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The American College of Radiology will periodically define new practice guidelines 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 guidelines and technical standards will be reviewed for revision or renewal, as appropriate, on their fifth anniversary or sooner, if indicated.

Each practice guideline 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, requiring the approval of the Commission on Quality and Safety as well as the ACR Board of Chancellors, the ACR Council Steering Committee, and the ACR Council. The practice guidelines 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 guideline and technical standard by those entities not providing these services is not authorized.

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

PREAMBLE

These guidelines are an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. They are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care. For these reasons and those set forth below, the American College of Radiology cautions against the use of these guidelines 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 physician or medical physicist in light of all the circumstances presented. Thus, an approach that differs from the guidelines, 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 the guidelines 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 the guidelines. However, a practitioner who employs an approach substantially different from these guidelines 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 these guidelines 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 these guidelines is to assist practitioners in achieving this objective.

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 disease, evaluation of treatment response, and guidance for biopsy and localization. Breast MRI should be bilateral except for women with a history of mastectomy or when the MRI is being performed expressly to further evaluate or follow findings in one breast. 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. Screening of high-risk patients – Recent clinical trials have demonstrated that breast MRI can significantly improve the detection of cancer that is otherwise clinically and mammographically occult. Patients should be referred for screening breast MRI, preferably after careful risk assessment, 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. Screening of the contralateral breast in patients with a new breast malignancy
MRI can detect occult malignancy in the contralateral breast in at least 3% to 5% of breast cancer patients.
- c. Breast augmentation - postoperative reconstruction and free injections
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). MRI can detect occult disease up to 15% to 30% of the time in the breast containing the index malignancy. MRI determines the extent of disease more accurately than standard mammography and physical examination in many patients. It remains to be conclusively shown that this alters recurrence rates relative to modern surgery, radiation, and 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.

- 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 highly recommended. 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. Breast MRI can sometimes locate the primary tumor and define the disease extent to facilitate treatment planning.
 - c. Lesion characterization – 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 could not be performed (e.g., possible distortion on only one mammographic view without a sonographic correlate).
 - d. Postoperative tissue reconstruction – Breast MRI may be useful in the evaluation of suspected cancer recurrence in patients with

tissue transfer flaps (rectus, latissimus dorsi, and gluteal).

- 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. Precautions

1. Screening of general population

Screening breast MRI is not recommended at the present time in the general population of asymptomatic, average-risk women.

2. False positives

Breast MRI may detect abnormalities that are not evident clinically, mammographically, or sonographically. They 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 biopsy rates for MRI are similar to those for mammography.

3. Treatment choices

Information from the MRI examination 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. Clinical trials are needed to determine the outcome significance of MRI-detected, clinically occult disease in the patient with a new breast cancer diagnosis.

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 Guideline for Performing and Interpreting Magnetic Resonance Imaging \(MRI\)](#) and the ACR Guidance Document for Safe MR Practices.

Peer reviewed literature pertaining to MR safety should be reviewed on a regular basis.

IV. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

See the [ACR Practice Guideline for Performing and Interpreting Magnetic Resonance Imaging \(MRI\)](#).

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. Whenever possible 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 examination shall supervise patient selection and preparation. Patients shall 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 moderate or "conscious" sedation may be needed to achieve a successful examination. If moderate sedation is necessary, refer to the [ACR Practice Guideline for Adult Sedation/Analgesia](#). A recovery area is necessary, and appropriate personnel must be available to monitor the patient following sedation. Sedation shall 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 can give rise to false positive MRI scans. It is therefore recommended that breast MRI scans be performed during the second week of the menstrual cycle whenever possible. Bilateral imaging may help to improve specificity, as enhancement characteristics vary from patient to patient and during the menstrual cycle, and enhancement of some benign conditions such as fibrocystic changes is often bilateral.

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 Guideline 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 Lexicon for Breast MRI. Analysis of abnormalities on breast MRI may consider both morphologic and kinetic features of the abnormality. The BI-RADS[®] assessment category should be included in the conclusion of the report.

VII. EQUIPMENT SPECIFICATIONS

The MRI equipment specifications and performance shall 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. Resolution, contrast, and field strength – The selection of field strength is a major technical decision. A 1.5 Tesla 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. Bilateral imaging is favored over unilateral imaging as the breasts are symmetric organs, and there is negligible time penalty for imaging both breasts. Unilateral imaging is reserved for mastectomy patients or individuals requiring a specifically tailored follow-up examination.

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. If a single postcontrast scan is acquired, the scan time should not extend beyond 5 minutes after bolus injection. If kinetic information is reported, enhancement curves should be calculated at specified intervals separated by 3 minutes or less. Sites reporting kinetics should have adequately short temporal resolution for accurate capture of lesion kinetics.
5. Examinations should be performed with a dedicated breast MRI coil unless obesity or other patient consideration requires modification of the imaging procedure.

VIII. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION CONCERNS

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 Concerns appearing elsewhere in the ACR Practice Guidelines and Technical Standards book.

Equipment monitoring should be in accordance with the [ACR Technical Standard for Diagnostic Medical Physics Performance Monitoring of Magnetic Resonance Imaging \(MRI\) Equipment](#).

A basic audit of breast MRI should be performed similar to the requirements for mammography: follow-up of all positive findings as BIRADS[®] 0, 4, and 5 should be correlated with follow-up pathology or other imaging. Evaluations of BIRADS 6 “extent of disease” studies, where feasible, should be compared to final pathology.

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Imaging for Appropriateness Criteria and Practice Guidelines of the Commission on Breast Imaging.

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