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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 on 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 (US) 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), computed tomography (CT), and magnetic resonance imaging (MRI).

II. GENERAL PRINCIPLES

Reducing the number of diagnostic surgical procedures by substituting less invasive procedures has become possible because of the following advantages of percutaneous procedures:

- A. Similar accuracy.
- B. Lower or similar morbidity.
- C. Lower cost.

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 these images (see Section IV below).

Successful utilization 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 positioning of the sampling or localization device, and effective methods of obtaining tissue for analysis. The imaging assessment and the cytopathologic or histopathologic interpretations should be correlated for concordance, 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, patient comfort, efficiency, economy, 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 cysts, complicated cysts, and complex masses
 - a. Masses that do not fulfill the ultrasound criteria for simple cysts.
 - b. Cysts that are symptomatic.
 - c. Cysts for which documentation of evacuation is desirable.
 - d. Cysts for which imaging guidance would help avoid complications.
 - e. Suspected abscesses or infected cysts for diagnostic aspiration and therapeutic drainage.

2. Solid masses (see Appendix)

- a. Lesions that are assessed as highly suggestive of malignancy using the Breast Imaging Reporting and Data System, Breast Imaging Atlas (BI-RADS[®] Category 5), to confirm the diagnosis so that definitive treatment options can be selected.
- b. Multiple suspicious masses, particularly in a multicentric distribution (two or more quadrants), to facilitate treatment planning.
- c. Lesions that are assessed as suspicious abnormalities (BI-RADS[®] Category 4).
- d. Lesions that are assessed as probably benign (BI-RADS[®] Category 3) when there are valid clinical indications.

3. Rebiopsy

Ultrasound-guided percutaneous sampling is an alternative for repeat biopsy in cases when the initial biopsy results are discordant with the imaging assessment.

4. Presurgical localization

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

B. Contraindications

While there are no absolute contraindications to ultrasound-guided percutaneous interventional procedures, 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 bleeding diatheses.

IV. QUALIFICATIONS AND RESPONSIBILITIES OF THE PHYSICIAN

A. General Qualifications

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 Mammography](#) and the [ACR Practice Guideline for the Performance of Diagnostic Mammography](#) or should review the mammographic findings with a MQSA-qualified physician. The physician should have a thorough understanding of the indications for ultrasound examinations as well as a familiarity with the basic physical principles and limitations of the instrumentation and technology of ultrasound imaging. He/she should be capable of correlating the results of mammographic and other examinations and procedures

with the sonographic findings. The physician responsible for breast ultrasound examinations and procedures should be familiar with breast ultrasound anatomy.

See the [ACR Practice Guideline for Performing and Interpreting Diagnostic Ultrasound Examinations](#).

B. Specific Qualifications

The physician performing breast interventional procedures should adhere to the maintenance of competence recommendations in the [ACR Practice Guideline for Performing and Interpreting Diagnostic Ultrasound Examinations](#). The following specific qualifications are also recommended:

Initially, 3 hours of Category 1 CME didactic instruction in ultrasound-guided biopsy and performance of at least three 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. For maintenance of competence, the performance of at least 12 ultrasound-guided biopsies per year is recommended.

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

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 scope of practice requirements. (2006 - ACR Resolution 35)

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.
- At the least, include:
 - 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 organization should have processes and systems 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. Depending on the probe configuration, the geometry of the acoustic beam, and the route of needle entry, either a small portion of the needle may be visible as an echogenic dot or, preferably, if the needle entry is in alignment with the long axis of the transducer, the entire shaft of the needle, including its tip, should be visible. Documentation of appropriate needle positioning for sampling should be obtained as part of the medical record. Coaxial techniques may also be used with ultrasound FNA and CNB.

To minimize hematoma formation, the skin entry site and the region of needle sampling should be compressed after each needle pass, or at the conclusion of the procedure, if multiple passes are made to sample a lesion.

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. Imaging labeling should include permanent identification containing:

1. Facility name and location.
2. Designation of the left or right breast.
3. Examination date.
4. Patient's first and last names.
5. Identification number and/or date of birth.
6. Location of the lesion in the breast using diagrammatic, clock face, or other consistent notation.
7. Scan plane.
8. Initials of physician(s) performing the procedures.

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

1. Procedure performed.
2. Description and location of the lesion in the breast using diagrammatic, clock face, or other consistent notation.
3. Type and amount of local anesthesia, if used.
4. Designation of the left or right breast.
5. Skin incision, if made.
6. Complications and treatment, if any.
7. Specimen radiographs or sonograms, if performed, and their results.
8. Clip placement, if performed.
9. Postprocedure mammography and/or sonography, if obtained.

C. Postprocedure patient follow-up should include:

1. Identification of delayed complications and required treatment, if any.
2. A determination of concordance of pathology results with imaging findings, if any.
3. Record of communications with the patient and/or referring physician.
4. Recommendations based on tissue sampling results and imaging information.

D. 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. These results should be communicated to the referring physician and/or to the patient, as appropriate.

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

F. 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

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 7 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](#).

VIII. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION CONCERNS

Results of ultrasound-guided and other imaging-guided percutaneous breast interventional procedures should be monitored.

Records should be kept of the number of cancers diagnosed and the number of complications requiring treatment. Also to be recorded are the numbers of inconclusive results, inadequate samples, and recommendations for rebiopsy or complete excision of a lesion. Imaging findings and pathologic interpretations should be correlated. Biopsy follow-up should be performed to detect and record any false-negative and false-positive results.

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 Concerns 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](#).

This guideline was revised according to the process described in the ACR Practice Guidelines and Technical Standards book by the Guidelines and Standards Committee of the Commission on General and Pediatric Radiology and the Committee on Breast Cancer.

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APPENDIX A

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 US 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 safety of follow-up rather than biopsy based on US 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.