the breast must be adequate to allow the full throw of the automated biopsy device. For a typical 23-mm throw device, the breast should measure 42 mm in thickness. Some abnormalities in smaller breasts can be biopsied using a shorter throw device; however, the yield from such devices is often scanty, increasing the chances for a nondiagnostic result.47,48 Abnormalities just under the skin may pose technical problems because the tip of the needle is optimally placed 5 mm proximal to the center of an abnormality, with the cutting edge of the outer cannula outside of the skin nick before the sample is obtained. Some superficial abnormalities, if not visualized by ultrasound, may be best referred to surgical biopsy.

A vague asymmetric density or a diffuse group of widely separated calcifications may pose difficulties in generating useful coordinates for stereotactically guided CNB. When microcalcifications are not tightly clustered or when the sensitivity or resolution of the stereotactic imaging system is hampered so that individual microcalcifications are not well visualized, accurate localization and retrieval of microcalcifications within core biopsy specimens may be difficult.

Patient motion can invalidate localization data, especially if the motion occurs in the interval between obtaining the localization stereotactic image pair and placing the core biopsy needle. Patients who cannot remain prone or those who are unable to cooperate (for example, patients with heart failure, arthritis, or psychiatric disorders) for the duration of the procedure (20 to 40 minutes) are not suitable candidates. Cognitively impaired patients should be excluded only if they are unable to cooperate. Patients with a known bleeding disorder or those on anticoagulant therapy may not be suitable for this procedure. A nonpalpable lesion in a woman with a breast implant should provide...

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**Composited stereotactically guided core-needle biopsy results are analyzed by a comparison of stereotactically guided core-needle biopsy results with outcome data, a process that evaluates the overall effectiveness of the procedure.**
be investigated by the most appropriate biopsy approach.

Physicians performing stereotactically guided CNB on small lesions should be cautious about totally removing the lesion. If there are no surrounding landmarks to mark the site of the lesion and if re-excision is necessary, a larger volume of tissue may need to be excised than would have been necessary if the lesion remained in place and was surgically excised. This can result in deformity of the breast contour and scarring that make later interpretation of the mammogram difficult. Because postbiopsy changes on the mammogram can be minimal or resolve quickly, they should not be relied upon as landmarks for needle localization to be performed at a later date.

Informed Consent

As is the case for any invasive medical procedure, the patient’s written informed consent is required before stereotactically guided CNB can be performed. The patient must be informed of the alternative method of diagnosis (image-directed open surgical biopsy) as well as the advantages, potential complications, and limitations of stereotactically guided CNB. The patient should also be informed that minor morbidity is common and consists of local pain and mild bruising, which may require limitation of activity for about a day. Fewer than 1% of women undergoing stereotactic biopsy are reported to have had an infection requiring antibiotics or a hematoma requiring surgical drainage.

The patient should be informed that a significant limitation of stereotactically guided CNB is the possible need for a repeat biopsy. Repeat biopsy may be required because of (1) lack of concordance between the radiographic and histologic diagnoses, (2) inability to demonstrate calcifications in the specimen when suspicious calcifications prompted the biopsy, and (3) histologic diagnoses that require wider excision to confidently exclude malignancy.

The informed consent should be documented in writing, and a copy should be maintained with the patient’s official records. Practitioners should consult state law for any additional requirements.

Specimen Handling and Reporting

Stereotactically guided CNB of the breast is usually performed for nonpalpable lesions and results in a specimen significantly smaller than that obtained by the traditional excisional breast biopsy. Although the handling of these specimens must comply with standard practice for breast biopsies in general, several issues are particularly important with this type of specimen.

Handling of Tissue at the Time of Biopsy

Fresh biopsy cores can be placed initially in sterile saline until the procedure is completed or be placed in standard fixative. Simple visual examination of the cores may help determine when enough cores have been obtained. Specimens that have been placed in sterile saline should be submitted to the pathology laboratory in a standard fixative (for example, 10% neutral buffered formalin) for routine processing. For samples from a solitary lesion, the cores may be submitted in one specimen container and subsequently embedded in a single paraffin block. If more than one mammographic lesion is sampled, cores from each lesion must be submitted separately and clearly identified. Complete identifying information should be included for each lesion.

Any biopsy performed because of the detection of microcalcifications should be examined by specimen radiography to verify that the calcifications have been sampled. If calcifications are present in only one or two cores, these can be submitted separately to facilitate prepa-
ration of multiple sections from the paraffin block. To optimize histologic-radiographic correlation, it is important for the pathologist to have appropriate information about the number or type of calcifications present in the specimen as well as clinical information and specimen radiographs.58

Frozen section preparations of tissue obtained from nonpalpable microcalcifications are strongly discouraged.53,57,59 Lesions such as atypical ductal hyperplasia, radial scar, and complex papillary proliferations may be difficult to interpret in frozen section preparations, and small foci of ductal carcinoma in situ or microinvasive carcinoma may be lost or rendered uninterpretable by freezing artifact. In general, frozen sections should be prepared only when there is sufficient tissue that the final diagnosis will not be compromised and when the information is necessary for immediate therapeutic decisions. Touch preparations for immediate cytologic evaluation can be made to avoid unnecessary frozen sections and may provide information on specimen adequacy, particularly when suspicious lesions are sampled.

**CLINICAL INFORMATION**

Detailed clinical and mammographic information should be available to the pathologist and should be included in the final pathology report, if possible. The following data should be provided with each biopsy:

1. The location of the lesion (e.g., laterality and quadrant of the breast)
2. The type of lesion (e.g., spiculated mass, circumscribed nodule, or cluster of microcalcifications)
3. The size of the lesion as estimated on the mammogram
4. A mammographic differential diagnosis

Other relevant information, such as past medical history and family history, should be included as appropriate. The radiographic description (not just the numerical category shown in Table 1) may be useful if the pathologist is familiar with the system.

**HISTOLOGIC EVALUATION**

The goal of microscopic evaluation is to determine the presence or absence of cancer. The pathologist must often examine multiple levels through the tissue block to accomplish this goal and to avoid missing small but significant lesions. Some tissue may be preserved in the paraffin block for additional studies (for example, special stains, hormone receptors, and so forth), but a definitive histologic diagnosis is the highest priority and takes precedence over ancillary tests.

An accurate and complete description of the histologic features should be provided to facilitate correlation with the imaging and clinical findings. It is important to identify the lesion for which the biopsy was performed; thus, a specific histologic diagnosis should be reported whenever possible. Reporting a lesion that may require repeat biopsy or surgical excision, such as atypical ductal hyperplasia,21 is particularly important.

When the biopsy is performed for microcalcifications, their presence must be confirmed microscopically. If calcifications are identified in the specimen radiograph but not identified in the initial histologic sections, deeper levels should be examined. If needed, the paraffin block may be radiographed to determine whether calcifications remain in the block. In some cases, mammographic calcifications are caused by calcium oxalate crystals, which are colorless in routinely stained tissue sections and may be overlooked; these refractile crystals are easily detectable using polarized light microscopy.57 The location of calcifications should also be included in the pathology report (e.g., within ductal carcinoma in situ, in benign lobules adjacent to ductal carcinoma in situ, in calcified blood ves-
sels, and so forth).

The following features should be clearly identified in the pathology report when there is sufficient tissue:

For invasive cancer:
1. The histologic type and the presence of any special types
2. The presence or absence of coexistent ductal carcinoma in situ
3. Blood vessel and/or lymphatic vessel invasion

For ductal carcinoma in situ:
1. The architectural type (e.g., comedo, cribriform, and so forth)
2. Nuclear grade (that is, low, intermediate, or high)

Another histologic feature that may be included in the pathology report when sufficient tissue is present for evaluation is the grade of invasive cancer.51,52

**ANCILLARY STUDIES**

Estrogen and progesterone receptor analyses and other ancillary studies can be done on formalin-fixed cores if sufficient tissue remains in the paraffin block. Hormone receptor analysis by immunohistochemistry is replacing the traditional cytosol assay performed on frozen tissue.60-62 DNA analysis can be performed on paraffin-embedded tissue by either flow cytometry or image analysis; the latter is usually preferred when the quantity of tissue is limited, such as in needle biopsies. For nonpalpable lesions sampled by stereotactically guided CNB, submission of a random core of tissue directly for receptor analysis or flow cytometry is not appropriate because it may compromise the pathologist’s ability to make an accurate histologic diagnosis.

When either hormone receptor or DNA analysis is performed on needle biopsy specimens, the possibility of sampling error exists when only a small quantity of tumor is present. Shortcomings in the use of immunohistochemistry in formalin-fixed tissue include variable antigenic loss from fixation and tissue processing as well as intratumoral antigenic heterogeneity.63 Positive staining of tumor cell nuclei is a reliable indicator of the presence of receptors, but negative immunostains in small biopsies need to be interpreted with caution, particularly when only a small quantity of tumor is present in the paraffin block. Correlating the results of receptor analysis and ploidy analysis with the histologic findings is particularly important in such cases.

**LESIONS REQUIRING REPEAT BIOPSY**

The results of stereotactically guided CNB should always be correlated with all available data about the patient in the making of a final diagnosis. Definitive diagnosis can be made by histopathologic interpretation of tissue obtained by large-core stereotactically guided breast biopsy in 80 to 97% of cases.19-21,31,34,49,64 The remaining patients require further biopsy. To minimize the likelihood of missing a carcinoma in a patient undergoing stereotactically guided CNB, physicians performing this procedure must understand the indications for wider, surgical tissue sampling or repeat stereotactically guided CNB. Occasionally, the pathologist will not be able to make a definitive diagnosis because of the small volume of tissue excised; this should be communicated in the pathology report with a request that a larger volume of tissue be obtained. Such a report should result in the patient undergoing surgical biopsy.

**LESIONS REQUIRING WIDER, SURGICAL EXCISION**

Certain benign lesions have a relatively high incidence of coexistent carcinoma, and the small volume of tissue obtained at stereotactically guided CNB may not be adequate to exclude coexistent malignancy. Atypical ductal hyperplasia is the most commonly encountered of these lesions. Several investigators have found that on surgical excision, carcinoma is
present near the site of the stereotactically guided CNB in 50% of patients with atypical ductal hyperlasia. This diagnosis at stereotactic core biopsy should, therefore, be followed by surgical excision of the area.

Likewise, radial scar has been found by some investigators to have coexistent carcinoma present in 20% of cases. A stereotactically guided CNB diagnosis of radial scar, therefore, requires wider, surgical excision to assess the possibility of coexistent carcinoma.

**INDETERMINATE HISTOPATHOLOGY**

The small volume of tissue obtained at stereotactically guided CNB may limit the pathologist’s ability to make a definitive determination of the histopathology of some other, less common breast lesions. The most frequently encountered example of this problem is the inability to differentiate a phyllodes tumor from a fibroadenoma. This situation can also arise, however, with other, more unusual lesions such as breast sarcomas. When this is the case, the pathologist should recommend a wider surgical excision, which should be done for definitive diagnosis.

**HISTOPATHOLOGIC DIAGNOSIS NOT CONCORDANT WITH IMAGING FINDINGS**

In some cases, tissue from the lesion in question will not be obtained at the time of stereotactically guided CNB. The fail-

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**Table 5**

**Benign Breast Disease and Relative Risk for Subsequent Invasive Breast Cancer**

| Category I: | No increase in risk |
|------------|---------------------|
| Cysts, micro or macro |
| Duct ectasis |
| Fibroadenoma |
| Mild epithelial hyperplasia |
| Mild sclerosing adenosis |
| Fibrosis |
| Mastitis |
| Metaplasia, squamous or apocrine |

| Category II: | Slight (1.5- to 2.0-fold) increase in risk |
|-------------|------------------------------------------|
| Florid sclerosing adenosis |
| Moderate or florid ductal hyperplasia |
| Papilloma with fibrovascular core |

| Category III: | Moderate (4- to 5-fold) increase in risk |
|---------------|------------------------------------------|
| Atypical hyperplasia, lobular or ductal |

| Category IV: | High (8- to 10-fold) increase in risk |
|--------------|---------------------------------------|
| Lobular carcinoma in situ |
| Ductal carcinoma in situ |

Data from Hutter and Kamel et al.
ure to obtain tissue from the suspicious lesion may not be evident at the time of the procedure; instead, it may be apparent only when the histopathologic results are compared with the imaging findings. Once the pathology report is available, the physician who performed the stereotactically guided CNB should review the imaging work-up to determine if the pathology results are concordant with the imaging characteristics. Nonconcordance of the pathology results with the differential diagnosis for the imaging findings suggests that the lesion was not successfully biopsied and that repeat biopsy of the lesion is necessary. This can be performed as a repeat stereotactically guided CNB or as a surgical biopsy. In one series of repeat biopsies performed because of nonconcordance, carcinoma was found in 47% of cases.50

A diagnosis of lobular carcinoma in situ should not be accepted as consistent with imaging findings requiring biopsy. This entity has no characteristic mammographic findings, and so a stereotactically guided CNB diagnosis of lobular carcinoma in situ without a second lesion being identified should be considered nondiagnostic for a suspicious lesion seen on mammography. In this setting, repeat biopsy may be required.

Communication of Results, Management, and Follow-Up

COMMUNICATION OF RESULTS

The performance of a stereotactically guided CNB carries with it the obligation to inform the patient of the results of the biopsy and the potential implication of these results. For biopsies that show invasive carcinoma, this would include being certain that the patient is informed about her treatment options, including breast conservation therapy and modified radical mastectomy, alone or with reconstruction. For carcinoma in situ, it would include a discussion of breast conservation surgery with or without radiation therapy, total mastectomy, and mastectomy with reconstruction. Unless the physician performing the biopsy has training and experience in the selection of local therapy for breast cancer, specific recommendations should be avoided.

When a stereotactically guided CNB shows benign pathology, the patient should be advised of any change in her risk status and of follow-up monitoring necessitated by the biopsy. A standard classification of risk on the basis of histology has been adopted by the College of American Pathologists (Table 5).67,68 However, a meaningful discussion of risk requires a complete medical history to evaluate multiple factors that contribute to an individual’s risk.69 In addition, the use of relative risk in discussion with patients is frequently not helpful because they have a limited understanding of their baseline level of risk. Although patients with category 2 lesions have a statistically significant increase in relative risk, in the absence of other risk factors, this increase is usually not clinically meaningful. Risk estimates are best discussed with patients as an absolute risk over a defined time interval. Evaluation by a physician experienced in risk assessment is particularly important for the patient with a final diagnosis of atypical hyperplasia or lobular carcinoma in situ.

MANAGEMENT

Stereotactically guided CNB is a diagnostic and not a therapeutic procedure. Even if the mammographic target is removed, the potential for a significant amount of residual tumor in the breast exists, as demonstrated by the detailed tumor mapping studies reported by Holland et al.70-72 The use of automated breast tissue excisional devices to remove tumors is an investigational procedure. This procedure should be performed only as part of an
approved study protocol until important questions regarding tumor measurement, assessment of margin status, and long-term local control rates after breast conservation surgery are answered.

FOLLOW-UP

The timely diagnosis of carcinoma after a false-negative stereotactically guided CNB depends on patient compliance with recommendations for follow-up mammography. Although the specific follow-up protocol may differ based on the morphology of the lesion, the histologic diagnosis obtained, and the physician’s experience with the stereotactically guided CNB technique, a system must be in place to inform the patient and her referring physician of the appropriate follow-up and to monitor compliance with follow-up recommendations. Reports of follow-up compliance after stereotactically guided CNB at 2 years indicate compliance rates of 46 to 95%.73-75 Awareness of risk status

| Table 6: Medical Physicist’s Annual Quality Control Tests |
|----------------------------------------------------------|
| **Stereotactic Unit Assembly** | Performed to ensure that the mechanical components of the system are reliable and safe for patient use |
| **Evaluation of Focal Spot Performance** | Performed to ensure that the focal spot is sufficiently small to minimize the geometric blur in the image |
| **kVp Accuracy/Reproducibility** | Performed to ensure that the indicated peak x-ray energy is accurate and reproducible, so that consistent contrast may be maintained |
| **Beam Quality Assessment (Half-Value Layer Measurement)** | Performed to ensure that the x-ray beam is sufficiently penetrating to minimize patient dose but not so penetrating that contrast is reduced |
| **Exposure Reproducibility** | Performed to ensure the performance capability and consistency of the imaging system |
| **Breast Entrance Exposure, Average Glandular Dose** | Performed to ensure that breast radiation doses are adequately low to protect the patient but sufficient to maintain adequate image quality |
| **Image Quality Evaluation** | Performed to ensure that image quality is consistently high enough to meet the demands of the procedure |
| **Artifact Evaluation** | Performed to detect the presence of artifacts, isolate their sources, and ensure that they are eliminated or minimized |
| **Digital Field Uniformity** | Performed to ensure field uniformity of digital image receptors so that abnormalities can be visualized without interference from the imaging system |
| **Localization Simulation (Gelatin Phantom) Test** | Performed to ensure the accuracy of the localization system, including needle position, stereo position calculations, and user interface |
has been shown to affect compliance with physician recommendations for screening mammography, further emphasizing the importance of a detailed communication with both the patient and her referring physician about the meaning of a benign stereotactically guided CNB.

Equipment and Quality Control

Equipment
Radiographic equipment that can be used for stereotactically guided percutaneous breast interventional procedures includes prone stereotactic units and add-on stereotactic devices for dedicated mammographic units.

The equipment should be calibrated by the manufacturer at the time of installation. Verification of calibration and acceptance testing should be completed by a qualified medical physicist before use.

Quality Control
A documented quality control program with procedure manuals and records should be maintained for stereotactically guided preoperative localizations, fine-needle aspirations, and stereotactically guided CNBs. The quality improvement/quality control program should include regular meetings of the entire team, including the physician, the radiologic technologist, and the medical physicist. Table 6 shows the quality control tests that the medical physicist should perform annually. The radiologic technologist’s quality control tests are shown in Table 7.

Quality Assurance and Quality Improvement
The quality control procedures listed in the previous section involve the more technical aspects of the stereotactically guided CNB procedure. Additional quality assurance activities are needed to ensure the accuracy and appropriateness of

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Table 7
Radiologic Technologist’s Quality Control Tests

| Test                                      | Description                                                                 |
|-------------------------------------------|-----------------------------------------------------------------------------|
| Localization Accuracy                     | Performed daily before the system is used on a patient to verify system alignment and performance. The test procedure varies with manufacturer and system type. Users should follow the manufacturer’s recommendation for which type of system alignment and performance to use on their systems. |
| Visual Checklist                          | Performed weekly to ensure that the mammography x-ray system and, if applicable, the digital imaging system are working properly and that the mechanical rigidity and stability of the system are optimal. |
| Phantom Image                             | Performed weekly to ensure that the film density, contrast, uniformity, and image quality of the x-ray imaging system are optimal. |
| Compression Force                         | Performed semi-annually to ensure that the x-ray imaging system can provide adequate compression in the manual and automatic powered mode. |
| Film Processor                            | Performed daily to ensure consistent performance of the film processor. |
the procedures performed. For stereotactically guided CNB, these activities include an imaging-pathology correlation for each biopsy done (see the section on specimen handling and reporting), ongoing analyses of composited stereotactically guided CNB results, and periodic review of the utilization of the procedure. These activities should also serve as quality improvement instruments for the personnel who perform stereotactically guided CNB.

**ANALYSES OF COMPOSITED STEREOTACTICALLY GUIDED CORE-NEEDLE BIOPSY RESULTS**

Composited stereotactically guided CNB results are analyzed by comparison of the stereotactically guided CNB diagnoses with outcome data. The outcome is determined by surgical excision or clinical and imaging follow-up. This process provides a method to evaluate both the overall effectiveness of the procedure and the performance of individual physicians performing the procedure. Records should be kept on every stereotactically guided CNB performed. These records should document patient identification, physician performing the procedure, pathology diagnosis, concordance with imaging assessment, inadequate sampling, management recommendations, and outcome. Any complications that occurred should also be documented.

For evaluating the effectiveness of the procedure, each biopsy is placed in one of four categories: true positive, false positive, true negative, or false negative (Fig. 1). If the stereotactically guided CNB diagnosis is carcinoma and surgical excision confirms this, the case is a true positive. Since a tiny lesion could be completely removed by stereotactically guided CNB, the original...
stereotactically guided CNB specimens should be reviewed before a case is categorized as false positive. In addition, imaging may have to be repeated to verify that the suspicious abnormality was removed at the time of the excisional biopsy. If the stereotactically guided CNB diagnosis is benign but a carcinoma is detected at that location within an established time interval (usually 2 years), the diagnosis is considered a false negative. Statistics on the stereotactically guided CNB procedures are calculated using the following formula:

Sensitivity = true positives ÷ (true positives + false negatives)

The true-negative and false-negative rates are determined by follow-up of benign cases for at least 2 years. Specificity is calculated with the following formula:

Specificity = true negatives ÷ (true negatives + false positives)

The positive predictive value (PPV), or biopsy yield of malignancy, should also be calculated for CNB with the following formula:

PPV = number of cancers diagnosed ÷ number of biopsies performed

In addition to the analysis of stereotactically guided CNB results for the diagnosis of cancer, data should be maintained on the success of the histologic evaluation for all of the imaging abnormalities that are sampled, benign or malignant. For example, if a fibroadenoma is suspected based on imaging, a stereotactically guided CNB diagnosis of fatty tissue would be discordant and deemed inadequate; a repeat biopsy would be required. The analyses should include the overall rate of repeat biopsies and the individual rates of repeat biopsy for inadequate sampling, discordance with imaging findings, and specific lesions such as atypical ductal hyperplasia and radial scar.

As a quality assurance and improvement activity, the data for the stereotactically guided CNB procedure can be evaluated for the practice as a whole and for individual physicians. The data can then be compared with reports in the literature or other defined goals.

**Utilization Review**

Utilization review is an assessment of the appropriateness of the stereotactically guided CNBs performed. The PPV, also referred to as the biopsy yield of malignancy or the positive biopsy rate, is an important indicator as to the appropriateness of the procedures. The PPV for the biopsies performed is calculated by dividing the number of cancers detected by the number of biopsies performed. Reasonable goals for the PPV for the biopsy of nonpalpable abnormalities have been published in the literature. Many experienced physicians believe that if a thorough imaging work-up has been performed, the PPV for biopsies of nonpalpable abnormalities should range from 25 to 40%. This number is derived from all women referred for biopsy on the basis of screening mammograms, not only those biopsied using stereotactically guided CNB.

One of the major advantages of stereotactically guided CNB is a reduction in the cost of biopsies performed for benign abnormalities. However, if the overall PPV decreases significantly after the introduction of stereotactically guided CNB in a practice, overall costs for breast biopsies may actually increase. Lowering the biopsy threshold to include probably benign findings would significantly increase the number of biopsies performed, yield very few additional carcinomas, and possibly eliminate the economic advantages of stereotactically guided CNB. Since only about 1% of the abnormalities in the probably benign final assessment category represent malignancy, this group of imaging abnormalities is managed most appropriately with short-term imaging follow-up. In some practices, stereotactically guided CNB tends to be limited to abnormalities with
the lowest likelihood of malignancy, whereas excisional biopsy preceded by needle-wire localization is performed in those patients with abnormalities having a higher likelihood of malignancy. Therefore, to determine whether the threshold for biopsy has been inappropriately lowered after the introduction of stereotactically guided CNB, an overall PPV should be calculated. The overall PPV should include all biopsies performed for nonpalpable abnormalities, including stereotactically guided CNBs and excisional biopsies.

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