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STANDARDS FOR PERFORMANCE OF THE ULTRASOUND EXAMINATION OF THE BREAST

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The following are recommended standards for ultrasound evaluation of the breast. The document consists of two parts:

Part I: Equipment and Documentation

Part II: Ultrasound Examination of the Breast

- 1. Indications
- 2. Conduct of the Examination
- 3. Guidance of Interventional Procedures

The standards have been developed to provide assistance to practitioners performing ultrasound examinations of the breast.

Part I

Equipment and Documentation

Equipment

Ultrasonographic examinations of the breast should be conducted with a real-time scanner, usually using high-resolution linear or curved linear transducers.

The transducer should be operated at the highest clinically appropriate frequency, realizing that there is a tradeoff between resolution and beam penetration. A transducer center frequency of 10.0 MHz or higher is required for diagnostic breast imaging. A transducer center frequency of 5-7 MHz is needed occasionally for beam penetration in a large breast or for a deep lesion. The resolution of the transducer should be adequate to clearly depict normal structures, such as mammary ducts, fibrous septa, and the superficial fascia.

Elevation resolution (also known as slice thickness) is important for the detection and characterization of lesions. A transducer having poor elevational resolution will not define the margins of lesions as clearly as one having high elevational resolution. This is particularly true for lesions near to the skin surface. If the elevational focal point is fixed, as is the case for most conventional broadband linear and curved array, then knowledge of the depth at which the transducer is focused in the elevational direction is important. One may need to have transducers focused at different depths to obtain optimal images. Alternatively, one can use a standoff pad to bring tissue near the skin surface closer to the elevational focal point.

An adequate frame rate (>12 fps) is necessary to avoid missing lesions between successive frames during scan sweeps. Equipement performance should be monitored daily from clinical images as suggested in the AIUM Quality Assurance Manual for Gray-Scale Ultrasound Scanners: Stage 2. Thorough testing should be performed at least annually.

Documentation

Adequate documentation of the study is essential for high-quality patient care. Images of all appropriate areas, both normal and abnormal, should be recorded on an appropriate imaging or storage format.

1. The images should be labeled with examination date, patient name and identification number, facility name and location, image orientation (transverse and longitudinal or radial and antiradial), side of patient (right or left), and anatomic location using a clock notation, which can be supplemented by adding a diagram of the breast. When using the clock notation, one must identify both the "hour" location of the lesion or image and the distance from the nipple. Also, for more centrally located images, the orientation of the image with respect to the nipple should be labeled if it is not apparent on the image itself. If a lesion is identified, the transducers should be rotated to find the largest horizontal dimension.

This measurement should be recorded on the image along with the lesion dimension at right angles to the longest dimension. Also the maximum vertical (antero-posterior) thickness of the lesion should be recorded. For clarity, the units of measurement should be cosistent, i.e., all measurements in either millimeters or centimeters or centimeters. It is advisable to include the sonographer's or sonologist's identification number, initials, or other symbol on the image.

- 2. As noted in Part II, for screening studies of the entire breast, images at 12:00, 3:00, 6:00, and 9:00 o'clock positions may be taken to document that all areas of the breast were examined
- 3. A report of the ultrasonographic findings should be placed in the patient's medical record.
- 4. Retention of the breast ultrasonographic images should be consistent with clinical need and the accompanying mammograms, and should be in compliance with legal and local healthcare facility requirements.
- 5. The breast ultrasonographic report should contain at least the following items:
 - a. The size of each lesion in three dimensions. If numerous lesions are present, then two or three "index" lesions may be measured in three dimensions with measurement in one or two dimensions of the others.
 - b. The location of each lesion in the breast by means of clockface position and distance from the nipple.
 - c. Relevant ultrasonographic characteristics of lesions.
 - d. Categorization of lesions as to whether they are likely to be benign or malignant using an accepted classification scheme (see Part II, Conduct of the Examination section).

e. A recommendation for either no further evaluation, further studies, clinical followup, or biopsy.

Part II

Ultrasound Examination of the Breast

Indications

The indications for breast ultrasound include

- Abnormal or questionably abnormal history, physical examination, or mammogram
- Guidance for interventional procedures, such as core needle biopsy
- Evaluation of breast implants for leakage

Ultrasound also may be used to survey the breast for abnormalities in patients with mammographically dense breasts, in pregnant patients, or in patients with previously irradiated breasts.

Conduct of the Examination

Where to scan

In addition to scanning the area of abnormality described or marked by the referring physician and patient, the entire quadrant containing that abnormality should be scanned. In some cases, such as suspected cancer, it may be desirable to survey the entire breast for additional abnormalities. If cancer is suspected, it is suggested that the ipsilateral parasternal chest wall and axilla be examined for lymphadenopathy.

How to scan

- 1. The patient should be placed in a supine or oblique supine position to produce maximum flattening and thinning of the area of interest. The patient's should be abducted and the hand placed behind the head.
- 2. The scan sweeps should cover the area of interest in two orthogonal planes. One common approach is to scan in longitudional and transverse planes (figure A). A second approach is to scan radially with the transducer held parallel to each radial line, adding short orthogonal sweeps by moving the transducer in a direction perpendicular to the radial line just scanned (figure B). If logitudional and transverse planes are used, additional radial scans will be needed to obtain good visualization of the ducts and their contents.

Characterization of masses and abnormalities

1. GRADING SYSTEMS FOR MASSES: Wile scanning, attention should be directed toward distinguishing solid from cystic masses and distinguishing benign from malignant solid masses. The system used for classification of solid masses should be based on one of the published sets of diagnostic criteria. Useful sets of published criteria include, but are not limited to, those listed in the following publications:

- * Kasumi F. The diagnostic criteria for breast lesions of the Japan Society of Ultrasonics in Medicine and topical issues in the field of breast ultrasonography in Japan. In: Kasumi F, Ueno E (eds). Topics in Breast Ultrasound Seventh International Congress on the Ultrasonic Examination of the Breast. Tokyo, Japan: Shinohara Publishers, Inc., 1991, pp 48-57.
- * Stavros At, Thickman D, Rapp CL, et al. Solid breast nodules: Use of sonography to distinguish benign and malignant lesions. Radiology 196: 123-134, 1995.

* Teboul M: Ductal echography. In: Madjar H, Teubner J, Hackeloer B (eds).

Breast Ultrasound Update. Basel, Karger, 1994, pp 110-126.

2. IMAGE RECORDING AND DOCUMENTATION: When obtaining images of lesions with measurement markers, some images should be obtained without markers as markers may obscure small lesions and border irregularities. To document that no lesions are present in an area, an image may be taken of the location with the exact location of the palpable abnormality or marked spot labeled at the top of the image. If a breast survey is being performed, images at 12:00, 3:00, 6:00, and 9:00 o'clock positions may be taken to document that all areas of the breast were examined.

- 3.CORRELATION WITH PHYSICAL EXAMINATION AND MAMMOGRAPHY: Regardless of where the ultrasonographic examination of the breast is performed, it should be correlated with physical examination and with mammography, if it has been performed. The sonologist performing the examination should perform palpation during sonography to obtain images over the exact location of any palpable abnormality. Similarly, the sonologist must correlate any mammographic abnormality with an exact location on the patient's breast to assure that sonographic images of the proper area are obtained. As a further confirmation that the mammographic lesion is the same as the sonographic one, the size and shape of the sonographic abnormality and the type of tissue surrounding the sonographic lesion should be consistent with the mammogram.
- 4. TRANSDUCERS AND SCANNER SETTINGS: Mass characterization with ultrasonography is highly dependent on technical factors. Transducer selection should be appropriate to the size and depth of the abnormality. The focal zone should be centered at the depth of the lesion. Gain settings should be adjusted to allow differentation of simple cysts and solid masses. Gain settings should not be so high that too many echoes are placed within simple cysts. Note that with higher frequency transducers, many cysts will normally exhibit internal echoes. By the same token, power and time gain compensation settings should not be too low to prevent recognition of internal echoes that are truly present in a mass.
- 5. STANDOFF PADS: Even with 7.5 MHz or 10 MHz transducers, proper imaging of the skin and superficial breast tissues within 1.5 cm of the skin may require the use of a standoff pad between the transducer face and skin surface. This brings the tissue being examined into the fixed elevational focal zone of the transducer and can improve the detectability of small lesions. Some of the most modern transducers give high-contrast, high-resolution images of the skin and superficial tissues, and for these instruments, a standoff pad is unnecessary. The user should consult with the manufacturer of the instrument on the potential advantages of using a standoff pad, and may also try a pad to see if small superficial lesions are better seen with a standoff pad.
- 6. ANATOMIC LANDSCAPE: The anatomic landscape in which a lesion is located should be recognized and commented on to enable restudy of the same area in future examinations. For example, a cyst scanned transversely from the 6:00 o'clock location of the right breast also might be related to its distance from the visualize pectoral muscle layer.

Guidance of interventional Procedures

- 1. The interventional procedures that can be performed with ultrasonographic guidance include, but are not limited to, cyst aspiration, presurgical needle hookwire localization, and fine-needle or core biopsy.
- 2. A full ultrasonographic examination should first be completed of the mass or area of the breast in which the procedure is planned.
- 3. There is no single correct method for accomplishing interventional procedures with ultrasound-imaging guidance. Both freehand technique with direct ultrasound visualization and use of a probe with a needle guide are suitable for breast interventions. The type of equipment on hand and the experience of the physician performing the procedure will determine selection of a technique.

- 4. High-frequency transducers of 7.0 MHz and higher used for imaging breast tissues are suitable for guiding interventional procedures. With these transducers, 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, if the needle entry is aligned with the acoustic beam and neary perpendicular to it, the entire shaft, including the needle tip, may be visible.
- 5. Local anesthetic injection is useful to decrease pain during biopsies. It should be injected along the course that will be traversed by the biopsy needle, taking care not to inject small air bubbles that may obscure the region of interest. Ultrasonic guidance can be aid in infiltration of anesthetic around the mass.
- 6. A small incision is often required before introduction of a 14 gauge or larger biopsy needle. A coaxial needle system may also be used and will not generally require the skin incision.