# Breast biopsy

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## INTRODUCTION

For patients with a suspicious abnormality on breast imaging or a suspicious palpable breast mass, the initial diagnostic technique is percutaneous biopsy. Surgical biopsy should generally be used only if percutaneous palpation-guided or image-guided biopsy is not feasible [1].

The types and choices of methods for breast biopsy, the postprocedural care, and follow-up, including the review of biopsy results and the potential need for rebiopsy, are described here. The clinical scenarios that may lead to a biopsy, such as the clinical features and diagnosis of a breast mass and screening for breast cancer, are discussed elsewhere. (See "Clinical manifestations, differential diagnosis, and clinical evaluation of a palpable breast mass" and "Screening for breast cancer: Strategies and recommendations".)

The treatment of specific breast diagnoses identified through breast biopsy (eg, invasive ductal carcinoma, ductal carcinoma in situ) is discussed in a specific topic review. (See "Overview of the treatment of newly diagnosed, invasive, non-metastatic breast cancer".)

## PREPROCEDURE IMAGING EVALUATION

Breast lesions that raise concern for cancer are usually detected on physical exam (eg, palpable mass) or on imaging (eg, screening mammography).

**Breast Imaging-Reporting and Data System (BI-RADS) categorization —** An imaging evaluation, usually with mammography, breast ultrasound (US), or both, precedes biopsy

( algorithm 1). Imaging serves to select the lesion(s) that should undergo biopsy and to plan the biopsy method and approach. Abnormalities are categorized on imaging based upon their likelihood of cancer according to the Breast Imaging-Reporting and Data System (BI-RADS) ( table 1). (See "Breast imaging for cancer screening: Mammography and ultrasonography" and "Clinical manifestations, differential diagnosis, and clinical evaluation of a palpable breast mass".)

Practice guidelines recommend biopsy for all BI-RADS 4 and 5 lesions. If there are clinical factors (eg, age, comorbidities, etc) for which the patient, in consultation with the clinician, chooses to defer biopsy, the reasoning should be documented in the medical record. It should be noted that BI-RADS 4 spans a wide range of risk from 3 to 95 percent and includes risk for either ductal carcinoma in situ (DCIS) or invasive cancer. BI-RADS 4A is a low risk category (<10 percent risk).

**Palpable breast lesions** — For palpable breast lesions, diagnostic breast imaging is still mandatory and should always precede biopsy [2]. Correlation between imaging and the palpable area of concern is essential and involves radiopaque skin markers on mammography and patient and radiologist input during imaging for breast ultrasound.

In contemporary practice, most palpable lesions deemed suspicious on diagnostic imaging are biopsied with imaging guidance. However, biopsy under palpation guidance without imaging can be performed at select sites where the necessary proceduralist and on-site cytopathologist expertise is available. (See 'Fine needle aspiration' below.)

**Lesions seen on mammography** — For mammographic abnormalities, core needle biopsy (CNB) under imaging guidance has largely replaced surgical excision following wire localization as the former is better tolerated and less invasive [1,3,4]. For lesions detected on screening mammography, diagnostic mammography is performed to better characterize the lesion and to define the biopsy approach. Breast US is also performed to determine whether the mammographic abnormality is seen and amenable to US-guided CNB. If the abnormality on mammography consists of microcalcifications alone without a mass, US may not be required, as stereotactic or tomosynthesis CNB, which like mammography involves x-ray imaging, would be the standard biopsy approach. An image-guided biopsy should include placement of a marker clip for post-biopsy management.

**Lesions seen on ultrasound** — US is used to evaluate mass abnormalities detected on palpation, mammography, or magnetic resonance imaging (MRI). In addition, some abnormalities are detected primarily on US as this modality is used as an adjunct to mammography for breast cancer screening (see "Breast imaging for cancer screening: Mammography and ultrasonography", section on 'Role of ultrasound' and "Breast density and screening for breast cancer", section on 'Whole-breast ultrasound screening'). Biopsy using US guidance is preferred over other imaging modalities when feasible as the

procedure is well tolerated by the patient, enables real-time visualization of where the lesion is sampled, and allows for placement of a marker clip for postbiopsy management.

**Lesions seen on magnetic resonance imaging —** Breast lesions are detected on MRI in patients undergoing cancer screening or those with breast cancer undergoing treatment planning or follow-up. If a lesion occult on mammography is detected on MRI, the patient may undergo US to determine whether the lesion is amenable to US-guided CNB [5-9]. US-guided CNB is usually preferred over an MRI-guided biopsy when feasible as the latter procedure is not available at some sites and is more resource intensive. Lesions not visible on US are biopsied under MRI guidance at sites with the necessary resources and expertise. It is important to verify on follow-up MRI that the lesion sampled under US or MRI guidance does indeed correlate with the original MRI finding [10,11].

## PATIENT PREPARATION

**Sedation and anesthesia —** Most breast biopsy procedures are performed under local anesthesia with the patient awake. Core needle biopsy (CNB) takes multiple samples, sometimes a significant amount of tissue, but in small pieces, and is performed as an outpatient clinic procedure. Sedation is not generally needed for CNB, but referring clinicians may provide short-acting anxiolytics to some patients. Because surgical biopsy removes more tissue as a single specimen, conscious sedation or general anesthesia may be needed for patients undergoing a surgical biopsy (incisional or excisional).

**Coagulation issues —** For patients undergoing CNB, we prefer to interrupt anticoagulation if possible. If it is not feasible to interrupt anticoagulation, we will proceed with CNB or perform fine needle aspiration (FNA) instead of CNB. Alternatively, open biopsy can be performed, where bleeding can be directly controlled. (See "Perioperative management of patients receiving anticoagulants" and 'Biopsy methods' below.)

Experts differ in their approach to anticoagulation [12-14]. In the past, the usual practice was to interrupt anticoagulation therapy before breast biopsy. Contemporary studies noted that clinically significant hematomas were uncommon after imaging-guided core needle biopsy, and thus withholding antithrombotic medications before core needle biopsy may not be necessary [15]. The American College of Radiology guidelines recommend that practitioners decide whether anticoagulation cessation is necessary on a case-by-case basis [16-18]. The Society of Interventional Radiology guidelines for patients undergoing imaging-guided interventions state that radiologists should consider patient factors and the bleeding risk associated with the procedure [19]. Withholding antithrombotic therapy prior to core needle biopsy may be unnecessary in most patients; however, practitioners should exercise caution when performing percutaneous biopsies in patients who are taking full-dose antiplatelet medications, in older patients, or when the radiologist plans to use a 9-gauge or larger

biopsy device [20]. Current practice varies among breast imagers, and further study and experience is needed regarding this important topic.

For patients receiving anticoagulation, communication between the radiologist performing the biopsy and the clinician managing the underlying condition requiring anticoagulation is important to safely and successfully manage both pre- and postprocedure care. Unless the patient is on anticoagulation therapy, preprocedure laboratory testing is not necessary before needle biopsy.

**Clinical trial-related issues** — Many centers can offer women the opportunity to participate in clinical trials, some of which require tissue from percutaneous core biopsy for participation. Generally, tissue sampling follows the research study protocol, which typically specifies the timing of sampling and how the samples should be processed (eg, stored in formalin and/or saline, transport, etc). Coordination of tissue collection for research at the time of diagnostic biopsy can spare patients a second biopsy for research; however, this does require established procedures for tissue banking without a tissue diagnosis. Thus, if such protocols are in place, this is the preferred approach, especially for the larger Breast Imaging-Reporting and Data System (BI-RADS) 5 lesions where neoadjuvant therapy will be considered.

## BIOPSY METHODS

Breast biopsy methods include core needle biopsy (CNB), fine needle aspiration (FNA), surgical biopsy, and skin punch biopsy.

**Choice of initial biopsy method** — CNB is the preferred initial approach for most scenarios. With lesions likely to be cellular and malignant (eg, invasive ductal carcinoma), FNA with intraprocedural cytopathology is an alternative as it may expedite patient management. Surgical biopsy is not used as the initial biopsy method unless percutaneous needle biopsy is not feasible or available, but it may be required to further investigate discordant or inconclusive results of percutaneous biopsies [1]. (See 'Reviewing results' below.)

Based on the prebiopsy imaging, the radiologist makes an assessment of which approach will yield the highest likelihood of success, while considering patient safety and comfort. The imaging findings are correlated with the clinical exam to determine whether the chosen biopsy target(s) account for the clinical abnormality. The requirements of subsequent therapy and/or clinical trial (eg, marker clip placement, tissue banking) are additional factors that are included in biopsy planning.

The choice of imaging guidance depends upon the modality on which the lesion is best visualized and whether it is palpable. Patient factors such as tolerance for positioning (eg,

prone position is usually needed for stereotactic or magnetic resonance imaging [MRI] guidance) are also considered.

**Core needle biopsy —** CNB is preferred as the initial biopsy procedure as it is minimally invasive and still likely to acquire sufficient tissue to adequately sample the intended target.

A small skin incision is made through which the core biopsy needle (typically 9 to 14 gauge [approximately 2.1 mm outer diameter]) is introduced. The shortest path to the lesion is typically chosen. Patient safety (eg, staying parallel to the chest wall to avoid pneumothorax) is another important factor in the approach. CNB is typically performed under local anesthesia.

In a meta-analysis, CNB under ultrasound (US) or stereotactic guidance demonstrated a sensitivity of 87 percent (95% CI 84 to 88 percent) and specificity of 98 percent (95% CI 96 to 99 percent) [21].

Careful radiologic-pathologic correlation is required to ensure that the pathologic diagnoses are concordant with the imaging findings (see 'Reviewing results' below). When targeting calcifications, specimen radiography should be performed. (See 'Handling the specimen' below.)

**Image guidance —** CNB is performed under image guidance with either US, x-ray (ie, stereotactic or tomosynthesis), or MRI without and with intravenous contrast. US guidance is preferred if the target lesion is well visualized with this modality. Stereotactic or tomosynthesis biopsy is performed for mammographic abnormalities without a clear US correlate. MRI-guided biopsy is available at some sites for lesions seen only on MRI ( algorithm 1).

**Ultrasound —** US-guided CNB is usually better tolerated than stereotactic or MRI-guided biopsies as the patient is lying supine during the procedure and does not require breast compression. However, the use of US guidance requires that the lesion is well visualized with US and that there is confidence that the US finding correlates with the target lesion detected on palpation, mammography, or MRI.

**Stereotactic —** For mammographic abnormalities not well visualized on US, stereotactic CNB is performed. The patient is upright or prone during the procedure, depending on the machine, and the biopsy needle is positioned under x-ray guidance. Breast compression during the procedure is required.

While the majority of mammographic lesions can be biopsied using the stereotactic technique, some lesions (eg, lesions close to the nipple or chest wall, very faint calcifications) are not amenable to this approach. Mammographic lesions not amenable to stereotactic

biopsy may undergo a localization procedure for surgical excision. (See 'Surgical biopsy' below.)

**Tomosynthesis —** For patients with an abnormality seen only on breast tomosynthesis (also known as "three-dimensional [3D] mammography"), tomosynthesis-guided biopsy can be performed. The necessary technology and expertise are available at some sites. The patient is in the upright or decubitus position, and breast compression is required during the procedure. Tomosynthesis guidance may also be used for any lesions amenable to stereotactic core biopsy. (See "Breast imaging for cancer screening: Mammography and ultrasonography", section on 'Digital breast tomosynthesis (DBT)'.)

**Magnetic resonance imaging —** Some patients will have nonpalpable lesions only seen on MRI. MRI-guided biopsy may not be available at every site, but each facility performing breast MRI should have a service available to refer a patient for an MRI-guided biopsy [22].

MRI-guided biopsy is performed with the patient prone and with the breast under compression. Intravenous gadolinium is administered to visualize the abnormality. Once adequate needle placement is confirmed, CNB samples are acquired with an MRI-safe vacuum-assisted biopsy device (VAB) [23-29]. (See 'Vacuum assistance' below.)

A single-center series of 557 MRI-guided CNBs demonstrated a sensitivity of 80 percent (95% CI 72 to 86 percent) and specificity of 92 percent (95% CI 90 to 93 percent) [30].

MRI-guided wire localization and surgical excision may be indicated if a suspicious lesion is not accessible to MRI-guided VAB and can only be visualized on MRI [24,31,32]. For discordant MRI-guided biopsy results, a biopsy clip may be localized under mammographic guidance for surgical excision. (See 'Reviewing results' below.)

**Vacuum assistance —** VAB is an option for CNB under any imaging guidance.

Use of a VAB device increases the volume of tissue that can be obtained quickly and may decrease the false negative rate for tumor detection [33-35]. In a series of 942 consecutive breast CNBs performed at one institution (342 without image guidance, 241 with US guidance, and 369 using a stereotactic VAB) [36], the false negative rate with 11-gauge stereotactic VAB was 3 percent, compared with 13 percent for non-image-guided and 5 percent for US-guided procedures [36]. Others report false negative rates as low as 0.45 percent with 11-gauge VAB [37-40].

Vacuum-assisted devices are available in different needle sizes, with the 9 gauge most commonly used for stereotactic and MRI-guided biopsies. Using a larger-diameter device will yield a larger volume of tissue, and fewer cores are needed for a diagnostic sample. For example, the 8-gauge VAB device yields approximately 245 to 310 mg of tissue per core

compared with the 11-gauge device, which yields 83 to 116 mg of tissue per core. When larger-bore needles are used, fewer cores should be taken to reduce the chance of hematoma, which can complicate surgical removal. If the lesion is a cancer, the diagnostic biopsy is meant to yield a diagnosis and not a complete excision.

VAB enables efficient collection of multiple samples in a rotational fashion with a single insertion of the biopsy device. Vacuum assistance is also suited for MRI-guided biopsies, where target lesion visualization is transient during uptake and washout of intravenous contrast, making speed of sampling a higher priority. (See 'Magnetic resonance imaging' above.)

For US-guided procedures, spring-loaded CNB is a lower-cost alternative to VAB devices. Spring-loaded devices are typically 12 to 14 gauge, self-contained, and light in weight, allowing for ease of handling with one hand while the other holds the US probe for real-time visualization. Multiple core samples of different regions of the target can be obtained under real-time imaging guidance.

The number of samples taken will vary depending on the size of target and differential considerations. At our institution, we generally take four to six samples for US-guided core biopsies and 12 samples on average for stereotactic and MRI-guided biopsies. As with any percutaneous biopsy, the radiologist should assess for radiologic-pathologic concordance of the biopsy results and recommend additional sampling or surgical excision as appropriate. In some cases, more cores may be necessary at the time of biopsy, for example to ensure adequate sampling of calcifications.

Care should be taken to avoid over-sampling. The purpose of the biopsy is to establish a diagnosis in the setting of suspected cancer and not to resect the entire lesion or group of calcifications. The latter approach may also disrupt margin assessment for future surgical management.

**Clip placement** — A marker clip is placed in the sampled region of the breast at the time of a CNB to mark the biopsy site for subsequent management and follow-up. Different shapes or types of clips may be used if more than one lesion is biopsied in order to differentiate the various sites. This becomes especially important in the event that surgery is required for only one of the lesions [41].

Clip placement following sample acquisition with CNB is useful in several settings:

- To document that the lesion has been sampled and that it correlates with the lesion originally detected on mammography or MRI if US guidance was used [42]. If a subsequent excisional surgical biopsy is necessary, the clip serves as a guide for lesion localization.

- To mark the biopsy site of small lesions that might be completely removed during CNB or are no longer visible following CNB.
- To mark the tumor site of patients in whom neoadjuvant therapy is planned. If complete clinical and imaging response is observed, the clip serves to guide subsequent surgery.

Clip migration following placement has been reported [41]. If this occurs, an additional clip with a different shape can be placed at the true biopsy site if feasible. Alternatively, the distance from the original biopsy cavity to the clip can be measured on postprocedure imaging, and the report should document the relative location of the biopsy site and the migrated clip. The report should specifically state that the migrated clip itself should **not** be used to localize the lesion during surgery.

**Fine needle aspiration** — FNA, under either palpation or US guidance, is another biopsy option. If intraprocedural cytopathology is available, FNA can provide rapid confirmation of a suspected malignant diagnosis. This may expedite planning for treatment and clinical trials. However, because FNA demonstrates higher rates of false negative results and insufficient samples, CNB following FNA is sometimes necessary.

FNA biopsy is performed with a 10 or 20 mL syringe and a 21- to 27-gauge needle under palpation or US guidance. The patient is supine and no breast compression is required.

While FNA can provide a rapid preliminary diagnosis of cancer, it cannot distinguish between in situ and invasive cancer. In addition, the specimen may not be sufficient for other laboratory analyses (eg, receptor status). In settings with the necessary cytologic expertise, receptor status can be assessed from a cell block made from an FNA specimen. However, if the specimen proves to be HER2 positive, cytology cannot distinguish whether this is associated with the ductal carcinoma in situ (DCIS) component or the invasive cancer. (See 'Assay for receptor status and molecular signatures' below.)

The sensitivity of FNA for cancer diagnosis is lower than that for CNB. In a meta-analysis, FNA demonstrated a sensitivity of 74 percent (95% CI 72 to 77 percent) and specificity of 96 percent (95% CI 94 to 98 percent) [21]. However, the accuracy varies with proceduralist experience and training [43].

Diagnostic performance of FNA varies with experience of the operator and of the cytopathologist, and availability of the necessary expertise is an important factor in selection of FNA for breast biopsy [43]. Overall, FNA demonstrates higher rates of nondiagnostic samples and false negative results (usually >15 percent) than with CNB (usually <5 percent) [36,44]. The rate of inadequate or nondiagnostic FNA cytologic samples averages 4 to 13 percent for palpable abnormalities but may be as high as 36 percent for nonpalpable abnormalities [45,46]. However, at sites with necessary proceduralist and cytopathologist

expertise, FNA can be a highly reliable diagnostic tool and offers the possibility of same-day assessment. If there is a known cancer, and suspicious lymph nodes are detected with US or palpation, FNA can be used to confirm the presence or absence of lymph node metastases. (See 'Axillary lymph node biopsy' below.)

Proper lesion selection for FNA may play a role in determining the diagnostic yield. A greater amount of material can be aspirated from cellular lesions, such as invasive ductal carcinoma and metastatic lymph nodes, compared with less cellular lesions, such as hyalinized fibroadenomas, fibrotic lesions, or infiltrating lobular cancers. CNB is more likely to provide a definitive diagnosis for the less cellular lesions.

**Cyst aspiration** — Cyst aspiration can be used as a definitive test for lesions that are indeterminate at US, with the differential diagnosis including a complicated cyst containing proteinaceous debris versus a solid mass. Simple cysts are benign and only require aspiration when the patient is symptomatic.

Bloody fluid aspirated from a breast cyst should prompt more formal evaluation for an underlying mass. Sometimes the fluid is bloody because a vessel is hit with the needle. If the fluid is not frankly bloody (eg, yellow, grey, green, blue, milk white), there is no need for cytologic analysis, as the diagnostic yield is <1 percent [47-53]. If a breast cyst does not resolve after US-guided aspiration, the residual lesion should undergo CNB and a clip marker should be placed. (See "Breast cysts: Clinical manifestations, diagnosis, and management", section on 'Management'.)

**Axillary lymph node biopsy** — Axillary lymph nodes may be sampled with either CNB or FNA. However, experts differ in their use of axillary US to evaluate for nodal metastases in patients with Breast Imaging-Reporting and Data System (BI-RADS) category 4C and 5 lesions, and there are no consensus guidelines that define which patients benefit from needle biopsy. Thus, each institution should develop its own workflow in a multidisciplinary fashion. (See "Overview of the treatment of newly diagnosed, invasive, non-metastatic breast cancer", section on 'Evaluation of the axillary nodes'.)

In patients who are offered neoadjuvant therapy, it is important to pathologically evaluate the nodes with needle biopsy at presentation as the subsequent surgical approach will depend on nodal status. A clip may be left in the biopsied axillary lymph node so that it can be removed at the time of surgical sentinel lymph node biopsy [54-57]. Combining dual tracers for sentinel node identification and removal of the clipped lymph node can avoid axillary dissection as it has a low false negative rate. This strategy may allow up to 40 percent of patients who receive neoadjuvant therapy to avoid axillary lymph node dissection [57-59]. (See "General principles of neoadjuvant management of breast cancer", section on 'Management of the axilla'.)

If the FNA of a suspicious node is negative for malignant cells, a sentinel lymph node biopsy alone can be conducted at the time of the primary surgery. (See "Overview of sentinel lymph node biopsy in breast cancer", section on 'Indications'.)

**Surgical biopsy** — Surgical biopsy is not the initial method, unless needle biopsy is not technically feasible. Surgical biopsy more often serves as the secondary method when CNB results are inconclusive or discordant with the imaging findings. Surgical biopsy is performed in fewer than 10 percent of cases [60] (see 'Need for rebiopsy' below). Surgical biopsy can remove the entire lesion (excisional biopsy) or only a portion of it (incisional biopsy). Whether to perform an incisional or an excisional biopsy depends upon the indications for the biopsy:

- Incisional biopsy is used to confirm a diagnosis when a biopsy is nondiagnostic and the mass is large. The intent is to try to reduce the tumor with neoadjuvant therapy.
- Excisional biopsy is used in cases where the lesion is in such a location that it is not amenable to CNB or where the result of a CNB is atypical or nondiagnostic/indeterminate, is discordant with imaging results, or yields benign but high-risk lesions ( table 2). High-risk lesions of the breast are discussed in another dedicated topic. (See "Atypia and lobular carcinoma in situ: High-risk lesions of the breast".)

In addition, a surgical biopsy may also be required when:

- Cysts do not completely resolve after aspiration, indicating that there may be a residual mass. Such lesions should undergo evaluation with a CNB if technically feasible or a surgical excision. However, excisional biopsy of simple cysts, clustered microcysts, or cysts with thin septa is not necessary. (See "Breast cysts: Clinical manifestations, diagnosis, and management".)
- Size increase of a mass or suspicious changes are seen on follow-up imaging after a CNB with benign results. (See 'Follow-up imaging' below.)

**Excisional biopsy** — The goal of an excisional biopsy is to obtain a histologic diagnosis. To perform complete excision of lesions likely to be cancer, or to excise CNB-proven cancers, is technically not a biopsy, but rather a partial mastectomy. Indications for and techniques of partial mastectomy are discussed in another dedicated topic. (See "Breast-conserving therapy", section on 'Breast-conserving surgery'.)

Nonpalpable lesions requiring surgical excision can be localized using a wire or another device under mammographic, US, or MRI guidance. A clip placed at the time of CNB will aid in localization of the biopsy area at the time of surgery [61-63]. Alternative, more modern techniques for localization include the use of magnetized seeds or clips with a radiofrequency emitter [64]. Localization techniques are discussed in another topic. (See

"Techniques to reduce positive margins in breast-conserving surgery", section on 'Localization of nonpalpable lesions'.)

Excisional biopsies can generate scar tissue inside the breast that may prompt future diagnostic evaluation if prior mammograms are not available for comparison.

**Skin punch biopsy —** A small skin biopsy using a punch biopsy device can differentiate between benign and malignant skin changes. Punch biopsy may be needed if there is concern for Paget disease, skin involvement with invasive breast cancer, inflammatory breast cancer, or skin recurrence of breast cancer. (See "Paget disease of the breast (PDB)", section on 'Skin biopsy and histology' and "Inflammatory breast cancer: Clinical features and treatment", section on 'Biopsy'.)

## HANDLING THE SPECIMEN

All specimens should be oriented by the surgeon. If additional margins are removed, the specimens should be oriented clearly. Some surgeons will orient all of the specimens and use a pathology inking protocol to reduce the chance of confusion when specimens are transported. (See "Techniques to reduce positive margins in breast-conserving surgery", section on 'Specimen orientation'.)

Careful documentation of the site of biopsy, patient name, and medical record number on the biopsy specimen is essential. Core and surgical biopsy specimens should be placed immediately into formalin and immediately sent to a pathology lab and promptly processed into paraffin blocks. The time at which the sample is placed in formalin should also be documented.

**Surgical specimen radiography —** Following surgical removal, whole specimen radiography is obligatory for clinically occult lesions excised under mammographic localization and is also recommended for palpable lesions that are associated with microcalcifications [65]. Specimen radiography is essential to confirm the accurate removal of the targeted abnormality and to guide the pathologist to the appropriate area for sectioning and microscopic study. Specimen radiography also confirms that the entire hook wire or alternative localization device(s) and any targeted clips have been removed. Visualization of the clip and/or foreign body material accompanying the clip helps the pathologist and the surgeon to identify the prior biopsy site.

Specimen radiography can also show whether the lesion has been transected or is in close proximity to the edge of the specimen. In such cases, additional tissue may need to be removed to increase the likelihood of negative margins [66]. The best opportunity to achieve clear margins is at the time of the original surgical excision. Some centers and surgeons use

digital imaging devices in the operating rooms (eg, Faxitrons) to provide an immediate picture of the specimen and improve the ability of the surgeon to see the lesion in relation to the margins. (See "Techniques to reduce positive margins in breast-conserving surgery", section on 'Specimen radiography'.)

**Assay for receptor status and molecular signatures** — Assays for expression of estrogen and progesterone and HER2 receptors, as well as multigene assays, are important for determining the optimal systemic treatment strategy and are performed on all primary breast cancers [67]. Performing these assays on the core biopsy material can facilitate treatment by expediting discussions as to the need for, timing of (neoadjuvant versus adjuvant), and type of systemic therapy (chemo- versus hormonal therapy). However, if receptors are negative, given tumor heterogeneity, the assays could be repeated at the time of definitive surgery. In up to 15 percent of cases, markers that are negative on a core sample will be positive on the larger surgical specimen. At sites with the necessary cytopathology expertise, these assays can also be performed on FNA samples, but intraprocedural cytopathology needs to be available to ensure that an adequate sample is obtained at time of FNA biopsy for this purpose. (See "Hormone receptors in breast cancer: Clinical utility and guideline recommendations to improve test accuracy" and "HER2 and predicting response to therapy in breast cancer".)

## POSTPROCEDURE CARE

**Patient activity** — Most patients tolerate core needle biopsy (CNB) and fine needle aspiration (FNA) well and can return to normal activities the day following the procedure. Vigorous physical activity should be avoided for several days after CNB.

**Complications** — Complications of CNB are few but include hematoma (3 percent or less) and infection (1 percent or less). The risk for severe complications is rare with CNB (<1 percent) and low with open surgical biopsy (1 to 3 percent) [68]. Wearing a sports bra or firm ACE bandage wrapped around the breasts for support for two to three days (day and night) reduces discomfort and hematomas. Patients experiencing rapid swelling of the breast and pain following a biopsy should immediately contact their clinicians.

Occasionally, CNBs can cause severe pain. This can happen when the target lesion is in the trajectory of the T4 or the T5 nerves (ie, 4 and 5 o'clock on the left breast and 7 and 8 o'clock in the right breast). In the unusual event that pain persists after core biopsy and is not relieved with nonsteroidal anti-inflammatory drugs (NSAIDs), it can be treated with gabapentin to reduce neuropathic pain. (See "Postmastectomy pain syndrome: Risk reduction and management".)

## REVIEWING RESULTS

**Imaging-pathologic correlation —** Review of images and pathology should be undertaken to ensure that the histopathology of a lesion biopsied is concordant with the imaging abnormality. This simultaneous review of the imaging and the pathologic findings may sometimes lead to a recommendation for additional tissue sampling.

Benign pathologies that include atypia need to be reviewed in conjunction with the imaging findings and the clinical scenario. If there is uncertainty regarding the pathologic diagnosis, review by an expert breast pathologist and/or additional tissue staining may be obtained to help clarify the diagnoses. (See "Atypia and lobular carcinoma in situ: High-risk lesions of the breast".)

Management is individualized, taking into account the overall picture of risk for the patient as well as the clinical presentation (clinical exam, patient factors) and imaging findings (including sampling confidence for image-guided biopsy).

**Diagnostic uncertainty with atypia and DCIS —** There is known inter- and intraobserver variation in the diagnoses of atypia and ductal carcinoma in situ (DCIS). B-Path quantified the magnitude of concordance of the interpretation of 6900 cases by 115 pathologists with a consensus-derived reference diagnosis [69]. When adjusted for the actual prevalence of various breast pathologies in women aged 50 to 59 years [70], the concordance rate was 92.3 percent (95% CI 91.4 to 93.1 percent). Over- and under-interpretation were seen in 4.6 and 3.2 percent of the cases, respectively. The diagnostic accuracy, however, differed significantly among the various pathologies. While more than 97 percent of the benign (without atypia) interpretations were confirmed by the expert panel, 54 percent of the atypia diagnoses were over-interpreted, and 8.6 percent were under-interpreted. Similarly, 9 percent of the DCIS diagnoses were over-interpreted, and 12 percent were under-interpreted.

Reader studies, where pathologic conclusions are made in isolation from other clinical information, do not reflect clinical practice in most settings. Pathologists often confer with colleagues and can obtain additional information (eg, special stains, clinical presentation, imaging, and patient overall health and risk factors). An interdisciplinary breast practice incorporates the expertise of the pathologist, radiologist, oncologist, and surgeon together to review any discordant cases in order to come to a consensus conclusion.

**Need for rebiopsy —** Breast biopsy should be repeated to obtain additional tissue under the following circumstances:

- For discordant findings between benign or inconclusive pathologic results from core needle biopsy (CNB) or fine needle aspirations (FNAs) and imaging findings suggesting

malignancy, additional tissue sampling is warranted with excisional surgical biopsy or imaging-guided CNB, respectively. (See 'Core needle biopsy' above and 'Surgical biopsy' above.)

- When FNA biopsy is malignant but the sample is insufficient for complete pathologic analysis (eg, hormone receptor assay), an imaging-guided CNB should be pursued if the information is needed prior to surgical excision.

- If a CNB shows atypical ductal hyperplasia (ADH), lobular neoplasia with atypia, papilloma, complex sclerosing adenosis, or radial scar, a surgical biopsy may be indicated in some cases [71-74]. Although these are benign entities, they can sometimes be associated with a malignancy ( table 2). Management of high-risk lesions of the breast is discussed in another dedicated topic. (See "Atypia and lobular carcinoma in situ: High-risk lesions of the breast".)

**Follow-up imaging** — Recommendation for follow-up imaging is provided at the time of imaging-pathologic assessment of the biopsy specimen.

**Benign concordant imaging-pathologic findings** — Imaging with mammography and/or ultrasound (US) is recommended at approximately 12 months from the time of the biopsy for most patients with benign pathology and concordant imaging findings. This generally corresponds to the time of routine screening mammography. Shorter interval follow-up is reserved for limited specific scenarios (eg, nonspecific or benign pathology results and a mixed solid and cystic lesion on US or a focal asymmetry on mammography).

Data suggest that a follow-up interval of <12 months is not necessary in most patients:

- In a retrospective review of 337 women with concordant imaging-pathologic findings, women (n = 182) undergoing follow-up imaging at an interval <12 months from the time of CNB (mean six months) had a similar rate of Breast Imaging-Reporting and Data System (BI-RADS) 1, 2, or 3 lesions compared with women imaged more than 12 months after the CNB (mean 15 months, 97 versus 92 percent) [75]. In this series, one woman (0.5 percent) was found to have a cancer at the previous biopsy site in the cohort imaged <12 months from the initial biopsy, and no women were found to have a cancer in the cohort imaged at the >12 month interval.

- A study using the Breast Cancer Surveillance Consortium (BCSC) registry compared cancer detection rates and stage for shorter-interval (3 to 8 months) versus longer-interval follow-up (9 to 18 months) following benign core breast biopsy (stereotactic or ultrasound-guided) [76]. A total of 17,631 biopsies with benign findings were identified. Similar rates of later cancer were detected for the groups with no significant differences in stage, tumor size, or nodal status. Thus, it appears to be safe for those with a benign imaging-pathologic-concordant percutaneous breast biopsy to return to a normal

screening schedule; however, the study did not identify the spatial relationship between the finding that prompted the initial biopsy and the site of the subsequent cancer (which could have represented a false negative result). However, in general, a shorter (six-month) follow-up interval is performed in cases of a nonspecific but benign diagnosis (eg, fibrocystic change) or where the imaging finding is not a discrete mass lesion (eg, focal asymmetry at mammography or enhancement on magnetic resonance imaging [MRI]). If there is concern for imaging-pathologic discordance, then additional sampling should be recommended, including surgical excision as appropriate. (See "Clinical manifestations, differential diagnosis, and clinical evaluation of a palpable breast mass", section on 'Diagnostic evaluation'.)

**Imaging after excisional biopsy —** Imaging after surgical biopsy (ie, partial mastectomy) should follow established guidelines for breast cancer and DCIS. Details are presented in other dedicated topics. (See "Approach to the patient following treatment for breast cancer" and "Ductal carcinoma in situ: Treatment and prognosis", section on 'Post-treatment surveillance'.)

## SOCIETY GUIDELINE LINKS

Links to society and government-sponsored guidelines from selected countries and regions around the world are provided separately. (See "Society guideline links: Breast surgery".)

## INFORMATION FOR PATIENTS

UpToDate offers two types of patient education materials, "The Basics" and "Beyond the Basics." The Basics patient education pieces are written in plain language, at the 5$^{th}$ to 6$^{th}$ grade reading level, and they answer the four or five key questions a patient might have about a given condition. These articles are best for patients who want a general overview and who prefer short, easy-to-read materials. Beyond the Basics patient education pieces are longer, more sophisticated, and more detailed. These articles are written at the 10$^{th}$ to 12$^{th}$ grade reading level and are best for patients who want in-depth information and are comfortable with some medical jargon.

Here are the patient education articles that are relevant to this topic. We encourage you to print or e-mail these topics to your patients. (You can also locate patient education articles on a variety of subjects by searching on "patient info" and the keyword(s) of interest.)

- Basics topic (see "Patient education: Breast biopsy (The Basics)")

## SUMMARY AND RECOMMENDATIONS

- Patients with a suspicious abnormality on breast imaging or a suspicious palpable breast mass should undergo percutaneous needle biopsy, rather than surgical biopsy, as the initial diagnostic technique. Surgical biopsy should generally be used only if percutaneous biopsy is not feasible or conclusive. (See 'Introduction' above.)

- An imaging evaluation, usually with mammography, breast ultrasound (US), or both, precedes biopsy ( algorithm 1). Imaging serves to select the lesion(s) that should undergo resection or neoadjuvant therapy for malignancy and provides the information needed to design the appropriate treatment approach. Abnormalities are categorized on imaging based on their likelihood of cancer according to the Breast Imaging-Reporting and Data System (BI-RADS) ( table 1). Practice guidelines recommend biopsy for all BI-RADS 4 and 5 lesions. (See 'Preprocedure imaging evaluation' above.)

- Core needle biopsy (CNB) is the preferred initial approach of breast biopsy for most patients. With lesions likely to be cellular and malignant (eg, invasive ductal carcinoma), fine needle aspiration (FNA) with intraprocedural cytopathology, if available, is an alternative as it may expedite patient management, particularly in the evaluation of suspicious nodes. Surgical biopsy, while not used as the initial biopsy method, may be required to further investigate discordant or inconclusive results of percutaneous biopsies. (See 'Choice of initial biopsy method' above.)

- CNB is performed under imaging guidance with either US, x-ray (ie, stereotactic or tomosynthesis), or magnetic resonance imaging (MRI) without and with intravenous contrast. US guidance is preferred if the target lesion is well visualized with this modality. Stereotactic or tomosynthesis biopsy is performed for mammographic abnormalities without a clear US correlate. MRI-guided biopsy is performed for lesions visible only on MRI. (See 'Core needle biopsy' above.)

- A marker clip is placed in the sampled region of the breast or lymph node at the time of a CNB to mark the biopsy site for subsequent management and follow-up. Different shapes or types of clips may be used if more than one lesion is biopsied in order to differentiate the various sites. (See 'Clip placement' above.)

- FNA can be performed under either palpation or US guidance. When cytopathology is available to review the specimen during the procedure, FNA allows for rapid confirmation of a suspected malignant diagnosis, which may expedite planning for treatment and clinical trials. CNB following FNA is sometimes necessary as the latter demonstrates higher rates of false negative results and insufficient samples. (See 'Fine needle aspiration' above.)

- Surgical biopsy is needed when CNB results are inconclusive or discordant. Surgical biopsy can remove the entire lesion (excisional biopsy), only a portion of it (incisional biopsy), or the overlying skin (skin biopsy). In patients with nonpalpable lesions requiring excision, localization with wire or other devices is required. (See 'Surgical biopsy' above.)

- Review of images and pathology should be undertaken to ensure that the histopathology of the biopsy is concordant with the imaging abnormality. This simultaneous review of the imaging and the pathologic findings may sometimes lead to a recommendation for additional tissue sampling (eg, CNB after FNA, surgical biopsy after CNB). (See 'Reviewing results' above.)

- Imaging follow-up, with mammography, US, and/or MRI, is recommended at approximately 12 months from the time of the biopsy for most patients with benign pathology and concordant imaging findings. Shorter interval follow-up at six months is reserved for limited specific scenarios (eg, nonspecific benign pathology results and a mixed solid and cystic lesion on US or a focal asymmetry on mammography). (See 'Follow-up imaging' above.)

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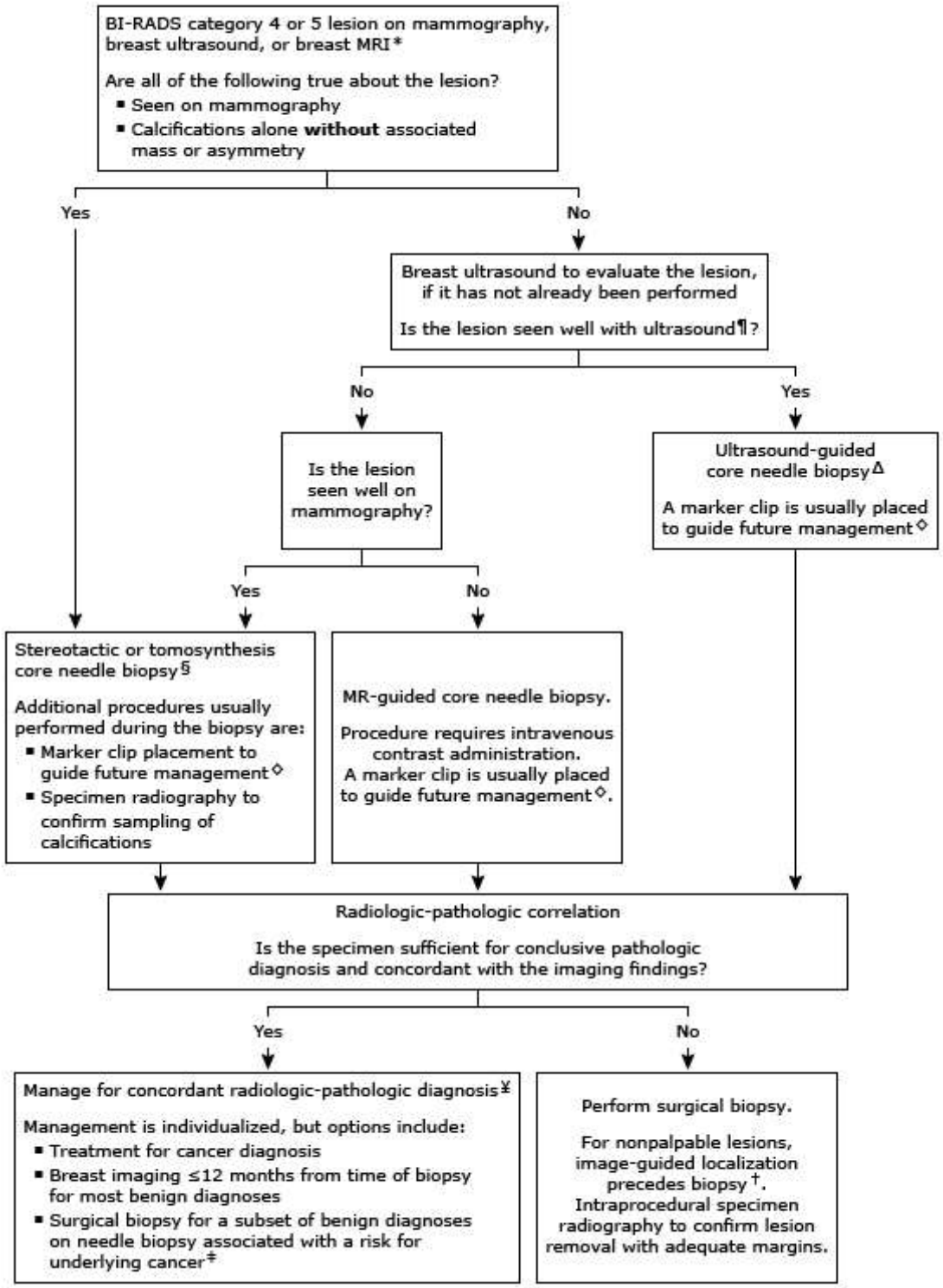
Topic 796 Version 33.0

## GRAPHICS

### Diagnostic biopsy of breast lesions seen on imaging




BI-RADS: Breast Imaging-Reporting and Data System; MRI: magnetic resonance imaging; MR: magnetic resonance; FNA: fine needle aspiration; 3D: three-dimensional.

* Breast abnormalities seen on imaging (ie, mammography, ultrasound, or MRI) are classified into BI-RADS categories based on their likelihood of cancer. BI-RADS categories are described elsewhere in UpToDate (refer to topic on breast biopsy).

Palpable breast lesions should undergo imaging evaluation with mammography and/or ultrasound to assess the BI-RADS category before biopsy.

¶ To ensure that the correct tissue is targeted for biopsy, ultrasound findings should be correlated with the imaging modality on which the abnormality was originally detected or, for palpable lesions, with the physical exam.

Δ FNA with intraprocedural cytopathology, if the necessary expertise is available, is an option for rapid confirmation of a suspected malignant diagnosis. However, core needle biopsy following FNA is necessary if the FNA is inconclusive or does not contain sufficient tissue for treatment planning. Refer to the UpToDate topic on breast biopsy for further discussion of FNA.

◇ For a malignant lesion, the clip guides localization for resection or marks a mass treated with neoadjuvant chemotherapy. For a benign lesion, a clip indicates a site of prior biopsy, thereby preventing redundant workup.

§ Stereotactic biopsy is used for most lesions best seen on mammography. Tomosynthesis-guided biopsy is an option for lesions only seen on tomosynthesis, also known as "3D mammography," and for lesions amenable to stereotactic biopsy.

¥ Refer to other UpToDate topics for further discussion of management options. For each case, management recommendations should be formulated from radiologic-pathologic correlation and documented in the patient's medical record.

‡ Some benign entities (ie, atypical ductal hyperplasia, lobular neoplasia with atypia, papilloma, complex sclerosing adenosis, or radial scar) are associated with malignancy and may warrant rebiopsy. Their management is discussed elsewhere in UpToDate in topics on high-risk benign breast lesions.

† Localization is performed using the imaging modality on which the lesion is best seen. Wire and other localization techniques are described in the UpToDate topic on techniques to reduce positive margins in breast-conserving surgery.

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Graphic 121089 Version 3.0

## BI-RADS assessment categories

| Assessment | Management | Likelihood of cancer |
|---|---|---|
| Category 0: Incomplete – Need additional imaging evaluation and/or prior mammograms for comparison | Recall for additional imaging and/or comparison with prior examination(s) | N/A |
| Category 1: Negative | Routine mammography screening | Essentially 0% likelihood of malignancy |
| Category 2: Benign | Routine mammography screening | Essentially 0% likelihood of malignancy |
| Category 3: Probably benign | Short-interval (6-month) follow-up or continued surveillance mammography | >0 but ≤2% likelihood of malignancy |
| Category 4: Suspicious | Tissue diagnosis* | >2 but <95% likelihood of malignancy |
| Category 4A: Low suspicion for malignancy | | >2 to ≤10% likelihood of malignancy |
| Category 4B: Moderate suspicion for malignancy | | >10 to ≤50% likelihood of malignancy |
| Category 4C: High suspicion for malignancy | | >50 to <95% likelihood of malignancy |
| Category 5: Highly suggestive of malignancy | Tissue diagnosis* | ≥95% likelihood of malignancy |
| Category 6: Known biopsy-proven malignancy | Surgical excision when clinically appropriate | N/A |

BI-RADS: Breast Imaging-Reporting and Data System.

* Practice guidelines recommend biopsy for all BI-RADS 4 and 5 lesions. If there are clinical factors (eg, age, comorbidities, etc) for which the patient, in consultation with the clinician, chooses to defer biopsy, the reasoning should be documented in the medical record.



Graphic 100197 Version 10.0

## High-risk breast lesions and management

| | Diagnosis | Management after core needle biopsy[1] | Upgrade rate with excision | Management of margins after excision | Relative risk for invasive cancer |
|---|---|---|---|---|---|
| Atypical ductal hyperplasia (ADH) | Found on biopsy performed for microcalcifications on screening mammogram | Surgical excision for most patients | 10 to 20% [2] | No re-excision for margins | 3.1 to 4.7[2] |
| Atypical lobular hyperplasia (ALH) | Incidental finding on biopsy performed for other reasons | Surgical excision for discordance or presence of other high-risk lesion<br>Observation for other lesions | <3% for concordant, small-volume disease[2] | No re-excision for margins | 3.1 to 5.9[2] |
| Lobular carcinoma in situ (LCIS) | Incidental finding on biopsy performed for other reasons | Surgical excision for non-classic features (pleomorphic, comedo necrosis, signet ring, or apocrine), or for discordance<br>Observation for concordant classic LCIS | <5% for concordant, small-volume disease[2] | Re-excision to negative margins for pleomorphic LCIS<br>No re-excision for margins for classic LCIS | 6.9 to 11[2] |
| Flat epithelial atypia (FEA) | Found on biopsy performed for microcalcifications on screening mammogram | Surgical excision for discordance or FEA associated with residual microcalcification<br>Observation for concordant pure FEA | 0 to 3.2% for pure FEA[2] | No re-excision for margins | 1.47[3] |

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