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

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 care[1]. 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 in light of 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 the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document 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 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 sole 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, ___ N.W.2d ___ (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

Image-guided core-needle biopsy (CNB) has become the procedure of choice for most image-detected breast lesions requiring tissue diagnosis. Its advantages over surgical biopsy are well recognized, including less scarring, fewer complications, faster recovery, less cost, and similar accuracy [1-9].

High-quality breast imaging evaluation is necessary to detect early or subtle breast lesions as well as to accurately target these lesions for image-guided biopsy. Several imaging modalities are commonly available and in clinical use for image-guided breast interventions, including stereotactic guidance, ultrasound (US), and magnetic resonance imaging (MRI). The choice of guidance technique will depend on lesion visualization and accessibility, availability of the imaging modality, efficiency, safety, patient comfort, and the practitioner's experience [1].

Stereotactic guidance enables percutaneous placement of a needle within the breast to sample mammographically detected suspicious breast lesions. This technique, along with the other methods of image-guided biopsy, has changed the management of breast disease. Percutaneous biopsy techniques have decreased the number of benign surgical biopsies generated from breast imaging programs and have decreased the number of surgical procedures needed to treat breast cancer [3,5-7].

Therefore, minimally invasive biopsy is preferable to open surgical biopsy for diagnosing breast lesions .

Successful use of stereotactic-guided breast interventional procedures relies on high-quality imaging, expertise in breast imaging feature analysis, experience in stereotactic-guided techniques for accurate lesion localization and sampling, and effective methods of obtaining tissue for analysis [10-13]. The imaging features and the histopathologic interpretations should be assessed for concordance by the physician performing the biopsy, and records should be kept to document results and patient management recommendations [1].

II. INDICATIONS/CONTRAINDICATIONS

A. Indications

Stereotactic-guided breast intervention is suitable for most mammographically depicted lesions, including microcalcifications, masses, asymmetries, and architectural distortions.

Indications for stereotactic-guided breast intervention include, but are not limited to, the following:

1. Biopsy for primary diagnosis (see Appendix) of:

    a. Lesions that are assessed as highly suggestive of malignancy in the Breast Imaging Reporting and Data System, Breast Imaging Atlas (BI-RADS®) Category 5 [14]
    b. Lesions that are assessed as suspicious abnormalities (BI-RADS® Category 4)
    c. Lesions that are assessed as probably benign (BI-RADS® Category 3) when there are valid clinical indications or when short-interval imaging follow-up would be difficult or unreasonable (eg, if the patient has a synchronous known breast cancer, is awaiting organ transplantation, plans to become pregnant in immediate future, etc) [15-18]
    d. Multiple suspicious lesions, particularly in a multifocal or multicentric distribution, to facilitate treatment planning
    e. Lesions seen on mammography that correlate with suspicious areas of enhancement present on contrast-enahnced breast MRI.

2. Repeat biopsy

    Repeat stereotactic-guided percutaneous sampling is an alternative to surgical biopsy in cases when the initial core biopsy results are nondiagnostic or are discordant with the imaging findings [1,19,20].

3. Presurgical localization

Stereotactic-guided localization may be used as an alternative to standard mammographic localization for mammographically identifiable lesions prior to surgical procedures [21]. Localization may be performed with wire, needle-wire combination, or radioactive seeds.

B. Contraindications

Inability to revisualize the target or breast lesion stereotactically at the time of the biopsy is a contraindication to stereotactic-guided breast intervention. For lesions that are equally well seen on mammography and ultrasound, ultrasound guidance is usually preferred. Prior to the procedure, the patient should be asked about allergies; use of medications such as aspirin, anticoagulants, or other agents known to impact bleeding times; and whether there is a history of a bleeding diathesis. However, a recent report suggested that it is safe to proceed with biopsy when patients are anticoagulated [22]. Decisions regarding postponement or cancellation of a procedure or cessation of anticoagulants can be made on a case-by-case basis at a programmatic level. The patient's weight (for prone table) and ability to remain in the position required for the procedure should also be assessed in determining the appropriateness of the procedure for that patient.

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A. Physician

Stereotactic-guided breast biopsy procedures should be performed by physicians who meet the "Physician Qualifications for Stereotactic Breast Biopsy" [23,24]. Stereotactic breast biopsies may be performed in either collaborative or independent settings[2].

Interpretative experience in screening and diagnostic mammography is essential for those performing stereotactic-guided breast procedures. Prior to the stereotactic procedure, the physician should be able to identify the significant lesion(s) on mammography so that the correct area of the breast is localized or biopsied. This is particularly important when small field-of-view imaging equipment is used.

1. Initial qualifications

Training in mammographic image interpretation, medical physics and specific hands-on training in the performance of stereotactic biopsy are imperative to successful performance of this procedure.

The initial qualifications as outlined for Stereotactic Breast Biopsy Accreditation Program Requirements provide this foundation [24].

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 in 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 (CME) [25].

[2]The following definitions are taken from the ACR Stereotactic Breast Biopsy Accreditation Program Requirements: A collaborative setting is one where both radiologists and surgeons (or other physicians) conduct stereotactic breast biopsy procedures. An independent setting is one where either radiologists or other physicians (typically surgeons) conduct stereotactic breast biopsies.

4. Responsibilities for assessment of concordance

   The physician who performs the procedure (either the radiologist or, in the collaborative setting, the surgeon) is responsible for determining adequacy of sampling. The performing physician or, if unavailable, his/her qualified physician-designee, is responsible for obtaining histopathologic results and determining concordance [1,19-21,26]. These results should be communicated to the referring physician and/or to the patient, as appropriate.

B. Qualified Medical Physicist

1. Initial qualifications

   Medical physicists should meet the qualifications specified in the ACR Practice Parameter for the Performance of Screening and Diagnostic Mammography [27]. In addition medical physicists should have performed at least 1 hands-on stereotactic breast biopsy unit survey under the guidance of a medical physicist qualified to perform such surveys [24].

2. Maintenance of competence

   Medical physicists should perform at least 2 stereotactic breast biopsy unit surveys every 2 years [24].

3. Continuing medical education

   Medical physicists should obtain 3 hours of CME in stereotactic breast biopsy unit physics every 3 years [24].

C. Radiologic Technologist

1. Initial qualifications

   Radiologic technologists should meet the qualifications specified in the ACR Practice Parameter for the Performance of Screening and Diagnostic Mammography [27]. Radiologic technologists should also have 3 hours of Category A continuing education units in stereotactic-guided breast intervention and must have participated in at least 5 hands-on procedures under the guidance of a qualified physician or radiologic technologist [24].

2. Maintenance of competence

   Radiologic technologists should participate in at least 24 stereotactic-guided breast interventions every 2 years [24].

3. Continuing medical education

   Radiologic technologists should be in compliance with the continuing education requirements of their certifying organization for the imaging modality for which they perform services [24].

IV. SPECIFICATIONS OF THE PROCEDURE

A. Prior to the Procedure

The written or electronic request for a stereotactic-guided breast intervention examination 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 a stereotactic-guided breast interventional procedure should be made by an MQSA certified physician and only after adequate imaging evaluation, including orthogonal views, of the breast is performed.

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 [1].

Adherence to the Joint Commission's Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery™ is required for procedures in nonoperating room settings (see http://www.jointcommission.org/standards_information/up.aspx for more information).

The organization should have processes and systems in place for reconciling differences in staff responses during the "time-out."

B. Procedure Technique

The breast is compressed between the image receptor and the compression plate. Imaging is performed to confirm that the targeted lesion lies within the accessible area. Lesion targeting should be performed by the physician performing and/or supervising the procedure. The computer-generated coordinates are then transferred to the stereotactic targeting device, and the skin entry site is prepared.

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

Documentation of appropriate needle positioning for sampling or localization should be obtained as part of the medical record.

When the biopsy is performed for microcalcifications, a magnification image of the core biopsy specimens should be obtained to verify that the microcalcifications have been adequately sampled [1,26,28].

Following performance of stereotactic-guided breast biopsy, a tissue marker should be placed at the biopsy site whenever a lesion may be difficult to see after the biopsy (eg, complete removal of the target or a subtle target), when needing confirmation that the proper lesion has been sampled, or if neoadjuvant chemotherapy is contemplated. When multiple lesions are present and biopsy of >1 suspicious lesion is performed, placement of markers with different characteristics should be considered.

To minimize hematoma formation, the skin entry site and the region of needle sampling should be adequately compressed until hemostasis is achieved.

Postprocedure mammography should be performed in 2 orthogonal views to document tissue marker position, and the report should state the position in relation to the biopsy site.

V. DOCUMENTATION

Permanent records of stereotactic-guided breast interventions should be documented in retrievable image storage format.

A. Image labeling should include permanent identification containing 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 left or right breast
6. Annotation of mammographic view (eg, craniocaudal, mediolateral oblique (MLO), 90° mediolateral [ML])
7. Technologist's identification number or initials

Physician identification may be included on the permanent image record.

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

1. Procedure performed
2. Designation of the left or right breast
3. Description and location of the lesion
4. Safety time-out having been performed
5. Approach used
6. Type and amount of local anesthesia
7. Skin incision, if made
8. Gauge of needle and type of device (spring-loaded, vacuum-assisted, etc)
9. Number of specimen cores or samples, if applicable
10. Specimen images, if performed, and their results
11. Tissue marker placement, if performed
12. Complications and treatment, if any
13. Postprocedure mammography, if obtained, documenting tissue marker placement and location of the marker with respect to the biopsied lesion
14. Other information may include presence or absence of residual calcification or mammographically evident residual mass for future localization and follow-up purposes.

C. Postprocedure patient follow-up should consist of the following:

1. Documentation of any delayed complications and treatment administered
2. A determination of concordance of pathology results with imaging findings by the physician who performed the procedure or his/her physician-designee. When discordant, biopsy should be repeated by imaging guidance or surgical excision [1,19,20].
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 [29-41]. However, controversies exist regarding high-risk lesions, and care should be individualized when appropriate [42,43]. For malignant results, patients are usually referred for consultation to a surgeon or oncologist.
4. Record of communications with the patient and/or referring physician

D. Reporting should be in accordance with the ACR Practice Parameter for Communication of Diagnostic Imaging Findings [44].

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

VI. EQUIPMENT SPECIFICATIONS

Radiographic equipment used for stereotactic-guided breast intervention procedures includes prone and add-on systems. The equipment should be calibrated by the manufacturer, and the medical physicist should complete verification of calibration and acceptance testing upon installation [45,46].

Several needle biopsy devices are available for stereotactic-guided procedures, including automated core needles, vacuum-assisted devices, and other tissue biopsy systems. The choice of biopsy device depends on the type of lesion as well as the operator's experience. However, vacuum-assisted devices of 11 gauge and larger have been shown to be most effective in the performance of stereotactic biopsy for microcalcifications [47].

VII. EQUIPMENT QUALITY CONTROL

Refer to ACR stereotactic breast biopsy quality control manual [46].

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 under the heading *Position Statement on QC & Improvement, Safety, Infection Control, and Patient Education* on the ACR website (http://www.acr.org/guidelines).

A documented quality control program with procedure manuals and records should be maintained for stereotactic-guided breast interventions. Imaging findings and pathologic interpretations should be correlated. Results of stereotactic-guided breast interventions should be monitored.
The following records should be maintained for the facility, practice, and individual physicians:

- Total number of procedures
- Total number of cancers found
- Total number of benign lesions
- Total number of stereotactic biopsies needing repeat biopsy, categorized by reason and type of biopsy:

Reason for Repeat Biopsy	Data
Insufficient sample	• Total number of cases • Number with repeat biopsy • Final pathology results
Discordance	• Total number of cases • Number with repeat biopsy • Final pathology results
High-risk lesions	• Total number of cases • Number with repeat biopsy • Final pathology results

Imaging findings and pathologic interpretation should be correlated by the physician who performs the biopsy or his/her qualified physician-designee. Postbiopsy patient follow-up should be performed to detect and record any false-negative and false-positive results.

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APPENDIX

ACR BI-RADS® ATLAS (BREAST IMAGING REPORTING AND DATA SYSTEM 2013 [14] (BI-RADS® Category 5)

Assessment	Management	Likelihood of Cancer
Category 0: Incomplete – need additional imaging	Recall for additional imaging	N/A

evaluation		
Category 1: Negative	Routine screening	Essentially 0% likelihood of malignancy
Category 2: Benign	Routine screening	Essentially 0% likelihood of malignancy
Category 3: Probably benign	Short-interval (6-month) follow-up or continued surveillance	>0% but ≤2% likelihood of malignancy
Category 4: Suspicious Category 4A: *Low suspicion* for malignancy Category 4B: *Moderate suspicion* for malignancy Category 4C: *High suspicion* for malignancy	Tissue diagnosis	>2% but <95% likelihood of malignancy >2% to ≤10% likelihood of malignancy >10% to ≤50% likelihood of 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

*Practice parameters and technical 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 practice parameters and technical standards published before 1999, the effective date was January 1 following the year in which the practice parameter or technical standard was amended, revised, or approved by the ACR Council.

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