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Revised 2013 (Resolution 12)*

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

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 care¹. 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 in light of 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 the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document is advised to document in the patient record information sufficient to explain the approach taken.

The practice of medicine involves not only the science, but also 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 sole purpose of this document is to assist practitioners in achieving this objective.

¹ Iowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing, ___ N.W.2d ___ (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 disease, assessment of local extent of the disease, evaluation of treatment response, and guidance for biopsy and localization. MRI findings should be correlated with clinical history, physical examination results, and the results of mammography and any other prior breast imaging.

II. CURRENT INDICATIONS

A. Current indications for breast MRI include, but are not limited to:

1. Screening

- a. For high-risk patients – Clinical trials from the United States and Europe have demonstrated that breast MRI can significantly improve the detection of cancer that is otherwise clinically, mammographically, and sonographically occult [1-13]. Patients should be referred for screening breast MRI, preferably after risk assessment and counseling of high risk patients by personnel trained in the assessment of hereditary breast cancer or by their referring physician who has used a risk assessment model. Breast MRI may be indicated in the surveillance of women with more than a 20% lifetime risk of breast cancer (for example, individuals with genetic predisposition to breast cancer by either gene testing or family pedigree, or individuals with a history of mantle radiation for Hodgkin's disease). Although there is no direct evidence that screening with MRI will reduce mortality, it is thought that early detection by using annual MRI as surveillance, in addition to mammography, may be useful.
- b. For patients with a new breast malignancy - Screening of the contralateral breast with MRI in patients with a new breast malignancy can detect occult malignancy in the contralateral breast in at least 3% to 5% of breast cancer patients [5,14-16]. For this reason, it may be used as a diagnostic tool to identify more completely the extent of disease in patients with a recent breast cancer diagnosis.
- c. For patients with breast augmentation - Breast MRI using contrast may be indicated in the evaluation of patients with silicone or saline implants and/or free injections with silicone, paraffin, or polyacrylamide gel in whom mammography is difficult. The integrity of silicone implants can be determined by noncontrast MRI.

2. Extent of disease

- a. Invasive carcinoma and ductal carcinoma in situ (DCIS) – Breast MRI may be useful to determine the extent of disease and the presence of multifocality and multicentricity in patients with invasive carcinoma and ductal carcinoma in situ (DCIS). Multiple clinical trials in the United States and Europe show that on average MRI can detect occult disease in the ipsilateral breast (containing the index malignancy) in approximately 15% of patients, with ranges reported from 12 to 27% and disease in the contralateral breast in 4% of patients [14,15,17-23]. MRI determines the extent of disease more accurately than standard mammography and physical examination in many patients. It remains to be shown conclusively, however, that this increased accuracy results in any reduction in recurrence rates following surgery, radiation, or systemic therapy.
- b. Invasion deep to fascia – MRI evaluation of breast carcinoma prior to surgical treatment may be useful in both mastectomy and breast conservation candidates to define the relationship of the tumor to the fascia and its extension into pectoralis major, serratus anterior, and/or intercostal muscles [24,25].

- c. Postlumpectomy with positive margins – Breast MRI may be used in the evaluation of residual disease in patients whose pathology specimens demonstrate close or positive margins for residual disease.
- d. Neoadjuvant chemotherapy – Breast MRI may be useful before, during, and/or after chemotherapy to evaluate treatment response and the extent of residual disease prior to surgical treatment. If used in this manner, a pretreatment MRI is recommended [26] to facilitate assessment of subsequent treatment response. MRI-compatible localization tissue markers placed prior to neoadjuvant chemotherapy may be helpful to indicate the location of the tumor in the event of complete response with no detectable residual tumor for resection.

3. Additional evaluation of clinical or imaging findings

- a. Recurrence of breast cancer – Breast MRI may be useful in women with a prior history of breast cancer and suspicion of recurrence when clinical, mammographic, and/or sonographic findings are inconclusive.
- b. Metastatic cancer when the primary is unknown and suspected to be of breast origin – MRI may be useful in patients presenting with metastatic disease and/or axillary adenopathy and no mammographic or physical findings of primary breast carcinoma. Clinical trials demonstrate that breast MRI can locate primary tumor in the breast in over half of women presenting with metastatic axillary adenopathy and an occult primary [27-30]. Breast MRI can also define the disease extent to facilitate treatment planning.
- c. Lesion characterization – In rare cases, breast MRI may be indicated when other imaging examinations, such as ultrasound and mammography, and physical examination are inconclusive for the presence of breast cancer, and biopsy cannot be performed (e.g., possible distortion on only one mammographic view without a sonographic correlate). MRI should not replace ultrasound or diagnostic mammography to evaluate clinical focal signs or symptoms in the breast or to evaluate lesions identified on screening mammography [31].
- d. Postoperative tissue reconstruction – Breast MRI may be useful in the evaluation of suspected cancer recurrence in patients with tissue transfer flaps.
- e. MRI-guided biopsy – MRI is indicated for guidance of interventional procedures such as vacuum assisted biopsy and preoperative wire localization for lesions that are occult on mammography or sonography and demonstrable only with MRI.

B. Other Considerations

1. Screening of general population

Screening breast MRI is not recommended for the general population of asymptomatic, average-risk women.

2. False positives

Breast MRI may yield findings that are not evident clinically or on mammography or ultrasound. The findings may or may not be clinically significant. As with mammography or any other diagnostic test, false positive results can be expected, and the literature shows a wide range of specificity for breast MRI. The additional abnormalities detected on MRI may result in a follow-up examination or recommendation for biopsy. Published results for MRI directed biopsy are similar to those for mammography.

3. Treatment choices

Information from the MRI may change the planned treatment management. Caution should be exercised in changing management based on MRI findings alone without initial biopsy confirmation. Additional biopsies and/or correlation with other clinical and imaging information should be used together with clinical judgment. There is currently no evidence that identification of additional ipsilateral or contralateral occult malignancies improves patient outcomes.

4. Inappropriate uses of breast MRI

MRI should not supplant careful problem-solving mammographic views or ultrasound in the diagnostic setting. Because MRI will miss some cancers that mammography will detect, it should not be used as a substitute for screening mammograms. MRI should not be used in lieu of biopsy of a mammographically, clinically, and/or sonographically suspicious finding.

III. SAFETY GUIDELINES AND POSSIBLE CONTRAINDICATIONS

See the ACR Practice Parameter for Performing and Interpreting Magnetic Resonance Imaging (MRI), the [ACR Manual on Contrast Media](#), and the [ACR Guidance Document on MR Safe Practices](#) [32,33].

Peer reviewed literature pertaining to MR safety should be reviewed on a regular basis [34-36].

IV. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

See the ACR Practice Parameter for Performing and Interpreting Magnetic Resonance Imaging (MRI) [33].

In addition, interpreting physicians should have knowledge and expertise in breast disease and breast imaging diagnosis. Facilities performing breast MRI should have the capacity to perform mammographic correlation, directed breast ultrasound, and MRI-guided intervention, or create a referral arrangement with a cooperating facility that could provide these services. The histopathology of the biopsy should be available to the interpreting physician as well as the physician performing the breast MRI procedure.

V. SPECIFICATIONS OF THE EXAMINATION

Patients should undergo standard mammography in addition to breast MRI (unless patient consideration precludes X-ray imaging), and the mammography study images and report should be available for review. Additionally, an attempt should be made to obtain prior breast MRI studies for correlation. If the patient has had recent biopsy(ies) and/or excisional surgery, the histopathologic results should also be available for review.

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)

A. Patient Selection and Preparation

The physician responsible for the breast MRI should supervise patient selection and preparation. Patients should be interviewed and screened for possible contraindications for MRI as discussed in section III.

Patients suffering from anxiety or claustrophobia may require sedation or additional assistance. Administration of anxiolysis or moderate sedation may be needed to achieve a successful examination (see the [ACR–SIR Practice Parameter for Sedation/Analgesia](#)). A recovery area is necessary, and appropriate personnel must be available to monitor the patient following sedation. Sedation must be administered in accordance with institutional policy and state and federal law by a physician or by a nurse with training in cardiopulmonary resuscitation.

Increased parenchymal enhancement has been observed normally during the secretory phase of the menstrual cycle. This normal enhancement may give rise to false positive and false negative MRI scans. It is therefore recommended that breast MRI scans be performed during the second week of the menstrual cycle for patients undergoing screening examinations. This may not be warranted for women undergoing evaluation for breast cancer treatment planning.

B. Facility Requirements

Appropriate emergency equipment with medications must be immediately available to treat adverse reactions associated with administered medications. 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.

VI. DOCUMENTATION

Reporting should be in accordance with the [ACR Practice Parameter for Communication of Diagnostic Imaging Findings](#). 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 [37].

VII. EQUIPMENT SPECIFICATIONS

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 [38,39].

Technical Guidelines

1. Resolution, contrast, and field strength – The selection of field strength is a major technical decision. A 1.5T magnet has traditionally been considered a minimum technical requirement 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 the problem of volume averaging effects. Optimized contrast between tumor and surrounding tissue is important. When high-resolution images are being obtained, chemical fat suppression is helpful as a method to reduce fat signal while preserving the signal-to-noise ratio. Sole reliance on subtraction imaging for assessment of enhancement may result in misregistration due to patient motion; use of fat suppression is recommended on sequences used to assess contrast enhancement. Some protocols may

incorporate both fat suppression and subtraction. Motion correction may be helpful in reducing artifacts encountered with image subtraction.

2. Simultaneous bilateral imaging – Simultaneous bilateral high resolution imaging should be performed as the breasts are symmetric organs, and the extra time required is negligible.
3. Contrast – Gadolinium contrast enhancement is generally needed in the evaluation of breast cancer but is not generally necessary in the evaluation of implant integrity and rupture. 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.
4. Scan time – A precontrast scan should be obtained. Scan time in relation to contrast injection is extremely important for lesion characterization. Kinetic information should be reported, based on enhancement data determined at specified intervals separated by 4 minutes or less. Imaging sites should have adequately short temporal resolution for accurate capture of lesion kinetics.
5. Examinations should be performed with a dedicated bilateral breast MRI coil.

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 (<http://www.acr.org/guidelines>).

Equipment monitoring should be in accordance with the [ACR Technical Standard for Diagnostic Medical Physics Performance Monitoring of Magnetic Resonance Imaging \(MRI\) Equipment](#), including testing of the breast coil(s) by a Qualified Medical Physicist or Qualified Medical Scientist.

Examinations should be systematically reviewed and evaluated as part of the overall quality improvement program at the facility. Monitoring should include evaluation of the accuracy of interpretation as well as the appropriateness of the examinations. Complications and adverse events or activities that may have the potential for sentinel events must be monitored, analyzed, and reported, and periodically reviewed in order to identify opportunities to improve patient care. These data should be collected in a manner that complies with statutory and regulatory peer-review procedures in order 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.) The audit should include evaluation of the accuracy of interpretation as well as appropriate clinical indications for the examination. Facilities should use the Breast Imaging Reporting and Data System (BI-RADS®) final assessment codes and terminology for reporting and tracking outcomes. The BI-RADS® Atlas contains guidance on monitoring outcomes and conducting the audit. Summary statistics and comparisons generated for each physician and for each facility should be reviewed annually by the lead interpreting physician.

ACKNOWLEDGEMENTS

This guideline was revised according to the process described under the heading *The Process for Developing ACR Practice Guidelines and Technical Standards* on the ACR website (<http://www.acr.org/guidelines>) by the Joint Committee on Breast Imaging for Appropriateness Criteria and Practice Guidelines of the ACR Commission on Breast Imaging.

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*Practice parameters and technical standards are published annually with an effective date of October 1 in the year in which amended, revised, or approved by the ACR Council. For practice parameters and technical standards published before 1999, the effective date was January 1 following the year in which the practice parameter or technical standard was amended, revised, or approved by the ACR Council.

Development Chronology for this Practice Parameter

2004 (Resolution 11)

Amended 2006 (Resolution 35)

Revised 2008 (Resolution 25)

Revised 2013 (Resolution 12)

Amended 2014 (Resolution 39)