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ACR PRACTICE GUIDELINE FOR THE PERFORMANCE OF STEREOTACTICALLY GUIDED 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

Imaging guided fine-needle aspiration (FNA) and core needle biopsy (CNB) are alternatives to excisional biopsy following conventional mammographic needle localization for many mammographically depicted breast lesions that require tissue sampling for diagnosis. High quality breast imaging evaluation is necessary to establish the need for biopsy. Several imaging modalities are currently available and in clinical use for imaging guidance for breast interventional procedures, including stereotactic mammographic guidance, conventional mammographic guidance (alphanumeric fenestrated paddle), ultrasound (US), magnetic resonance imaging (MRI), and computed tomography (CT). The choice of guidance techniques will depend on lesion visualization and access, availability of the imaging modality, efficiency, safety, and the practitioner's experience.

For mammographically visible lesions, stereotactically guided biopsy is an option. Presurgical needle localization can also be performed with stereotactic guidance.

II. GENERAL PRINCIPLES

Stereotactic guidance uses off-angled views for computer-aided targeting of mammographically visible lesions. 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.

III. INDICATIONS/CONTRAINDICATIONS

A. Indications

Indications for stereotactically guided needle localization or biopsy include, but are not limited to, the following:

1. Primary diagnosis (see Appendix)

    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), to confirm the diagnosis so that definitive treatment options can be selected.
    b. Multiple suspicious lesions, particularly in a multicentric distribution (two or more different 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 findings (BI-RADS® Category 3) when there are valid clinical indications.

2. Rebiopsy

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

3. Presurgical localization

    Stereotactic localization may be used as an alternative to standard mammographic localization for mammographically identifiable lesions prior to surgical procedures.

B. Contraindications

While there are no absolute contraindications to stereotactically guided interventional procedures, prior to the procedure the patient should be asked about allergies, use of medications such as aspirin or anticoagulants, and whether she has a history of bleeding diatheses. The patient's weight 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.

IV. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

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.

A. General Qualifications

Interpretative experience in screening and diagnostic mammography is essential for those performing stereotactically guided FNA or CNB. 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 employed. Technologists and medical physicists need specialized skills to optimize their participation in this procedure.

Medical physicists and radiologic technologists who work in mammography must meet the requirements of the Mammography Quality Standards Act (MQSA) final rule as published by the Food and Drug Administration (FDA), and the ACR Practice Guideline for the Performance of Screening Mammography and the ACR Practice Guideline for the Performance of Diagnostic Mammography.

B. Specific Qualifications

In addition to the qualification requirements stated above for personnel performing mammography, the following specific qualifications for personnel participating in stereotactically guided biopsy are recommended:

1. Physician

    Initially, 3 hours of Category 1 CME didactic instruction in stereotactically guided biopsy and performance of at least three stereotactic breast biopsy procedures under the supervision of a qualified physician. Completion of a residency

or fellowship program that includes instruction in stereotactic breast needle procedures is also acceptable. For maintenance of competence, the performance of at least 12 stereotactically guided biopsies per year is recommended.

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

2. Qualified medical physicist

   Initially perform at least one hands-on stereotactic breast biopsy physics survey under the guidance of a medical physicist qualified to perform such surveys. In addition, 3 hours of continuing education in stereotactic breast biopsy physics every 3 years as well as the performance of at least one survey of a stereotactic breast biopsy unit each year.

3. Radiologist assistant

   A radiologist assistant is an advanced level radiographer who is certified and registered as a radiologist assistant by the American Registry of Radiologic Technologists (ARRT) after having successfully completed an advanced academic program encompassing an ACR/ASRT (American Society of Radiologic Technologists) radiologist assistant curriculum and a radiologist-directed clinical preceptorship. Under radiologist supervision, the radiologist assistant may perform patient assessment, patient management and selected examinations as delineated in the Joint Policy Statement of the ACR and the ASRT titled "Radiologist Assistant: Roles and Responsibilities" and as allowed by state law. The radiologist assistant transmits to the supervising radiologists those observations that have a bearing on diagnosis. Performance of diagnostic interpretations remains outside the scope of practice of the radiologist assistant. 2006 (Res. 34)

4. Radiologic technologist

   Initially, 3 hours of Category A continuing education units in stereotactically guided biopsy, plus documentation of five hands-on procedures under the guidance of a qualified technologist and/or the manufacturer's application specialist. For maintenance of competence, participation in at least 12 stereotactically guided biopsies per year is recommended.

V. SPECIFICATIONS OF THE PROCEDURE

The written or electronic request for a stereotactically guided breast examination should provide sufficient information to demonstrate the medical necessity of the examination and allow for the proper performance and interpretation of the examination.

Documentation that satisfies medical necessity includes 1) signs and symptoms and/or 2) relevant history (including known diagnoses). The provision of 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 (Res. 35)

The decision to perform an interventional procedure should conform to the general principles noted in Section II above. A complete mammographic examination of the mass or area of the breast in which the procedure is planned should be performed.

Benefits, limitations, and risks of the procedures as well as alternative procedures should be discussed with the patient. Informed consent should be obtained and documented.

Adherence to the JCAHO 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 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.

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

To minimize hematoma formation, the skin entry site and the region of needle sampling should be compressed at the conclusion of the procedure.

VI. DOCUMENTATION

Permanent records of stereotactically guided FNA, CNB, or preoperative localization should be documented in retrievable image storage format.

A. Image labeling should include permanent identification containing:

1. Facility name and location.
2. Examination date.
3. Patient's first and last names.
4. Identification number and/or date of birth.
5. Designation of right or left breast.
6. Technologist's identification number or initials.

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

1. Procedure performed.
2. Designation of right or left breast.
3. Description and location of lesion in the breast.
4. Type and amount of local anesthesia, if used.
5. Approach used.
6. Skin incision, if made.
7. Complication and treatment, if any.
8. Specimen radiographs if performed and their results.
9. Clip placement, if performed.
10. Postprocedure mammogram, 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.
3. Record of communication with the patient and/or referring physician.
4. Recommendations based on biopsy 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 radiographs if obtained, should be consistent with the facility's policies for retention of mammograms and in compliance with federal and state regulations.

VII. EQUIPMENT SPECIFICATIONS

Radiographic equipment that can be used for stereotactically guided percutaneous breast interventional procedures includes prone stereotactic units and add-on stereotactic devices for dedicated mammographic units. The equipment should be calibrated by the manufacturer at the time of installation. The medical physicist should complete verification of calibration and acceptance testing before use.

VIII. EQUIPMENT QUALITY CONTROL

A. Technologist's Quality Control Tests

1. Localization accuracy (daily before use on patients).
2. Darkroom cleanliness (daily if film used).
3. Processor QC (daily if film used).
4. Phantom image (weekly).
5. Screen cleanliness (weekly if film used).
6. Viewboxes and viewing conditions (weekly if film used).
7. Hard copy output quality (monthly digital only).
8. Visual checklist (monthly).
9. Compression (semiannually).
10. Repeat analysis (semiannually).
11. Screen film contact (semiannually if film used).
12. Darkroom fog (semiannually if film used).

B. Annual Medical Physicist Survey

1. Collimation assessment.
2. Focal spot performance and system limiting resolution.
3. kVp accuracy and reproducibility.
4. Beam quality assessment (half-value layer measurement).
5. Automatic exposure control (AEC) system or manual exposure performance assessment.
6. Screen speed uniformity (screen-film) or digital receptor uniformity.
7. Breast entrance exposure, average glandular dose and exposure reproducibility.
8. Image quality evaluation.
9. Artifact evaluation.
10. Localization accuracy.

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

A documented quality control program with procedure manuals and records should be maintained for stereotactically guided preoperative localizations, FNAs, and CNBs. The quality improvement/quality control program should include regular meetings of the entire team, including the radiologist, the technologist, and the medical physicist.

Results of stereotactically 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.

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Principal Reviewer: Carl J. D'Orsi, MD

Committee on Breast Cancer
Carl J. D'Orsi, MD, Chair
Lawrence W. Bassett, MD
Wendie A. Berg, MD
Robyn L. Birdwell, MD
W. Phil Evans, III, MD
Stephen A. Feig, MD
Debra M. Ikeda, MD
Valerie P. Jackson, MD
Daniel B. Kopans, MD
Lawrence Mason, MD
Ellen B. Mendelson, MD
Barbara S. Monsees, MD
Richard L. Morin, PhD
Elizabeth A. Morris, MD
Ellen S. Shaw de Paredes, MD
Edward A. Sickles, MD
Robert A. Smith, PhD
Linda J. Warren-Burhenne, MD

Guidelines and Standards Committee
Kimberly E. Applegate, MD, MS, Chair
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Bob W. Gayler, MD
Sam Kottamasu, MD
Arnold C. Merrow, MD
Diane C. Strollo, MD
Susan L. Voci, MD
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Comments Reconciliation Committee
Marcela Bohm-Velez, MD, Chair, CSC
Paul A. Larson, MD
Thomas S. Chang, MD
Carl J. D'Orsi, MD
W. Phil Evans, III, MD
Rita I. Freimanis, MD
Valerie P. Jackson, MD
Ellen B. Mendelson, MD
Steve H. Parker, MD
Ellen S. Shaw de Paredes, MD
Julie K. Timins, MD

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APPENDIX A

ACR BREAST IMAGING REPORTING AND DATA SYSTEM (BI-RADS®), BREAST IMAGING ATLAS

Assessment Categories

A. Mammographic Assessment Is Incomplete

Category 0 - Need Additional Imaging Evaluation and/or Prior Mammograms for Comparison:

Finding for which additional imaging evaluation is needed. This is almost always used in a screening situation. Under certain circumstances this category may be used after a full mammographic workup. A recommendation for additional imaging evaluation may include, but is not limited to, the use of spot compression, magnification, special mammographic views, and ultrasound.

Whenever possible, if the study is not negative and does not contain a typically benign finding, the current examination should be compared to previous studies. The radiologist should use judgment in how vigorously to attempt obtaining previous studies. Category 0 should only be used for old film comparison when such comparison is required to make a final assessment.

B. Mammographic Assessment Is Complete – Final Categories

Category 1 - Negative

There is nothing to comment on. The breasts are symmetric and no masses, architectural distortion or suspicious calcifications are present.

Category 2 - Benign Finding(s)

Like Category 1, this is a “normal” assessment, but here the interpreter chooses to describe a benign finding in the mammography report. Involuting, calcified fibroadenomas, multiple secretory calcifications, fat-containing lesions such as oil cysts, lipomas, galactoceles, and mixed-density hamartomas all have characteristically benign appearances, and may be labeled with confidence. The interpreter may also choose to describe intramammary lymph nodes, vascular calcifications, implants, or architectural distortion clearly related to prior surgery while still concluding that there is no mammographic evidence of malignancy.

Note that both Category 1 and Category 2 assessments indicate that there is no mammographic evidence of malignancy. The difference is that Category 2 should be used when describing one or more

specific benign mammographic findings in the report, whereas Category 1 should be used when no such findings are described.

Category 3 - Probably Benign Finding – Initial Short-Interval Follow-Up Suggested

A finding placed in this category should have less than a 2% risk of malignancy. It is not expected to change over the follow-up interval, but the radiologist would prefer to establish its stability.

There are several prospective clinical studies demonstrating the safety and efficacy of initial short-term follow-up for specific mammography findings.

Three specific findings are described as being probably benign (the noncalcified circumscribed solid mass, the focal asymmetry and the cluster of round (punctate) calcifications; the latter is anecdotally considered by some radiologists to be an absolutely benign feature). All the published studies emphasize the need to conduct a complete diagnostic imaging evaluation before making a probably benign (Category 3) assessment; hence it is inadvisable to render such an assessment when interpreting a screening examination. Also, all the published studies exclude palpable lesions, so the use of a probably benign assessment for a palpable lesion is not supported by scientific data. Finally, evidence from all the published studies indicates the need for biopsy rather than continued follow-up when most probably benign findings increase in size or extent.

While the vast majority of findings in this category will be managed with an initial short-term follow-up (6 months) examination followed by additional examinations until longer-term (2 years or longer) stability is demonstrated, there may be occasions where biopsy is done (patient wishes or clinical concerns).

Category 4 - Suspicious Abnormality: Biopsy Should Be Considered

This category is reserved for findings that do not have the classic appearance of malignancy but have a wide range of probability of malignancy that is greater than those in Category 3. Thus, most recommendations of breast interventional procedures will be placed within this category. By subdividing Category 4 into 4A, 4B, and 4C as suggested in the guidance chapter[1], it is encouraged that relevant probabilities for malignancy be indicated within this category so the patient and her physician can make an informed decision on the ultimate course of action.

Category 5 - Highly Suggestive of Malignancy - Appropriate Action Should Be Taken (almost certainly malignant)

These lesions have a high probability (≥95%) of being cancer. This category contains lesions for which one-stage surgical treatment could be considered without preliminary biopsy. However, current oncologic management may require percutaneous tissue sampling as, for example, when sentinel node imaging is included in surgical treatment or when neoadjuvant chemotherapy is administered at the outset.

Category 6 - Known Biopsy – Proven Malignancy – Appropriate Action Should Be Taken

This category is reserved for lesions identified on the imaging study with biopsy proof of malignancy prior to definitive therapy.

[1]American College of Radiology (ACR), ACR BI-RADS® - Mammography. 4th Edition. In: ACR Breast Imaging Reporting and Data System, Breast Imaging Atlas. Reston, VA: American College of Radiology, 2003.