ACR PRACTICE PARAMETER FOR THE PERFORMANCE OF CONTRAST- ENHANCED MAGNETIC RESONANCE IMAGING (MRI) OF THE BREAST

Revised 2023 (Resolution 8)

The American College of Radiology, with more than 30,000 members, is the principal organization of radiologists, radiation oncologists, and clinical medical physicists in the United States. The College is a nonprofit professional society whose primary purposes are to advance the science of radiology, improve radiologic services to the patient, study the socioeconomic aspects of the practice of radiology, and encourage continuing education for radiologists, radiation oncologists, medical physicists, and persons practicing in allied professional fields.

The American College of Radiology will periodically define new practice parameters and technical standards for radiologic practice to help advance the science of radiology and to improve the quality of service to patients throughout the United States. Existing practice parameters and technical standards will be reviewed for revision or renewal, as appropriate, on their fifth anniversary or sooner, if indicated.

Each practice parameter and technical standard, representing a policy statement by the College, has undergone a thorough consensus process in which it has been subjected to extensive review and approval. The practice parameters and technical standards recognize that the safe and effective use of diagnostic and therapeutic radiology requires specific training, skills, and techniques, as described in each document. Reproduction or modification of the published practice parameter and technical standard by those entities not providing these services is not authorized.

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

Magnetic resonance imaging (MRI) of the breast is a useful tool for the detection and characterization of breast cancer, assessment of local disease extent, evaluation of neoadjuvant treatment response, and guidance for biopsy and localization. MRI findings should be correlated with the clinical history, physical examination findings, and results of any recent breast imaging.

II. INDICATIONSAND CONTRAINDICATIONS

A. Current indications for breast MRI include, but are not limited to, the following:
1. High-risk screening
    a. Patients with greater than or equal to 20% lifetime risk (eg, genetic predisposition, history of mantle radiation for Hodgkin lymphoma) [1-14].
    b. Patients with a personal history of breast cancer and dense breast tissue, or those diagnosed with breast cancer under age 50 [15-20].
2. Evaluate the extent of disease with newly diagnosed breast cancers
    a. Characterize and detect ipsilateral and contralateral ductal carcinoma in situ and invasive carcinoma, particularly invasive lobular carcinoma [21-31].
    b. Determine the invasion of underlying fascia and muscle [32-34].
    c. Neoadjuvant treatment response assessment [35,36].
3. Metastatic cancer when the primary is unknown and suspected to originate from breast [37-40].
4. Pathologic nipple discharge with no abnormality on diagnostic mammography or ultrasound [41,42].
5. Lesion characterization: when other diagnostic imaging examinations, such as ultrasound and mammography, and physical examination are inconclusive or when biopsy cannot be otherwise performed [43-50].
6. Breast augmentation: implant integrity can be determined by noncontrast breast MRI, but the use of contrast may be indicated in patients with free injections of silicone, paraffin, or polyacrylamide gel in whom mammographic screening may be compromised. Additionally, patients who have undergone implant reconstruction following lumpectomy or mastectomy may benefit from contrast-enhanced breast MRI screening.

B. Other Considerations
1. Treatment planning
   MRI findings in patients with breast cancer may change their planned treatment. Caution should be exercised in altering management based on MRI findings alone without biopsy confirmation.
2. Inappropriate uses of breast MRI
   MRI should not supplant careful problem-solving mammographic views or ultrasound in the diagnostic setting. MRI should not be used in lieu of biopsy of a suspicious finding identifiable by mammography, ultrasound, or clinical examination.
3. Abbreviated MRI protocols
   Studies with reported shortened or abbreviated MRI protocols have similar sensitivities and specificities compared with a full MRI protocol [51-57]. This practice parameter document is specific to conventional breast MRI because the utility and protocols for abbreviated MRI are under investigation.
4. Diffusion-weighted imaging
   Studies have reported that diffusion-weighted imaging has the potential to improve the specificity of breast MRI by better characterizing lesions as benign versus malignant [58]. Optimal scanning and interpretation protocols remain under investigation

C. Contraindications
Possible contraindications include, but are not limited to, the presence of cardiac pacemakers, ferromagnetic intracranial aneurysm clips, neurostimulators, cochlear implants, some intrauterine devices, and certain other ferromagnetic foreign bodies or electronic devices [59-63]. Due to the unknown effects of gadolinium contrast on the fetus, contrast-enhanced breast MRI is contraindicated in pregnant women [59]. All patients should be screened for potential contraindications prior to MRI scanning [64,65]. All general MR safety precautions should be observed, and gadolinium risk should be assessed [36-41,43,44].

For further information, see the ACR Manual on Contrast Media [59] and the ACR Manual on MR Safety [66].

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

See the ACR Practice Parameter for Performing and Interpreting Magnetic Resonance Imaging (MRI) [67].

Interpreting physicians should have knowledge and expertise in breast disease and breast imaging diagnosis. Facilities performing breast MRI should have the capacity to perform correlation with prior breast imaging examinations, directed breast ultrasound, and MRI-guided intervention. Alternatively, if these services are not available at the facility performing breast MRI, the facility should create a referral arrangement with a cooperating facility that can provide these services. If MRI-guided breast biopsy is performed, histopathologic results should be available to the interpreting physician as well as the procedural physician. The MRI biopsy facility should have the physician expertise to determine radiologic-pathologic concordance and the ability to report management recommendations in the biopsy report. For suspicious or indeterminate findings detected on breast MRI that are occult and/or unlikely to be seen on mammography and breast ultrasound, an MRI-guided biopsy should be performed. For further information, see the ACR Practice Parameter for the Performance of Magnetic Resonance Imaging-Guided Breast Interventional Procedures [68].

IV. SPECIFICATIONS OF THE EXAMINATION

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

Documentation that satisfies medical necessity includes 1) signs and symptoms and/or 2) relevant history (including known diagnoses). 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 stated scope of practice requirements. (ACR Resolution 35, adopted in 2006 – revised in 2016, Resolution 12-b)

IV. SPECIFICATIONS OF THE EXAMINATION

A. Patient Selection and Preparation

The physician responsible for the breast MRI should supervise patient selection and preparation. Patients should be screened for possible contraindications for MRI as discussed in section III. Patients suffering from anxiety or claustrophobia may require anxiolysis to achieve a successful examination (see the ACR–SIR Practice Parameter for Minimal and/or Moderate Sedation/Analgesia [69]). MRI bore constraints, the patient's size, and the patient's ability to remain in the prone position for the duration of the examination should be considered.

Recent evidence suggests that background parenchymal enhancement (BPE) and diagnostic performance of breast MRI are not significantly affected by menstrual cycle phase [70,71]. Consequently, for premenopausal women, menstrual cycle phase should not necessarily factor into breast MRI scheduling. Additionally, when clinically indicated, breast MRI may be performed in lactating patients, because MRI successfully detects cancers despite the elevated BPE associated with lactating breast tissue [72-74]. For guidance regarding the use of gadolinium-based contrast agents in lactating women, please see the ACR Manual on Contrast Media [59].

IV. SPECIFICATIONS OF THE EXAMINATION

B. Facility Requirements

Appropriate emergency equipment with medications must be immediately available to treat adverse reactions associated with administered medications, including gadolinium-based contrast agents. The equipment and medications should be monitored for inventory and drug expiration dates on a regular basis. The equipment, medications, and other emergency support must also be appropriate for the range of ages and sizes in the patient population. Facility staff should be trained in the use of emergency equipment and medications in accordance with the ACR Manual on Contrast Media [59].

V. DOCUMENTATION

Reporting should be in accordance with the ACR Practice Parameter for Communication of Diagnostic Imaging Findings [75]. The report should follow the guidelines for terminology, including descriptions of lesion features and location, as published in the ACR BI-RADS® Lexicon for Breast MRI. Analysis of abnormalities on breast MRI ought to consider both morphologic and kinetic features of the abnormality. The BI-RADS assessment category should be included in the conclusion of the report [66].

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 including testing of the breast coil(s) by a Qualified Medical Physicist or Qualified Medical Scientist [76].

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 [66,77].

Technical Guidelines

1. Resolution, contrast, and field strength

   Facilities performing contrast-enhanced breast MRI should meet ACR Breast MRI Accreditation Program Requirements [78]. The selection of field strength is a major technical decision. A 1.5T magnet has traditionally been considered a minimum technical recommendation because of the relationship between field strength and resolution. However, improvements in other components of the scanning process have resulted in improved scan quality at lower field strengths. High spatial and temporal resolutions are needed to detect and characterize small abnormalities on MRI. The slice thickness should be 3 mm or less, and in-plane pixel resolution should be 1 mm or less to minimize volume-averaging effects. Simultaneous bilateral high-resolution breast imaging should be performed. Gadolinium contrast enhancement is required for the evaluation of breast parenchyma and identification of abnormalities including breast cancer but is not necessary in the evaluation of implant integrity [79,80]. Gadolinium contrast 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.

2. Pulse sequences

   Comprehensive breast MRI scans should include a T2-weighted/bright fluid sequence and a multiphase pre- and postcontrast T1-weighted series. Optimized contrast between the tumor and surrounding tissue is important. When high-resolution images are being obtained, fat-suppressed sequences help to more easily identify contrast enhancement while preserving the signal-to-noise ratio. Sole reliance on subtraction imaging for the assessment of enhancement may be compromised by misregistration due to patient motion; use of fat suppression is recommended on sequences used to assess contrast enhancement. Often protocols incorporate both fat suppression and subtraction. Motion correction may be helpful in reducing artifacts encountered with image subtraction. A single non-fat-suppressed, precontrast T1-weighted sequence should also be considered to facilitate the characterization of fat-containing breast lesions. Specific imaging parameters (eg, repetition time and echo time, etc) and types of T2- and T1-weighted pulse sequences (eg, short tau invasion recovery, conventional spin echo, gradient echo, etc) should be

determined at the facility or programmatic level.

3. Scan time for T1-weighted sequences

   A precontrast scan is obtained. Scan time in relation to contrast injection is extremely important for lesion identification and characterization. Kinetic information should be reported and based on enhancement data determined at specified postcontrast intervals separated by 4 minutes or less for the T1-postcontrast series. Imaging sites should have adequately short temporal resolution for accurate lesion identification, characterization, and BPE assessment, ideally performed at 90 seconds postcontrast administration [81]. Computer-aided evaluation (CAE) software is commonly used at image interpretation to perform postprocessing and display kinetic information.

4. Positioning

   Examinations should be performed with a dedicated bilateral breast MRI coil. Patients should be positioned within the coil to ensure that the field-of-view includes the entire bilateral breasts, from the axillae to the inframammary folds. Skin folds should be minimized. If feasible, the nipples should be positioned to symmetrically point down to the ground.

VII. SAFETY GUIDELINES

See the ACR Practice Parameter for Performing and Interpreting Magnetic Resonance Imaging (MRI), the ACR Manual on Contrast Media, and the ACR Manual on MR Safety [59,66,67].

Peer-reviewed literature pertaining to MR safety should be reviewed on a regular basis [53,54,82,83].

VIII. 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 *Position Statement on QC & 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).

Examinations should be systematically reviewed and evaluated as part of the overall quality improvement program at the facility. Monitoring should evaluate the accuracy of interpretation as well as the appropriateness of indications for the examinations. Complications and adverse events or activities that may have the potential for sentinel events must be monitored, analyzed, reported, and periodically reviewed to identify opportunities to improve patient care. These data should be collected in a manner that complies with statutory and regulatory peer-review procedures to ensure the confidentiality of the peer-review process.

Each facility should establish and maintain a medical outcome audit program to follow up positive assessments and to correlate pathology results with the interpreting physician's findings. (If the facility does not perform MRI-guided intervention, it should have access to correlative pathology results from the accredited facility with which it has a referral arrangement.) As above, such audits should encompass interpretation accuracy and examination appropriateness. Facilities should use the BI-RADS final assessment codes and terminology for reporting and tracking outcomes. The BI-RADS Atlas contains guidance on monitoring outcomes and conducting audits [53]. Summary statistics and comparisons generated for each physician and for each facility should be reviewed annually by the lead interpreting physician.

For further information, please see the ACR Breast MRI Accreditation Program Requirements [78].

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