Standards for the Performance of Ultrasound-Guided Percutaneous Breast Interventional Procedures

Adopted in October 2003

The standards of the Canadian Association of Radiologists (CAR) are not rules, but are guidelines that attempt to define principles of practice that should generally produce radiological care. The physician and medical high-quality physicist may modify an existing standard as determined by the individual patient and available resources. Adherence to CAR standards will not assure a successful outcome in every situation. The standards should not be deemed inclusive of all proper methods of care or exclusive of other methods of care reasonably directed to obtaining the same results. The standards are not intended to establish a legal standard of care or conduct, and deviation from a standard does not, in and of itself, indicate or imply that such medical practice is below an acceptable level of care. The ultimate judgment regarding the propriety of any specific procedure or course of conduct must be made by the physician and medical physicist in light of all circumstances presented by the individual situation.

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. These 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 include mammography, computed tomography (CT), and magnetic resonance imaging (MRI).

II. GENERAL PRINCIPLES

An advantage of percutaneous sampling procedures is to reduce the number of diagnostic surgical procedures by substituting procedures that have one or more of the following:
1. Less or similar morbidity.
2. Similar accuracy.
3. Reduced cost.

A recommendation for performing an ultrasound-guided percutaneous breast interventional procedure is based upon high-quality breast imaging.

Prior to the performance of any ultrasound-guided percutaneous procedure, the lesion should be evaluated completely with an ultrasound study in accordance with the CAR Standard for the Performance of the Breast Ultrasound Examination and assessed by a physician qualified to render an interpretation of 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 is identified and characterized using ultrasound, this imaging technique 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

Indications for percutaneous ultrasound-guided breast interventional procedures include, but are not limited to, the following:

A. Cysts and Cystic Masses

1. Masses that do not fulfill the ultrasound criteria for simple cysts.
2. Cysts that are symptomatic.
3. Cysts where documentation of evacuation is desirable.
4. Cysts where imaging guidance would help avoid complications.
5. Suspected abscesses or infected cysts for diagnostic aspiration and drainage.

B. Solid Masses (See Appendix A)

1. A mass that is assessed as highly suggestive of malignancy using the Breast Imaging Reporting and Data System, (BI-RADS™ Category 5), to confirm the diagnosis so that definitive treatment options can be selected.
2. Multiple suspicious masses, particularly in a multicentric distribution (two or more different quadrants), to facilitate treatment planning.
3. Diagnosis of suspicious masses (BI-RADS™ Category 4).
4. Diagnosis of probably benign masses (BI-RADS™ Category 3) when there are valid clinical indications.

C. Lesions where the initial percutaneous procedure or the surgical biopsy has provided insufficient material for analysis or is discordant with the imaging assessment. Percutaneous sampling and surgical excisions are alternatives for repeat biopsy.

D. Presurgical Localizations

Ultrasound-guided localization may be performed when the lesion is identifiable with ultrasound.

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, or a history of bleeding diatheses.

IV. **QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL**

A. SONOLOGIST'S CREDENTIALS CRITERIA
Physicians involved in the performance, supervision and interpretation of ultrasonography should be Diagnostic Radiologists and must have a Fellowship or Certification in Diagnostic Radiology with the Royal College of Physicians and Surgeons of Canada and/or the Collège des médecins du Québec. Also acceptable are equivalent foreign Radiologist qualifications if the Radiologist is certified by a recognized certifying body and holds a valid provincial license.

As new imaging modalities and interventional techniques are developed additional clinical training, under supervision and with proper documentation, should be obtained before radiologists interpret or perform such examinations or procedures independently. Such additional training must meet with pertinent provincial/regional regulations. Continuing professional development must meet with the requirements of the Maintenance of Certification Program of the Royal College of Physicians and Surgeons of Canada.

B. SONOGRAPHER'S CREDENTIALS CRITERIA

Sonographers should be graduates of an accredited School of Sonography or have obtained certification by the American Registry of Diagnostic Medical Sonographers (ARDMS) or the Canadian Association of Registered Diagnostic Ultrasound Professionals (CARDUP). They should be members of their national or provincial professional organization. Continuing medical education should be mandatory consistent with the requirements of ARDMS or CARDUP.

CARDUP will have a national exam process for sonographers in place by 2004. At that time this will become the accepted standard for sonographers. As an interim measure, individual consideration of training and qualifications by a Task Force consisting of members of relevant societies can be recommended for all those whose training does not fall within appropriate guidelines.

C. SUPERVISION AND INTERPRETATION OF ULTRASOUND EXAMINATIONS

A sonologist must be available for consultation with the sonographer on a case by case basis. Ideally the sonologist should be on site and available to participate actively in the ultrasound examination when required.

It is recognized however that the geographic realities in Canada do not permit the presence of an on-site sonologist in all locations. Adequate documentation of each examination is critical. A videotape record may be useful as an adjunct to the hard copy images in difficult cases. Despite the geographic isolation of a community the reports must be timely. Furthermore, the sonologist must be available by telephone for consultation with the sonographer and the referring physician. The sonologist should visit the facility on a regular basis to provide on site review of ultrasound procedures and sonographer supervision.

V. **SPECIFICATIONS OF THE EXAMINATION**

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.

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.

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 preferentially, if the needle entry is in alignment with the acoustic beam, 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 a medical record.

To minimize hematoma formation, the skin entry site and region of needle sampling should be compressed after each needle pass, if multiple passes are made to sample a lesion. Coaxial techniques may also be used with ultrasound FNA and CNB.

VI. **DOCUMENTATION**

A permanent record of interventional procedures should be documented on a retrievable image storage format. Where appropriate, correlative mammography should be performed in conjunction with the procedures.

A. Imaging 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 the left or right breast.
6. Location of the lesion in the breast using diagrammatic, clock, or other consistent notation.
7. Scan plane.

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

1. Procedure performed.
2. Local anesthesia, type and amount, if used.
3. Designation of the left or right breast.
4. Location of the lesion in the breast using diagrammatic, clock, or other consistent notation.
5. Immediate complications and treatment, if any.
6. Specimen radiographs or sonograms, if performed, and results.
7. Clip placement, if done.
8. 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. Determination of pathology results, if any.
3. Record of communications with the patient and/orreferring physician.
4. Recommendations based on tissue sampling results and imaging information.

D. Retention of the procedure's image, including those of the specimen if obtained, should be consistent with the policies for retention of mammograms and breast sonograms in compliance with federal and state regulations, local health care facility procedures, and with clinical need.

E. 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 or to the patient, as appropriate. These communications should be documented in accordance with the CAR Standard for Communication: Diagnostic Radiology.

Reporting should be in accordance with the CAR Standard for Communication: Diagnostic Radiology.

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 guidelines described in the CAR Standard for the Performance of the 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 re- biopsy or complete excision of a lesion. Imaging findings and pathologic interpretations should be correlated in every instance and provisions for review of these findings be made. Biopsy follow-up should be performed to detect and record any false-negative and false-positive results.

As with all interventional procedures, the procedure should be fully described and the relative risks, limitations, benefits, and alternatives should be explained to the patient.

Procedures should be systematically monitored and evaluated as part of the overall quality improvement program of the facility. Monitoring should include the evaluation of the accuracy of interpretation as well as the appropriateness of the examination.

Incidence of complications and adverse reactions should be recorded and periodically reviewed in order to identify opportunities to improve patient care.

Data should be collected in a manner which complies with the statutory and regulatory peer review procedures in order to protect confidentiality of the peer review data.

REFERENCES

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APPENDIX A

BREAST IMAGING REPORTING AND DATA SYSTEM (BI-RADS ®) REPORTING CATEGORIES

Category 0 - Need Additional Imaging Evaluation

Finding for which additional imaging evaluation is needed. This is almost always used on a screening situation and should rarely be used after a full imaging workup. A recommendation for additional imaging evaluation includes the use of spot compression, magnification, special mammographic views, ultrasound, etc.

Whenever possible, the present mammogram should be compared to previous studies. The radiologist should use judgment in how vigorously to pursue previous studies.

Category 1 - Negative

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

Category 2 - Benign Finding

This is also a negative mammogram, but the interpreter may wish to describe a finding. Involuting, calcified fibro-adenomas, multiple secretory calci-fications, fat containing lesions such as oil cysts, lipomas, galactoceles, and mixed density hamartomas all have characteristic appearances, and may be labeled with confidence. The interpreter might wish to describe intramammary lymph nodes, implants, etc., while still concluding that there is no mammo- graphic evidence of malignancy.

Category 3 - Probably Benign Finding: Short Interval Follow-Up Suggested

A finding placed in this category should have a very high probability of being benign. It is not expected to change over the follow-up interval, but the radiologist would prefer to establish its stability. Data are becoming available that shed light on the efficacy of short interval follow-up. At the present time, most approaches are intuitive. These will likely undergo future modification as more data accrue as to the validity of an approach, the interval required, and the type of findings that should be followed.

Category 4 - Suspicious Abnormality: Biopsy Should Be Considered

These are lesions that do not have the characteristic morphologies of breast cancer but have a definite probability of being malignant. The radiologist has sufficient concern to urge a biopsy. If possible, the relevant probabilities should be cited so that the patient and her physician can make the decision on the ultimate course of action.

Category 5 - Highly Suggestive of Malignancy: Appropriate Action Should Be Taken

These lesions have a high probability of being cancer.