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

PREAMBLE

These guidelines are an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. They are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care. For these reasons and those set forth below, the American College of Radiology cautions against the use of these guidelines 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 physician or medical physicist in light of all the circumstances presented. Thus, an approach that differs from the guidelines, 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 the guidelines when, in the reasonable judgment of the practitioner, such course of action is indicated by the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication of the guidelines. However, a practitioner who employs an approach substantially different from these guidelines is advised to document in the patient record information sufficient to explain the approach taken.

The practice of medicine involves not only the science, but also 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 these guidelines 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 sole purpose of these guidelines is to assist practitioners in achieving this objective.

I. INTRODUCTION

Breast interventional procedures may be diagnostic, such as tissue sampling, or therapeutic, such as abscess drainage, or both diagnostic and therapeutic, such as cyst aspiration. They include, but are not limited to, cyst aspiration, abscess drainage, presurgical needle localization, fine needle aspiration (FNA) biopsy, and core needle biopsy (CNB).

Ultrasound is one of several imaging techniques that may be used to guide interventional procedures. Other breast imaging modalities used for guidance include mammography (conventional and stereotactic), magnetic resonance imaging (MRI), and computed tomography (CT).

Developers of other techniques for detecting suspicious breast lesions should acknowledge the need for a capability to biopsy lesions that are uniquely detected by those modalities, and they should attempt to develop such a capability along with their techniques.

II. GENERAL PRINCIPLES

Minimally invasive biopsy is preferable to open surgical biopsy for diagnosing breast lesions under appropriate circumstances.

Advantages of percutaneous procedures include:

- A. Reduced morbidity, with better cosmetic results and less scarring detectable on future breast imaging.
- B. Improved cost effectiveness with less time lost from normal activities.
- C. Accuracy comparable to open surgical biopsy.

Prior to the performance of any ultrasound-guided percutaneous procedure, the lesion should be evaluated completely with an ultrasound study in accordance with the [ACR Practice Guideline for the Performance of a Breast Ultrasound Examination](#) 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 on ultrasound before the interventional procedure is undertaken.

Successful use of ultrasound to guide breast interventional procedures relies on high-quality imaging, expertise in lesion characterization and patient selection, experience in ultrasound-guided techniques for accurate lesion localization and sampling, and effective methods of obtaining tissue for analysis. The imaging assessment and the cytopathologic or histopathologic interpretations should be correlated for concordance by the physician performing the biopsy, and records should be kept to document results and patient management recommendations.

When a lesion can be identified sonographically, ultrasound may be selected for interventional guidance because of operator experience or preference, patient comfort, efficiency, economy, absence of ionizing radiation or sampling accuracy (real-time visualization of the needle or other instrument within the lesion).

III. INDICATIONS/CONTRAINDICATIONS

A. Indications

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

1. Simple and complicated cysts when:
 - a. They are symptomatic.
 - b. Documentation of evacuation is desirable.
 - c. Imaging guidance would help avoid complications.
 - d. Correlation with other imaging findings (mammography, MRI) is likely to provide important diagnostic information that will guide patient management.

- e. Abscesses or infected cysts are suspected, and diagnostic aspiration and therapeutic drainage are clinically indicated.

2. Complex and solid masses (see Appendix) when:

- a. Masses are assessed as highly suggestive of malignancy (Breast Imaging Reporting and Data System, Breast Imaging Atlas [BI-RADS[®]] Category 5), to confirm the diagnosis and guide definitive treatment.
- b. Masses are assessed as suspicious abnormalities (BI-RADS[®] Category 4).
- c. There is more than 1 suspicious mass, particularly in a multicentric distribution, to facilitate treatment planning.
- d. Masses are assessed as probably benign (BI-RADS[®] Category 3) only when there are valid clinical indications [1].
- e. Masses seen on “targeted” ultrasound examination correlate with suspicious areas of enhancement present on contrast-enhanced breast MRI [2].

3. Repeat biopsy

Repeat ultrasound-guided percutaneous core or vacuum-assisted needle biopsy sampling is an alternative to surgical biopsy in cases when the initial core biopsy results are nondiagnostic or discordant with the imaging findings, or if an initial FNA biopsy yields atypical, suspicious, or nondiagnostic cytology.

4. Presurgical localization

Ultrasound-guided localization may be performed when the lesion or an appropriately positioned marking device placed during a previous biopsy is identifiable with ultrasound.

5. Biopsy of lymph nodes in the axilla/axillary tail in cases of known or suspected malignancy.

When the suspicion of malignancy is high, and if abnormal lymph nodes are seen within the axilla or axillary tail, FNA or core biopsy sampling of the cortex of the abnormal lymph node(s) can be performed at the time of initial imaging-guided core biopsy of the suspicious breast mass, or at a later time [3]. Care should be taken if core biopsy is performed in the axilla due to the presence of sensitive structures (the brachial plexus and axillary artery and vein).

B. Contraindications

Inability to visualize the target or breast lesion sonographically is a contraindication to ultrasound guided biopsy or drainage. Prior to the procedure the patient should be asked about allergies, use of medications such as aspirin or anticoagulants, and whether there is a history of a bleeding diathesis.

IV. QUALIFICATIONS AND RESPONSIBILITIES OF THE PHYSICIAN

A. General Qualifications

Ultrasound-guided percutaneous breast interventional procedures should be performed by qualified physicians. The physician should meet the qualifications outlined in the [ACR Practice Guideline for the Performance of a Breast Ultrasound Examination](#). In cases where mammography has been performed, the physician should either meet the initial qualifications specified in the [ACR Practice Guideline for the Performance of Screening and Diagnostic Mammography](#) or should review the mammographic findings with a physician who has the qualifications specified in the Mammography Quality Standards Act (MQSA). 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

Initial qualifications

Initial qualifications include a minimum of 8 hours of Category 1 CME didactic instruction in ultrasound-guided biopsy techniques and performance of at least 12 ultrasound-guided breast biopsy procedures under the supervision of a qualified physician. Completion of a residency or fellowship program that includes instruction in ultrasound-guided breast needle procedures is also acceptable.

Maintenance of competence

The physician should perform at least 24 ultrasound-guided breast biopsies every 2 years.

Continuing medical education

The physician should obtain at least 3 hours of Category 1 CME in ultrasound-guided breast biopsy every 3 years.

C. Responsibilities for Assessment of Concordance

The physician who performs the procedure is responsible for obtaining results of the cytopathologic or histopathologic sampling to determine if the lesion has been adequately biopsied and is concordant or discordant with the imaging findings. These results should be communicated to the referring physician and/or to the patient, as appropriate [4].

V. SPECIFICATIONS OF THE PROCEDURE

The written or electronic request for an ultrasound-guided breast procedure should provide sufficient information to demonstrate the medical necessity of the examination and allow for its proper performance and interpretation.

Documentation that satisfies medical necessity includes 1) signs and symptoms and/or 2) relevant history (including known diagnoses). Additional information regarding the specific reason for the examination or a provisional diagnosis would be helpful and may at times be needed to allow for the proper performance and interpretation of the examination.

The request for the examination must be originated by a physician or other appropriately licensed health care provider. The accompanying clinical information should be provided by a physician or other appropriately licensed health care provider familiar with the patient's clinical problem or question and consistent with the state's scope of practice requirements. (ACR Resolution 35, adopted in 2006)

The decision to perform an interventional procedure should conform to the general principles noted in section II above. A complete ultrasound examination of the mass or area of the breast in which the procedure is planned should be performed. (See the [ACR Practice Guideline for the Performance of a Breast Ultrasound Examination](#).)

Benefits, limitations, and risks of the procedure as well as alternative procedures 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 required for procedures in non-operating room settings including bedside procedures. "Time out" must be conducted in the location where the procedure will be done, just before starting the procedure and must:

- Involve the entire operative team.
- Use active communication.
- Be briefly documented, such as in a checklist, and include at least:
 - Correct patient identity.
 - Correct side and site.
 - Agreement on the procedure to be done.
 - Correct patient position.
 - Availability of any special equipment or special requirements.

The facility should have procedures in place for reconciling differences in staff responses during the “time out.”

The breast, the probe, and the field in which the procedure is to be performed should be prepared in conformity with the principles of cleanliness to minimize the risk of infection.

Using a high-frequency transducer, continuous visualization of the needle path is possible. During performance of an ultrasound-guided intervention, the long axis of the needle, especially its tip, should be visible along the long axis of the transducer. The needle/probe should be kept as parallel to the chest wall and transducer face as possible throughout the performance of an ultrasound-guided intervention. Occasionally, during an FNA biopsy or cyst aspiration, depending on the location of the lesion, a steeper (nonparallel) approach may be appropriate. If desired or if there is concern for partial volume averaging within a small lesion, the transducer can be rotated 90 degrees to visualize the echogenic dot of the needle within the lesion. Documentation of appropriate needle positioning for sampling should be part of the medical record. Coaxial techniques may also be used with ultrasound-guided FNA and CNB [5].

Following performance of core biopsy, and as appropriate following aspiration or FNA biopsy, placement of a localizing clip at the biopsy or aspiration site should be considered to facilitate surgical excision if necessary, especially for lesions that may be difficult to visualize on subsequent ultrasound examinations, for mammographically occult lesions, for those that may undergo neoadjuvant chemotherapy, and for correlating with findings on other imaging modalities [6]. When multiple lesions are present and biopsy of more than 1 suspicious lesion is performed to establish multicentricity, placement of markers of different shapes should be considered.

When a clip has been placed, a postbiopsy mammogram consisting of craniocaudal and 90-degree lateral views is recommended following the procedure to document clip location. Additional views, such as exaggerated craniocaudal (CC) or mediolateral oblique views, may be necessary to visualize the clip.

To minimize hematoma formation following core biopsy, or following FNA biopsy or aspiration in patients who are at risk for bleeding, the skin entry site and the path of the needle should be adequately compressed until hemostasis is achieved.

VI. DOCUMENTATION

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:

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 clock face notation or labeled diagram of the breast.
7. Transducer orientation.
8. Distance from the nipple to the abnormality or the area being scanned in centimeters.

Other information that can be entered on the permanent record includes the technologist’s and physician’s initials.

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

1. Procedure performed.
2. Designation of left or right breast.
3. Description and location of the lesion in the breast using diagrammatic, clock face, or other consistent notation.
4. Type and amount of local anesthesia, if used.
5. Gauge of needle and type of device (spring-loaded, vacuum-assisted, etc.).
6. Complications and treatment, if any.
7. Specimen radiographs or sonograms, if performed, and their results.
8. Clip placement, if performed.
9. Postprocedure mammogram and/or sonogram, if obtained, documenting clip placement and location of the clip with respect to the biopsied lesion.

Other information that can be put in the report includes the number of passes made or cores obtained.

C. Postprocedure patient follow-up should include:

1. Documentation of any delayed complications and treatment administered.

2. A determination of concordance of pathology results with imaging findings, with documentation in the record.
3. Recommendations based on tissue sampling results, imaging information, and concordance analysis.
4. Record of communications with the patient and/or referring physician.

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

E. Retention of the procedure images, including specimen images if obtained, should be consistent with the facility’s policies for retention of images and in compliance with federal and state regulations.

VII. EQUIPMENT SPECIFICATIONS

A. Ultrasound

High-resolution linear array 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 10 MHz or higher are used for breast imaging and interventional procedures. All equipment should be in accordance with the [ACR Practice Guideline for the Performance of a Breast Ultrasound Examination](#).

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 of the data support the use of larger caliber needles (14 gauge and larger). Vacuum-assisted needle and radiofrequency biopsy systems are also available for use in ultrasound-guided procedures; however, they have not been proven to offer any significant difference in outcome compared to spring-loaded systems [7-11]. Depending on the size of the needle, in general, 3 to 6 core samples should be taken at each site [12].

VIII. 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 elsewhere in the ACR Practice Guidelines and Technical Standards book.

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

Results of ultrasound-guided as well as other imaging-guided percutaneous breast interventional procedures should be monitored. The following records should be maintained for the facility, practice, and individual physicians:

1. Total number of procedures.
2. Total number of cancers found.
3. Total number of benign lesions.
4. Total number of ultrasound-guided biopsies needing repeat biopsy, categorized by reason and type of biopsy (i.e., CNB, FNA):

Reason for Repeat	Data
Insufficient sample	<ul style="list-style-type: none"> • Total number of cases. • Number with repeat biopsy performed by core. • Number with repeat biopsy performed by excision. • Final pathology results.
Discordance with imaging	<ul style="list-style-type: none"> • Total number of cases. • Number with repeat biopsy performed by core. • Number with repeat biopsy performed by excision. • Final pathology results.
Cellular atypia, radial scar	<ul style="list-style-type: none"> • Total number of cases. • Number with repeat biopsy performed by core. • Number with repeat biopsy performed by excision. • Final pathology results.
Other	<ul style="list-style-type: none"> • Total number of cases. • Number with repeat biopsy performed by core. • Number with repeat biopsy performed by excision. • Final pathology results.

Imaging findings and pathologic interpretation should be correlated by a qualified physician. Postbiopsy follow-up should be performed to detect and record any false-negative and false-positive results.

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APPENDIX

BREAST IMAGING REPORTING AND DATA SYSTEM, BREAST IMAGING ATLAS

Assessment Categories - Ultrasound

A. Assessment Is Incomplete

Category 0 - Need Additional Imaging Evaluation

In many instances, the ultrasound examination completes the evaluation of the patient. If ultrasound is the initial study, other examinations may be indicated. An example would be the need for mammography if ultrasound were the initial study for a patient in her late 20's evaluated with ultrasound for a palpable mass that had suspicious sonographic features. Another example might be where mammography and ultrasound are nonspecific, such as differentiating between scarring and recurrence in a patient with breast cancer treated with lumpectomy and radiation therapy. Here, MRI might be the recommendation. A need for previous studies to determine appropriate management might also defer a final assessment.

B. Assessment Is Complete – Final Categories

Category 1 - Negative

This category is for sonograms with no abnormality, such as a mass, architectural distortion, thickening of the skin or microcalcifications. For greater confidence in rendering a negative interpretation, an attempt should be made to correlate the ultrasound and mammographic patterns of breast tissue in the area of concern.

Category 2 - Benign finding(s)

Essentially a report that is negative for malignancy. Simple cysts would be placed in this category, along with intramammary lymph nodes (also possible to include in Category 1), breast implants, stable postsurgical changes, and probable

fibroadenomas noted to be unchanged on successive ultrasound studies.

Category 3 - Probably benign finding - short interval follow-up suggested

With accumulating clinical experience and by extension from mammography, a solid mass with circumscribed margins, oval shape and horizontal orientation, most likely a fibroadenoma, should have a less than 2% risk of malignancy. Although additional multicenter data may confirm the safety of follow-up rather than biopsy based on ultrasound findings, short-interval follow-up is currently increasing as a management strategy. Nonpalpable complicated cysts and clustered microcysts might also be placed in this category for short-interval follow-up.

Category 4 - Suspicious abnormality - biopsy should be considered

Lesions in this category would have an intermediate probability of cancer, ranging from 3% to 94%. An option would be to stratify these lesions, giving them a low, intermediate, or moderate likelihood of malignancy. In general, Category 4 lesions require tissue sampling. Needle biopsy can provide a cytologic or a histologic diagnosis. Included in this group are sonographic findings of a solid mass without all of the criteria for a fibroadenoma.

Category 5 - Highly suggestive of malignancy - appropriate action should be taken (almost certainly malignant)

The abnormality identified sonographically and placed in this category should have at least a 95% or higher risk of malignancy so that definitive treatment might be considered at the outset. With the increasing use of sentinel node imaging as a way of assessing nodal metastases and also with the increasing use of neoadjuvant chemotherapy for large malignant masses or those that are poorly differentiated, percutaneous sampling, most often with imaging-guided core needle biopsy, can provide the histopathologic diagnosis.

Category 6 - Known biopsy – proven malignancy – appropriate action should be taken

This category is reserved for lesions with biopsy proof of malignancy prior to institution of therapy, including neoadjuvant chemotherapy, surgical excision, or mastectomy.

*Guidelines and standards are published annually with an effective date of October 1 in the year in which amended, revised or approved by the ACR Council. For guidelines and standards published before 1999, the effective date was January 1 following the year in which the guideline or standard was amended, revised, or approved by the ACR Council.

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