ACR PRACTICE PARAMETER FOR THE PERFORMANCE OF MAGNETIC RESONANCE IMAGING–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 considering 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 variables such as the condition of the patient, limitations of available resources, or advances in knowledge or technology after publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document may consider documenting in the patient record information sufficient to explain the approach taken.

The practice of medicine involves the science, and 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 purpose of this document is to assist practitioners in achieving this objective.

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1 *Iowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing, 831 N.W.2d 826 (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 image-detected breast lesions requiring tissue diagnosis. Its advantages over surgical biopsy include less scarring, fewer complications, faster recovery, and lower cost while providing similar accuracy [1-4]. Additionally, performing biopsies under image guidance, including magnetic resonance imaging (MRI), has decreased both the number of benign surgical biopsies and the number of surgical procedures needed to treat breast cancer [1-4]. MRI guidance for breast biopsy enables percutaneous sampling of suspicious findings seen by MRI and not confidently seen by ultrasound

(US).

Breast MRI is the most sensitive imaging modality for detecting breast cancer and identifying cancer occult on mammography, US, and clinical breast examination [5,6]. MRI is one of several imaging modalities that can be used to guide breast interventions. The choice of modality used for guidance depends on many factors, including visibility and accessibility of the target, availability and cost of the imaging modality, safety, patient comfort associated with a particular technique, and the experience of the physician performing the biopsy [5,6].

The use of breast MRI as a screening and diagnostic tool has become increasingly common, with a marked rise in examinations performed in recent years [7-9]. The indications for screening breast MRI continue to expand, particularly for those at elevated risk for breast cancer [6,10]. Consequently, the number of MRI-guided procedures has also increased. It is therefore important that facilities performing breast MRI have the ability to offer MRI-guided biopsy given the possibility that a suspicious finding identified on MRI may not be visible on other imaging modalities.

Facilities performing breast MRI should have the ability to perform correlation with mammography, MRI-directed breast US, and MRI-guided interventions (see the ACR Practice Parameter for the Performance of Contrast-Enhanced Magnetic Resonance Imaging (MRI) of the Breast [11]). If MRI-guided biopsy is not offered at the facility performing the breast MRI, a referral arrangement should be established with a cooperating facility to provide these services without the need to repeat the MRI examination. Because breast MRI protocols can vary considerably from one imaging facility to another [12], such an agreement requires that the involved facilities establish compatible breast MRI protocols and technical factors [7]. Without compatible protocols, MRI examinations may need to be repeated prior to biopsy, resulting in unnecessary duplication of services, unnecessary costs, and patient inconvenience.

Radiologists who interpret breast MRI examinations without performing biopsies should make every attempt to follow up on their biopsy recommendations in order to audit their breast MRI programs. This allows the interpreting radiologist to gain insight into the feasibility of MRI-guided biopsy for a given scenario, their interpretive performance [13], and radiologic/pathologic correlation.

Successful performance of MRI-guided breast interventions relies on high-quality imaging, expertise in image interpretation and appropriate patient selection, as well as experience in MRI-guided techniques for accurate localization and sampling of suspicious findings [14-19]. The imaging findings and the pathology results should be correlated for concordance by the physician performing the biopsy [20], and records should be kept to document results and management recommendations.

II. INDICATIONS AND CONTRAINDICATIONS

A. Indications

MRI-guided breast intervention is suitable for many MRI-depicted suspicious abnormalities.

It is common to initially evaluate findings identified on breast MRI via targeted US, especially as US-guided biopsy has advantages over MRI-guided biopsy with respect to cost, time, and patient comfort. However, certain findings, such as nonmass enhancement, are less likely to be seen on US [21]. It may be appropriate to proceed directly to MR-guided biopsy when US investigation is thought unlikely to identify an imaging correlate. MRI-guided breast biopsy also may be indicated after targeted US if an US finding cannot be declared confidently to correlate to a finding detected on breast MRI [22-24]. Some practices perform a limited MRI after the US-guided biopsy to confirm biopsy of the MRI finding.

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

1. Lesions only seen with certainty on breast MRI or lacking definite correlate on mammography or US: Breast Imaging Reporting and Data System (BI-RADS®) assessment category is either suspicious (BI-RADS Category 4) or highly suggestive of malignancy (BI-RADS Category 5). Even if the probability of malignancy is very high, percutaneous biopsy is indicated both to confirm diagnosis and to obtain tissue for molecular profiling to guide treatment.
2. Lesions only seen with certainty on breast MRI or lacking definite correlate on mammography or US: BI-RADS assessment category is probably benign (BI-RADS Category 3) only when there are valid clinical indications or when short-term-interval imaging follow-up would be difficult or impractical (eg, if the patient has a synchronous known breast cancer, is awaiting organ transplantation, plans to become pregnant in the immediate future, etc) [25].
3. Repeat biopsy

Repeat MRI-guided breast biopsy is an alternative to surgical excision in some cases when the initial biopsy results are nondiagnostic or are discordant with the imaging findings.

4. MRI-guided presurgical localization may be performed in circumstances that may include:
   Lesions that are not technically amenable to MRI-guided core biopsy because of their location
   a. in the breast or the small size of the breast and are not visible on mammogram or US [26]
   b. Bracketed excision of an MRI-demonstrated malignancy when its extent is larger than outlined on mammography or US or by previous biopsy marker placement
   c. Excision of suspicious lesions seen only on MRI that yielded discordant or nondiagnostic pathology on biopsy and cannot be localized by mammography or US because of the absence of a biopsy marker.
5. In some circumstances, it may be desirable to place a biopsy marker rather than a localization wire under MRI guidance. This allows the biopsy marker to be subsequently localized with US or mammographic guidance using localization devices that otherwise may not be amenable to placement with MRI guidance.

B. Contraindications

Inability to visualize the target findings following contrast injection is a contraindication to MRI-guided breast biopsy. In this scenario, it should be verified that 1) the patient received a successful bolus of contrast and 2) arterial inflow is not impeded by excessive breast compression [27]. If it is suspected that the arterial inflow is affected by compression, obtaining delayed postcontrast imaging may be helpful in identifying the findings. Nonvisualization of a target's findings at the time of planned biopsy can occur in up to 13% of cases. If this occurs, short-interval follow-up MRI is recommended to be certain the findings are indeed absent to exclude the small possibility of a missed malignancy [28-31].

Prior to the procedure, the patient should be asked about potential pregnancy; allergies (including gadolinium-based contrast agents); use of medications such as aspirin, anticoagulants, platelet agents, or other agents known to impact bleeding times; and whether there is a history of bleeding diatheses. There is literature reporting that it is safe to proceed with biopsy despite anticoagulation [32]. Decisions regarding postponement or cancellation of a procedure or cessation of anticoagulants can be made on a case-by-case basis, weighing the risks of bleeding and hematoma formation with those of interrupting anticoagulation.

All general MRI safety precautions should be observed, and gadolinium risk should be assessed [33-40]. For further information, see the ACR Manual on Contrast Media [41] and the ACR Manual on MR Safety [34].

The patient's size and ability to remain in the prone position for the duration of the procedure should also be considered.

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A. Physician

MRI-guided breast biopsy procedures should be performed by qualified physicians who meet the qualifications outlined in the ACR Practice Parameter for the Performance of Contrast-Enhanced Magnetic Resonance Imaging (MRI) of the Breast [11]. The physician should thoroughly understand the indications for and limitations of breast MRI examinations and MRI-guided percutaneous breast procedures. The physician performing the procedure should have experience interpreting breast MRI studies and be able to correlate the MRI findings with the results of other breast imaging examination prior procedure results, and be able to assess concordance of biopsy histopathology results. The interpreting physician should thoroughly understand the basic physics of MRI techniques and MRI safety, including contrast safety issues.

Prior to the MRI procedure, the physician must correctly identify the salient target findings(s) on MRI so that biopsy or presurgical localization is accurate.

1. Initial qualifications

Training in breast MRI interpretation, medical physics, and specific hands-on training in the performance of MRI-guided biopsy are imperative to successful performance of this procedure.

The initial qualifications as outlined in the ACR Practice Parameter for the Performance of Contrast-Enhanced Magnetic Resonance Imaging (MRI) of the Breast provide this foundation [11].

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) [42].

4. Responsibilities for assessment of concordance

The physician who performs the MRI-guided breast biopsy or presurgical localization procedure (or a qualified designated physician) is responsible for obtaining results of the histopathologic sampling to determine whether the finding has been adequately sampled and is concordant or discordant with the imaging findings, and provide recommendations for appropriate follow-up. These concordance results and recommendations should be communicated to the referring physician and/or to the patient, as appropriate, and documented in the final report.

B. Qualified Medical Physicist

See the ACR–AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Magnetic Resonance (MR) Imaging Equipment [43].

C. Technologist

1. Initial qualifications

Technologists should meet the qualifications specified in the ACR Practice Parameter for the Performance of Contrast-Enhanced Magnetic Resonance Imaging (MRI) of the Breast [11].

2. Maintenance of competence

Technologists should participate in MRI-guided breast interventions.

3. Continuing medical education

Technologists should obtain continuing education in MRI-guided breast intervention.

IV. SPECIFICATIONS OF THE PROCEDURE

A. Prior to the Procedure

The decision to recommend an MRI-guided breast interventional procedure should be made only after a complete imaging evaluation of the breast has been performed, including diagnostic mammography and

breast US, if appropriate.

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

Adherence to the Joint Commission's Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery™ is strongly recommended for procedures in nonoperating room settings (confirm with local institutional requirements).

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

B. Procedure Technique

The patient is positioned prone with the breast of interest stabilized with light to moderate compression between an open interventional breast coil and localization system for either medial or lateral biopsy access. For unilateral biopsies, the unaffected breast is positioned out of the breast coil/field of view, which is particularly important to allow medial biopsy access. Unilateral breast biopsy of multiple findings is possible using the same access (medial or lateral) for both biopsy sites, or both medial and lateral access if localization devices are placed on both the lateral and medial sides of the breast. For concurrent bilateral biopsies, both breasts are compressed using open interventional breast coils and a localization system for bilateral lateral access. A grid localization system is most commonly used; however, the pillar and postlocalization method is also an option. For grid localization, a fiducial is placed within the grid to localize the grid position on the breast for targeting purposes. The specific fiducial type and grid position will vary depending on the targeting technique. After a 3-plane localizer sequence, precontrast T1-weighted MR images may be obtained to confirm that the breast is adequately positioned and the targeted finding is likely located within the accessible area. If necessary, the patient can be repositioned prior to contrast administration (for example, if the finding lies outside the grid). Postcontrast T1-weighted MR imaging is then performed to identify and target the suspicious finding(s). Subtraction images can be created to assist with identification of subtle findings if precontrast MR images were obtained. Manual targeting using a paper method or computer-aided evaluation (CAE) systems are both appropriate. Manual targeting includes worksheets for the specific coil and grid system used for the biopsy. The skin entry coordinates are obtained by locating the fiducial relative to the finding location on the grid. The target depth is calculated on the postcontrast images from the fiducial location on the skin to the target finding within the breast. CAE systems perform these calculations automatically once the target finding is identified. The coordinates for the skin entry site and the target finding depth should be noted for use during the procedure.

Once the target coordinates and depth are obtained, the patient table is then moved out of the bore of the MR scanner. The patient and the physician should be prepared in conformity with infection control principles. Local anesthetic is administered to the biopsy site. Once a biopsy guidance sheath with obturator is placed in the breast to the previously calculated depth, the patient table is moved back into the bore of the MR scanner, and T1-weighted MR images are obtained to confirm appropriate position. If the biopsy guidance sheath position is off-target, the targeting procedure can be repeated, as needed. When appropriate position is confirmed, the patient table is moved out of the bore of the MR scanner and sampling is performed using an MRI-compatible biopsy device. The number of samples required for adequate analysis depends upon the lesion size, the device gauge, and the specific clinical scenario; 6 to 12 samples are typical [14]. Once all the biopsy samples have been obtained, a tissue marker is deployed at the biopsy site. Final T1-weighted MR images may be obtained to document successful biopsy of the targeted finding and tissue marker placement. A similar process is followed for MRI-guided localization. Documentation of appropriate needle/biopsy device 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 adequately compressed until hemostasis is achieved.

A postprocedure mammogram should be performed in 2 orthogonal views to document biopsy marker position relative to the biopsy site.

V. DOCUMENTATION

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

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

A. Image labeling should include permanent identification containing:

1. Patient's first and last names
2. Identifying number and/or date of birth Examination date
3. Facility name and location
4. Designation of the left or right breast
5. Annotation of MRI sequence(s) used
6. MRI technologist's identification number or initials
   Physician identification may be included on the permanent image record.

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

1. Procedure performed
2. Designation of the left or right breast
3. Description and location of the lesion using clockface or other consistent accepted notation
4. Approach used
5. Safety time-out having been performed
6. Type and amount of contrast material
7. Type of local anesthesia
8. Skin incision, if made
9. Gauge of needle and type of biopsy or localization device (spring-loaded, vacuum-assisted, etc)
10. Number of specimen cores or samples, if applicable
11. Tissue marker placement, if performed, with specification of shape. If multiple tissue markers are placed, they should be clearly identified according to shape and site.
12. Complications and treatment, if any
13. Postprocedure mammogram documenting tissue marker placement and location of the marker with respect to the biopsied lesion.

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

1. Documentation of any delayed complications and treatment administered
   A determination of concordance of pathology results with imaging findings should be documented in the final report by the performing physician or designated physician. The technical constraints inherent to MRI biopsy may make the determination of radiologic-pathologic concordance challenging because there is no confirmatory method to verify adequate sampling. Unlike US-guided biopsy, the biopsy needle cannot be visualized in real time. Unlike stereotactic-guided biopsy, there is no specimen radiograph to confirm sampling. Therefore, radiologic-pathologic correlation is imperative [45]. Upgrade rates to malignancy and false-negatives at biopsy may be higher for MRI-guided biopsy than for stereotactic-guided biopsy and US-guided biopsy [46], which makes radiologic-pathologic review particularly essential [47,48]. The radiologist performing the procedure (or a qualified designated physician) is responsible for determining concordance or discordance and
2. recommending appropriate management [20,49-51].
3. Management recommendations based on pathology results and imaging pathology concordance or discordance

c. Patients with malignant results should be referred to a surgeon and/or oncologist for appropriate management.
d. For MRI-guided biopsy findings with a benign pathology result determined to be discordant at the time of radiology/pathology review, upgrade rates of at least 30% have been documented [20,49]. Thus, patients with a discordant biopsy are recommended to undergo repeat CNB or surgical excision.
e. Surgical consultation is usually recommended for high-risk findings with the potential for upgrade to malignancy at surgical excision. These include atypical ductal hyperplasia, flat epithelial atypia, lobular neoplasia (atypical lobular hyperplasia and both classic and pleomorphic lobular carcinoma in situ), radial scar, complex sclerosing lesions, phyllodes tumor, and, to a lesser degree, papilloma. Several studies have found higher upgrade rates for high-risk lesions detected by MRI rather than mammography or US [52-57]. However, high-risk findings management is controversial, and care should be individualized when appropriate [53,58,59].
f. If a finding is benign, not high risk, and deemed concordant after MRI-guided biopsy, further intervention/excision is usually not performed. However, because determination of concordance after MRI-guided biopsy may be challenging as described above, short-term follow-up with diagnostic breast MRI at 6 months may be warranted [51,60-63].

4. Record of communication of positive biopsy results with the patient and/or referring physician

D. 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.

E. For further information regarding breast accreditation requirements and quality assurance, see the Quality Assurance: Breast MRI and the ACR accreditation support.

VI. EQUIPMENT SPECIFICATIONS

Equipment monitoring should be in accordance with the ACR–AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Magnetic Resonance (MR) Imaging Equipment [43].

Several MR-conditional or MR-safe needle biopsy devices are available for MRI-guided procedures, including automated core needles and vacuum-assisted devices. The choice depends on the type of lesion as well as the operator's experience. However, vacuum-assisted devices have been shown to be most effective in performing MRI biopsy. MR-conditional or MR-safe wires and nonwire-based localization devices should be utilized.

The MRI equipment specifications and performance must meet all state and federal requirements. The requirements include, but are not limited to, specifications of maximum static magnetic field strength, maximum rate of change of magnetic field strength (dB/dT), maximum radiofrequency power deposition (specific absorption rate), and maximum acoustic noise levels.

Technical Guidelines

1. Imaging protocol – The spatial resolution for MRI-guided intervention needs to be high enough to identify the target(s) of interest, and images need to be obtained quickly to ensure visualization of the targeted finding prior to rapid contrast washout. Because the goal of the protocol is to identify the finding to target for biopsy, rather than detection and characterization, as in diagnostic breast MRI, the resolution may not match that utilized in diagnostic protocols. Faster sequence acquisition also helps minimize overall procedure time, reducing patient discomfort and potentially patient motion. Simultaneous bilateral imaging is performed when findings in each breast are being biopsied concurrently.

2. Resolution – Ideally, the slice thickness and the in-plane spatial resolution should be similar so that the finding can be adequately visualized. Sequences using fat suppression and subtraction imaging may assist with identification of the finding. Of note, subtraction imaging carries a risk of misregistration due to patient motion, which can result in spurious nonvisualization of the finding. Some imaging protocols for MRI-guided interventions may incorporate both fat suppression and subtraction, and motion-correction software may be helpful in reducing artifacts encountered with image subtraction.

3. Contrast – Gadolinium contrast enhancement is generally needed to identify the lesion that is to undergo biopsy. It should be administered as a bolus with a standard dose of 0.1 mmol/kg followed by a saline flush of at least 10 mL.

4. Scan time – Scan time in relation to contrast injection is extremely important for identification of the finding prior to contrast washout. If a single postcontrast scan is acquired, the scan time should not extend beyond 4 minutes after bolus injection.

5. Examinations should be performed with a dedicated open interventional breast MRI coil equipped with a localization device.

VII. 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 *ACR Position Statement on Quality Control & Improvement, Safety, Infection Control*, *and Patient Education* on the ACR website (https://www.acr.org/Advocacy-and-Economics/ACR-Position-Statements/Quality-Control-and-Improvement).

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