

ACR PRACTICE PARAMETER FOR THE PERFORMANCE OF ULTRASOUND-GUIDED PERCUTANEOUS BREAST INTERVENTIONAL PROCEDURES

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The American College of Radiology will periodically define new practice parameters and technical standards for radiologic practice to help advance the science of radiology and to improve the quality of service to patients throughout the United States. Existing practice parameters and technical standards will be reviewed for revision or renewal, as appropriate, on their fifth anniversary or sooner, if indicated.

Each practice parameter and technical standard, representing a policy statement by the College, has undergone a thorough consensus process in which it has been subjected to extensive review and approval. The practice parameters and technical standards recognize that the safe and effective use of diagnostic and therapeutic radiology requires specific training, skills, and techniques, as described in each document. Reproduction or modification of the published practice parameter and technical standard by those entities not providing these services is not authorized.

PREAMBLE

This document is an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. Practice Parameters and Technical Standards are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care¹. For these reasons and those set forth below, the American College of Radiology and our collaborating medical specialty societies caution against the use of these documents in litigation in which the clinical decisions of a practitioner are called into question.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the practitioner considering all the circumstances presented. Thus, an approach that differs from the guidance in this document, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in this document when, in the reasonable judgment of the practitioner, such course of action is indicated by variables such as the condition of the patient, limitations of available resources, or advances in knowledge or technology after publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document may consider documenting in the patient record information sufficient to explain the approach taken.

The practice of medicine involves the science, and the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment. Therefore, it should be recognized that adherence to the guidance in this document will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The purpose of this document is to assist practitioners in achieving this objective.

¹ *Iowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing*, 831 N.W.2d 826 (Iowa 2013) Iowa Supreme Court refuses to find that the "ACR Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures (Revised 2008)" sets a national standard for who may perform fluoroscopic procedures in light of the standard's stated purpose that ACR standards are educational tools and not intended to establish a legal standard of care. See also, *Stanley v. McCarver*, 63 P.3d 1076 (Ariz. App. 2003) where in a concurring opinion the Court stated that "published standards or guidelines of specialty medical organizations are useful in determining the duty owed or the standard of care applicable in a given situation" even though ACR standards themselves do not establish the standard of care.

I. INTRODUCTION

Breast interventional procedures may be diagnostic, such as with percutaneous biopsy or fine-needle aspiration (FNA); therapeutic, as with abscess drainage; or both diagnostic and therapeutic, such as cyst aspiration. This parameter does not address the use of ultrasound for preoperative image-guided localization. For further information, see the [ACR Practice Parameter for the Performance of Preoperative Image-Guided Localization in the Breast](#).

Ultrasound is one of several imaging techniques that may be used to guide interventional procedures. Other breast imaging modalities used for guidance include conventional mammography, stereotactic mammography, digital breast tomosynthesis (DBT), molecular breast imaging (MBI), and magnetic resonance imaging (MRI). When a lesion can be visualized sonographically, ultrasound guidance is generally preferred over other modalities because it is often faster, allows real-time imaging of the sampling process, and is more comfortable for the patient. Ultrasound requires neither ionizing radiation, unlike mammographic modalities, nor intravenous contrast, unlike MRI. Using ultrasound guidance when appropriate also has cost advantages because procedure times tend to be shorter and ultrasound equipment is less expensive and often more readily available than the other modalities. Additionally, both mammographic and MRI-guided biopsies generally require vacuum-assisted devices, whereas ultrasound biopsies can usually be performed with either lower-cost spring-loaded large-core biopsy devices or, when appropriate, vacuum-assisted devices.

Minimally invasive image-guided biopsy is the most common method for diagnosing breast lesions both palpable and nonpalpable. Image-guided biopsy has similar accuracy to surgical biopsy and several advantages, including superior patient convenience, lower cost, lower morbidity, superior cosmesis, and a lower complication rate [1-3].

Prior to the performance of any ultrasound-guided percutaneous procedure, the lesion should be evaluated completely with a diagnostic ultrasound in accordance with the [ACR Practice Parameter for the Performance of a Diagnostic Breast Ultrasound Examination](#) [4] and assessed by a physician qualified to interpret the examination (see section IV below). Findings on other imaging modalities (such as mammography or MRI) or on clinical examination should be correlated with those seen by ultrasound before the interventional procedure is undertaken.

Successful use of ultrasound to guide interventional breast procedures relies on high-quality imaging, expertise in lesion characterization, patient selection, patient positioning, and experience in ultrasound-guided techniques for accurate lesion localization and targeting. Correlation of the imaging characteristics with histopathologic or cytopathologic results for concordance by the physician performing the biopsy is essential. Documentation of results and patient management recommendation records should be retained in accordance with the [ACR Practice Parameter for Communication of Diagnostic Imaging Findings](#) [5].

II. INDICATIONS AND CONTRAINDICATIONS

A. Indications

Indications for percutaneous ultrasound-guided breast interventional procedures include, but are not limited to, the following:

1. Aspiration of a simple or complicated cyst when:
 - a. It is symptomatic and the patient desires relief.
 - b. It is unclear whether the lesion is a complicated cyst or a solid lesion.
 - c. Correlation with a finding on another modality (eg, mammography or MRI) is likely to provide important diagnostic information that will guide patient management. In this situation imaging with the other modality should be performed following the aspiration.
 - d. Abscess or infection is suspected, and diagnostic aspiration and/or therapeutic drainage is clinically indicated.

2. Biopsy of an ultrasound-visible lesion when:
 - a. The Breast Imaging Reporting and Data System (BI-RADS[®]) assessment of the lesion is either

suspicious (BI-RADS® Category 4) or highly suggestive of malignancy (BI-RADS® Category 5) [6]. Even if the probability of malignancy is very high, percutaneous biopsy is indicated both to confirm the diagnosis and to obtain tissue for molecular testing that can be used to guide treatment.

Examples of appropriate lesions, when assessed as above, include:

- i. Masses
 - ii. Calcifications, when clearly visible on ultrasound and ultrasound-guided biopsy is preferable to biopsy using stereotactic or DBT guidance. Specimen radiography should be performed in this setting to document adequate sampling of calcifications [7-9].
 - iii. Masses and nonmass lesions identified as sonographic correlates for MRI findings that are assessed as suspicious or highly suspicious on MRI as long as there is high confidence of correlation between MRI and ultrasound [10].
 - b. A lesion assessed as probably benign (BI-RADS® Category 3) when biopsy is preferable to short-interval follow-up based on shared decision making with the patient [11].
 - c. Additional lesions in patients with known malignancy (BI-RADS® Category 6), when knowledge of the histology of the lesion will affect treatment.
 - d. Suspicious axillary lymph nodes, especially in the setting of a suspicious breast mass or biopsy-proven cancer. FNA is an alternative to core biopsy in this setting [12]. If lymphoma is in the differential, then a portion of the material should be submitted in media that allows the performance of flow cytometry.
3. Vacuum-assisted biopsy (VAB) and removal of palpable or painful low- or moderate-suspicion lesions, generally BI-RADS® Category 3 or 4a, when the presence of the lesion will be bothersome to the patient, even after it is shown to be benign. Removal of the lesion at percutaneous biopsy avoids the need for surgical excision to relieve the symptomatic abnormality [13-15].
4. VAB of a mass suspected to be a papilloma, typically a solitary intraductal mass. Compared with CNB, large-gauge VAB is associated with a lower upgrade rate and often resolves any associated nipple discharge [16,17]. VAB has also been used successfully as an alternative to surgical excision for papillomas without atypia originally diagnosed by CNB.

If the pathological result of the VAB is papilloma without atypia, short-interval imaging follow-up can be used as an alternative to surgical excision. If atypia is found, however, the patient should be referred for surgical excision, even if the lesion appeared to have been removed entirely at biopsy [18-21].

5. Repeat biopsy

Repeat ultrasound-guided CNB or VAB sampling is an alternative to surgical biopsy in cases in which the initial core biopsy results are nondiagnostic or discordant with the imaging findings; if additional tissue is necessary for tissue biomarker analysis; or if an initial FNA yields atypical, suspicious, or nondiagnostic cytology.

6. Ablation

Some image-guided ablation devices are approved for removal of biopsy-proven benign lesions, specifically fibroadenomas [22-25]. Studies are underway to obtain approval for percutaneous treatment of small breast cancers [26-28]. Ablation methods vary by device and include cryoablation, thermal/laser ablation, and radiofrequency ablation.

7. Placement of a marker or wireless localization device

A marker or wireless localization device (eg, RF reflector or magnetic "seed") can be placed percutaneously at the biopsy site in order to mark the lesion location. The markers generally will be removed with the specimen if the associated lesion is excised; otherwise they are left in permanently. In rare cases in which a marker causes distress to the patient, it can be removed percutaneously with a VAB device. All available markers are visible mammographically; some also are visible by ultrasound either indefinitely or for a limited time after placement. Markers also may create visible artifact on MRI.

Potential indications for ultrasound-guided percutaneous placement of a marker include the following:

- a. To mark the location of a lesion no longer visible at the end of the biopsy procedure, usually because it has been completely or mostly removed. In such cases, care should be taken to ensure the marker is not inadvertently removed during biopsy.
- b. To correlate findings on different modalities or to correlate a specific lesion with its pathology on future imaging. This usage is especially important if there are multiple lesions or if the patient will be receiving treatment or future imaging at another center where complete record of her biopsy history may not be available.
- c. To mark the site of a cancer that may be treated with neoadjuvant systemic therapy and may consequently become less visible.
- d. To mark a biopsied axillary lymph node to aid in surgical removal, especially after neoadjuvant systemic therapy.

8. Presurgical localization

Ultrasound-guided localization for guiding surgical excision may be performed when the lesion or an appropriately positioned marker placed during a previous biopsy is identifiable with ultrasound [29]. Localization may be performed using a wire or a nonwire localization device. Details of presurgical localization, including the device types, are given in the [ACR Practice Parameter for the Performance of Preoperative Image-Guided Localization in the Breast](#).

9. Percutaneous drainage

Ultrasound-guided placement of a percutaneous drainage catheter may be performed in appropriate clinical scenarios by qualified radiologists. Radiologists should refer to and adhere to the [ACR–SIR–SPR Practice Parameter for Specifications and Performance of Image-Guided Drainage/Aspiration of Abscesses and Fluid Collections](#) for image-guided percutaneous drain placement [30].

B. Contraindications

Inability to confidently identify the target lesion sonographically at the time of the biopsy is a contraindication to ultrasound-guided biopsy or aspiration. Prior to the procedure, the patient should be asked about allergies; use of medications such as aspirin, anticoagulants, platelet agents, or other agents known to impact bleeding times; and whether there is a history of a bleeding diathesis. There is literature reporting that it is safe to proceed with biopsy despite anticoagulation [31]. Decisions regarding postponement or cancellation of a procedure or cessation of anticoagulants can be made on a case-by-case basis, weighing the risks of bleeding and hematoma formation with those of interrupting anticoagulation.

III. QUALIFICATIONS AND RESPONSIBILITIES OF THE PHYSICIAN

A. General Qualifications

Ultrasound-guided percutaneous breast interventional procedures should be performed by physicians who meet qualifications outlined in the [ACR Practice Parameter for the Performance of a Breast Ultrasound Examination](#) [4]. When the procedure is being performed for therapeutic reasons only (abscess drainage or aspiration), the physician should meet the initial qualifications above or meet those qualifications outlined in the [ACR–SIR–SPR Practice Parameter for Specifications and Performance of Image-Guided Percutaneous Drainage/Aspiration of Abscesses and Fluid Collections](#) [30]. In cases where mammography has been performed, the physician should either meet the initial qualifications specified in the [ACR Practice Parameter for the Performance of Screening and Diagnostic Mammography](#) [32] or should review the mammographic findings with a physician who has the qualifications specified in the Food and Drug Administration’s (FDA) Mammography Quality Standards Act Final Regulations [33]. The physician should thoroughly understand the indications for and limitations of ultrasound examinations and ultrasound-guided percutaneous breast interventional procedures. The physician performing the breast interventional procedure should be familiar with breast ultrasound anatomy and must be capable of correlating the results of mammographic and other examinations and procedures and the biopsy pathology with the sonographic findings. The physician should thoroughly understand the basic physics of ultrasound, ultrasound instrumentation, imaging techniques, and ultrasound safety.

B. Specific Qualifications

1. Initial qualifications

Training in sonographic (and mammographic for correlation) image interpretation, medical physics, and specific hands-on training in the performance of ultrasound-guided biopsy are imperative to successful performance of this procedure.

The initial qualifications as outlined for the [Breast Ultrasound Accreditation Program Requirements](#) provide this foundation [34].

2. Maintenance of competence

The physician should perform a sufficient number of procedures to maintain their skills. Continued competence should depend on participation in a quality control program as laid out under section VIII of this practice parameter.

3. Continuing Medical Education

The physician’s continuing education should be in accordance with the [ACR Practice Parameter for Continuing Medical Education](#) [35].

C. Responsibilities for Assessment Concordance

Concordance is the agreement of imaging and histopathological findings such that the histopathology satisfactorily explains the imaging findings.

The physician who performs the procedure or, if unavailable, a qualified physician-designee, is responsible for obtaining pathologic results to determine whether the lesion has been adequately biopsied and whether the pathology results are concordant or discordant with the imaging findings. The determination of concordance should be documented [36]. When discordant, biopsy should be repeated by imaging guidance or surgical excision [37]. These results should be communicated to the referring physician and/or to the patient, as appropriate.

IV. SPECIFICATIONS OF THE PROCEDURE

Benefits, limitations, and risks of the procedure as well as any alternatives should be discussed with the patient. Informed consent should be obtained and documented.

Adherence to the Joint Commission's Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery™ is strongly recommended.

The breast, ultrasound transducer, the field in which the procedure is to be performed, and the physician performing the procedure should be prepared in conformity with the principles of infection control.

The procedure should be performed under real-time imaging guidance. The use of a high-frequency linear transducer is recommended. During performance of the intervention, the long axis of the needle, especially its tip, should be visible along the long axis of the transducer.

The needle should be kept relatively parallel to the chest wall and transducer face throughout the performance of the intervention to ensure the chest wall is not penetrated. The insertion point of the needle should be chosen to balance the need to keep the needle somewhat parallel to the chest wall against the preference to limit the amount of tissue to be traversed. The need to keep the needle parallel is greater for devices with a throw than those without a throw. A parallel approach also improves ultrasound visibility of the needle during the procedure. The images that should be obtained depend on the procedure. For CNBs, FNAs, and wire localizations, an image should be taken after each sample showing the needle lengthwise in the lesion at a minimum. Another image with the transducer perpendicular to the needle can be obtained to show the echogenic dot representing the needle in cross-section within the lesion. This perpendicular image is useful to confirm that the needle is in the lesion, as the parallel view may make the needle look like it is through the target lesion when it is actually next to it because of the averaging within the width of the ultrasound beam. For VABs and cyst aspirations, lengthwise images should be taken showing the needle and the lesion before sampling/aspiration. The area should then be imaged after sampling/aspiration to document any residual lesion. Documentation of appropriate needle positioning for sampling should be part of the medical record, as below.

Coaxial techniques may also be used with ultrasound-guided FNA and CNB, per operator preference [38]. The number of samples required for adequate analysis depends upon lesion type and biopsy device; a minimum of 3 to 6 samples is usually obtained from each lesion [39].

Following performance of a core biopsy and, as appropriate, following aspiration or FNA biopsy, placement of a localizing tissue marker at the biopsy or aspiration site should be strongly considered to facilitate mammographic correlation and surgical excision, if necessary. This is especially important for lesions that may be difficult to visualize on subsequent ultrasound examinations, whether due to obscuration by postbiopsy change or treatment with neoadjuvant chemotherapy; for mammographically occult lesions; and for correlation with findings on other imaging modalities such as MRI [40]. When multiple lesions are present and biopsy of > 1 suspicious lesion is performed to determine disease extent, placement of markers of different shapes should be considered.

When a tissue marker has been placed, a postbiopsy mammogram consisting of craniocaudal and 90° lateral views can be performed following the procedure to document tissue marker location. Additional views, such as exaggerated craniocaudal or mediolateral oblique views, may be necessary to visualize the tissue marker and help correlate the biopsied lesion to the mammographic image.

To minimize hematoma formation following biopsy or aspiration, especially in patients who are at risk for bleeding, the biopsy and skin entry sites and the path of the needle should be adequately compressed until hemostasis is achieved. The length of compression needed is case-dependent and depends on patient factors, particularly the use of anticoagulants/antiplatelet medications, and on the amount of bleeding, both internal and external, during the procedure. It should be noted that an absence of bleeding from the skin entry site does not ensure adequate internal hemostasis.

V. DOCUMENTATION

Reporting should be in accordance with the [ACR Practice Parameter for Communication of Diagnostic Imaging Findings](#) [5].

Permanent records of ultrasound-guided breast interventional procedures should be documented in a retrievable image storage format. When appropriate, correlative mammography should be performed in conjunction with the procedure.

A. Image labeling should include the following:

1. Patient's first and last names
2. Identifying number and/or date of birth
3. Examination date
4. Facility name and location
5. Designation of the left or right breast
6. Anatomic location using clockface notation; a labeled diagram of the breast may be included
7. Distance from the nipple to the lesion in centimeters
8. Transducer orientation
9. Performing physician or sonographer

B. The physician's report of ultrasound-guided interventional procedures of the breast should include the following:

1. Procedure performed
2. Designation of left or right breast
3. Description and location of the lesion in the breast using clockface or other consistent accepted notation
4. Safety time-out having been performed
5. Skin incision, if made
6. Type and amount of local anesthesia
7. Needle gauge and device type (spring loaded, vacuum assisted, etc)
8. Percutaneous approach
9. Number of specimen cores or samples, if applicable
10. Complications and treatment, if any
11. Results of sonographic or radiographic specimen images, if performed
12. Localizing tissue marker information including shape, if placed. If multiple tissue markers are placed, they should be clearly identified according to shape and site.
13. Documented presence or absence of a sonographically evident residual mass for future localization and follow-up purposes
14. Postprocedure mammogram, if obtained, documenting tissue marker placement and location of the tissue marker with respect to the biopsied lesion if visible mammographically

C. Postprocedure patient follow-up should include the following:

1. Documentation of any delayed complications and treatment administered.
2. Determination of concordance of pathology results with imaging findings by the physician who performed the procedure or the physician-designee, with documentation in the record. When results are benign and concordant, the patient may return to annual screening. When discordant, biopsy should be repeated by imaging guidance or surgical excision [37].
3. Recommendations based on tissue sampling results, imaging information, and concordance analysis. Surgical consultation is usually recommended for high-risk lesions known to be subject to upgrade, including atypical ductal hyperplasia, flat epithelial atypia, lobular neoplasia (atypical lobular hyperplasia and lobular carcinoma in situ), radial scar, complex sclerosing lesion, phyllodes tumor, and, to a lesser degree, papilloma [41-52]. However, controversies exist regarding high-risk lesions, and care should be individualized when appropriate. For malignant results, patients are referred for consultation with a surgeon or oncologist.
4. Record of communications with the patient and/or referring physician.

D. Retention of the procedure images, including any specimen images, should be consistent with the facility's policies for retention of images and in compliance with federal and state regulations.

E. For further information regarding breast accreditation requirements and quality assurance, see the ACR accreditation support pages for [Quality Assurance: Breast MRI](#) and the [Quality Assurance: Breast Ultrasound](#).

VI. EQUIPMENT SPECIFICATIONS

Equipment performance monitoring should be in accordance with the [ACR–AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Real Time Ultrasound Equipment](#) [53].

A. Ultrasound

High-resolution, linear-array, broad-bandwidth transducers are preferred for breast ultrasound examinations and percutaneous procedures. The transducers should be operated at the highest clinically appropriate frequency. Ordinarily, transducer frequencies of 12 MHz or higher are used for breast imaging and interventional procedures.

B. Tissue Acquisition Needle Systems

For cyst aspiration and FNA biopsy, the appropriate gauge needle for the procedure should be used with any aspirating device, tubing, or syringes.

Assuming accurate targeting and sampling, spring-loaded needle systems provide samples adequate for diagnosis of most lesions amenable to ultrasound-guided biopsy. For spring-loaded devices, most data support the use of 14-gauge and larger needles. Vacuum-assisted core-needle biopsy and other biopsy systems are also available for use in ultrasound-guided procedures [54-59].

VII. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION

Policies and procedures related to quality, patient education, infection control, and safety should be developed and implemented in accordance with the ACR Policy on Quality Control and Improvement, Safety, Infection Control, and Patient Education appearing under the heading *ACR Position Statement on Quality Control & Improvement, Safety, Infection Control, and Patient Education* on the ACR website (<https://www.acr.org/Advocacy-and-Economics/ACR-Position-Statements/Quality-Control-and-Improvement>).

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