

The American Society of Breast Surgeons Performance and Practice Guidelines for Breast Ultrasound

The American Society of Breast Surgeons (the Society) was formed to encourage the study of breast surgery, promote research and development of advanced surgical techniques, improve standards of practice for breast surgery in the United States, and serve as a forum for the exchange of ideas.

Article I - Introduction

This publication, *The American Society of Breast Surgeons Performance and Practice Guidelines for Breast Ultrasound*, is intended to provide the surgeon sonographer with guidelines for performing and recording high-quality ultrasound examinations of the breast in order to attain optimal breast ultrasound practices. The following guidelines reflect what the Society considers to be the basic criteria for the complete diagnostic examination of the breast, as well as for ultrasound-guided invasive breast procedures. However, use of these guidelines may require modification to adapt to a specific clinical situation.

These guidelines are based on the opinions of a panel of Society members who are experts in breast ultrasound. Panel members have served on the faculty of breast ultrasound courses sponsored by the Society and the American College of Surgeons, as well as many stand-alone courses for more than a decade. Multiple published sources were also reviewed in establishing these guidelines.¹⁻⁴

Article II – Indications for Breast Ultrasound

Breast ultrasound is useful and appropriate in multiple clinical situations, including but not limited to the following:

- a. Identification and characterization of palpable abnormalities noted on clinical breast examination
- b. Identification and characterization of localized breast symptoms, such as breast pain, fullness, and nipple discharge
- c. Identification and characterization of nonpalpable abnormalities detected on other breast imaging modalities
- d. Guidance for percutaneous and surgical procedures
- e. Evaluation and assessment of the breast after surgical or medical therapy

- f. Preoperative evaluation of breast and axilla in diagnosed breast cancer (i.e., ultrasound mapping, BIRADS 6)
- g. Identification and characterization of abnormalities associated with implants.
- h. Evaluation and assessment for radiation therapy planning.
- i. Intraoperative assessment of lumpectomy margins

Article III – Qualifications of the Surgeon Sonographer

To be qualified as a surgeon sonographer, a surgeon should:

- a. Have successfully completed an American Board of Medical Specialties (ABMS) approved residency program and must have attained board certification by the appropriate certifying Board upon completion of training or be admissible for certification.
- b. Have at least 15 hours AMA-PRA Category I CME credits in breast ultrasound, including at least one full day course including diagnostic and interventional components.
- c. Demonstrate maintenance of skills by performing at least 50 breast ultrasound examinations and at least 12 ultrasound-guided invasive procedures per year, and must earn at least 3 hours of AMA category 1 CME credit in breast ultrasound every 3 years.

To perform ultrasound guided interventional procedures, the surgeon should:

Be proctored on at least two ultrasound guided interventional procedures. The proctor must be a physician that can satisfy at least one of the following:

- i. Current certification/accreditation in breast ultrasound by the Society, the American Institute of Ultrasound in Medicine, or the American College of Radiology.
- ii. Documentation of five years' clinical experience in breast ultrasound with at least 15 hours of American Medical Association (AMA) category 1 continuing medical education (CME) credit in breast ultrasound earned in the preceding five years.

Article IV – Ultrasound Examination Requirements

Diagnostic

For characterization of palpable or nonpalpable abnormalities:

- a. The patient should be properly positioned to minimize thickness of the portion of the breast examined.
- b. Minimally acceptable ultrasound device settings should include proper depth, proper gain, and appropriate focal zones.
- c. Described lesions should be imaged in two orthogonal projections.
- d. At least two sets of lesion images should be obtained, one set with calipers and one without, except for follow-up examination or lesions large enough that calipers would not significantly obscure the margins.
- e. All described lesions should be measured in three dimensions including length, width, and height unless shadowing obscures the accurate measurement of height.
- f. Each image should have complete labeling, including: date and time of the examination, a unique patient identifier; right or left breast, transducer orientation, and lesion location described by either written or pictorial methods. The location of the lesion should be recorded by either clock notation or the quadrant of the breast with distance of the lesion from the nipple noted in centimeters or by zone.
- g. The imaged lesion should be correlated with the physical examination of the breast and appropriate imaging studies.
- h. Each identified lesion should have complete documentation in a written report.

Interventional

A. Indications

- i. Guidance for office procedures, including cyst aspiration, fine needle aspiration cytology, core needle biopsy, rotational cutter or vacuum-assisted needle biopsy, placement of marking clips or guide wires, placement of brachytherapy devices, targeted breast tissue ablation, and similar procedures.
- ii. Intraoperative use, including guidance for surgical excision with or without placement of a hook wire or needle localization device, assessment of adequacy of surgical excision for both palpable and nonpalpable lesions, and the use of other intraoperative devices (e.g., ablative procedure).

B. Technical aspects

- i. Guidance technique should align the biopsy (needle) device as perpendicular to the acoustic beam as possible (parallel to the chest wall) in order to optimize visualization of the device and to minimize the risk of injury to surrounding structures.
- ii. Simple core tissue sampling should use a minimum of a 14-gauge needle, with or without a coaxial system.
- iii. Multiple images of the guidance procedure should be obtained, including an image just prior to intervention as well as an image showing the device in the proper location after deployment.

Article V – Written Documentation

- a. Each ultrasound study should have a permanent written record along with the accompanying set of images in retrievable image storage format. The images and report should become a part of the patient's permanent medical record.
- b. Each individual image should include the facility name, date of examination, patient's first and last name, and identification number, if applicable. A notation of left or right breast and the location of the lesion should be shown on all images. Diagnostic images should also indicate transducer orientation within the breast. ***All of the above notations should be made using the icon or the annotation script capability of the instrument.*** The distance of the lesion from the nipple should be noted either in centimeters or by zone ***using the instrument's script. Handwritten notes on the images should be used only to correct errors on previously printed images.***
- c. Standard form reports may be used as long as they are comprehensive in nature.
- d. Reports of diagnostic procedures should include the indication for the study (including correlation with physical and/or imaging studies), description of technique, findings (including size, shape, borders, echogenicity, and physics artifacts), impression (with provisional diagnosis, if possible), and recommendation. A BI-RADS assessment should be included.
- e. Reports of ultrasound-guided interventional procedures should include the location of the lesion; the approach (lateral to medial, etc.); the type of prep and local anesthesia; skin incision, if any; type of device used; the number of cores taken; and the type of clip placed, if any. If specimen radiographs or sonograms are done, the information should be recorded in the report.
- f. Final reports should be completed and sent to the referring clinician in a timely manner, if indicated.

- g.** A written note should be made documenting concordance (or discordance) of imaging findings with pathology, complications (if any), and a disposition based upon correlation of physical, imaging, and pathology findings.
- h.** Optional classification of breast ultrasound lesions may be used employing the American College of Radiology Breast Imaging Reporting and Data System, or BI-RADS (see Appendix).

Article VI – Equipment Specifications and Quality Control

- a.** High-resolution linear array transducers of at least 7.5 MHz frequency should be utilized for breast ultrasound diagnostic examinations and for ultrasound-guided interventional procedures.
- b.** Each facility should have written policies and procedures for monitoring and evaluating the effective management and proper performance of imaging equipment.
- c.** Quality control programs should be designed to maximize the quality of the diagnostic information. (See Article VII.)
- d.** Equipment performance should be monitored at least annually in conformity with standards for ultrasound imaging and phantom testing for resolution. Such monitoring may be accomplished as part of a routine preventive maintenance program unless such routine maintenance is not recommended by the manufacturer.

Article VII – Quality Assessment/Improvement

- a.** Policies and procedures related to quality, personnel and patient safety, and infection control should be developed in accordance with the appropriate American College of Surgeons policies.⁵
- b.** Quality assessment procedures should exist and should be systematically monitored for appropriateness of examinations, technical accuracy, and accuracy of interpretations. The Society encourages participation in quality monitoring programs that may exist on a national level.
- c.** The volume of examinations and procedures should be documented and assessed on a continuous basis.
- d.** Complications and adverse events incurred during ultrasound-guided interventional procedures should be recorded and regularly reviewed to identify opportunities to improve patient care.
- e.** Results of ultrasound-guided interventional procedures should be recorded, monitoring the false-negative rates, inadequate tissue samples, and follow-up recommendations.

Concordance/discordance of imaging findings and pathology reports should be addressed by policies developed for resolution of discordant findings.

Acknowledgements

These guidelines were developed by the members of The American Society of Breast Surgeons Breast Ultrasound Certification Committee and have been approved by the Board of Directors of The American Society of Breast Surgeons.

Sara Fredrickson, MD, Chair
 Stephen Auda, MD
 Aaron D. Bleznak, MD
 Beth Boyd, RN
 Kambiz Dowlatabadi, MD
 Richard A. Fine, MD
 Mark A. Gittleman, MD
 Linsey Gold, DO
 Ronda Henry-Tillman, MD
 Scott Karlan, MD

Dan Kopen, MD
 Alison L. Laidley, MD
 Arthur G. Lerner, MD
 Howard C. Snider, MD
 Angela Soto-Hamlin, MD
 Carrie Thoms, MD
 Gary Unzeitig, MD
 Dariush Vaziri, MD
 Eric Whitacre, MD
 Victor Zannis, MD

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Developed October 2006

Revised February 2007

Revised October 2008

Revised April 2010

Revised April 2012

APPENDIX

American College of Radiology Breast Imaging Reporting and Data System—Ultrasound Assessment Categories*

A. Assessment Is Incomplete

Category 0: Need additional imaging evaluation.

In many instances, the ultrasound (US) examination completes the evaluation of the patient. If US is the initial study, other examinations may be indicated. An example would be the need for mammography if US were the initial study for a patient in her late 20's evaluated with US for a palpable mass that had suspicious sonographic features.

Another example might be where mammography and US 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 90%. 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 90% 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 histopathological 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.

*American College of Radiology (ACR). ACR BI-RADS®—Ultrasound. First Edition. ACR Breast Imaging Reporting and Data System, Breast Imaging Atlas; BI-RADS—US Assessment Categories. Reston, VA. American College of Radiology; 2003. Reprinted with permission of the American College of Radiology. No other representation of this material is authorized without expressed, written permission from the American College of Radiology.