

# Consensus Guideline on Diagnostic and Screening Magnetic Resonance Imaging of the Breast

## Purpose

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To outline the recommended practice of diagnostic and screening magnetic resonance imaging (MRI) of the breast.

## Associated ASBrS Guidelines or Quality Measures

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1. This document replaces the previous ASBrS Statements of “Position Statement on the Use of Magnetic Resonance Imaging in Breast Surgical Oncology” (July 27, 2010) and “The Use of Magnetic Resonance Imaging in Breast Oncology” (May 6, 2007).
2. The ASBrS Choosing Wisely® Campaign endorses the statement “Don’t routinely order breast MRI in new breast cancer patients.” There are no other ASBrS Guidelines or Quality Measures on breast MRI.

## Methods

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A comprehensive, but not a systematic review of the literature, was performed, inclusive of recent randomized controlled trials and meta-analyses evaluating the efficacy of screening and diagnostic breast MRI. The ASBrS Research Committee developed a consensus document which was reviewed and approved by the ASBrS Board of Directors.

## Summary of Data Reviewed

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### Diagnostic MRI in the Breast Cancer Patient

MRI of the breast has been used for breast cancer detection since its approval by the FDA more than 25 years ago. MRI of the breast has higher sensitivity than mammography for cancer detection (> 90%) but variable specificity (range 30-90%).<sup>1-6</sup> MRI may aid diagnostic evaluation of the breast and surgical decision-making in selected patient populations as indicated below.<sup>7-10</sup> False-positive findings on breast MRI are common. Therefore, histologic confirmation of suspicious indeterminate MRI findings is necessary if the identification of new cancer(s) would change patient treatment from breast conserving to ipsilateral, contralateral, or bilateral mastectomy.<sup>2,11,12</sup> Multiple studies confirm an association between receipt of breast MRI in patients with cancer and increased ipsilateral and contralateral mastectomy rates, including contralateral prophylactic mastectomy, as well as increased time to treatment.<sup>13-19</sup>

MRI has been shown to increase identification of ipsilateral and contralateral malignancies. In 2008, a meta-analysis by Houssami et al reported on 2610 patients with breast cancer who underwent MRI.<sup>3</sup> Additional disease was identified in 16% of patients (range 6% to 34%). The impact of these MRI findings was a change from wide-local excision to mastectomy in 8.1% of women (95% CI 5.9–11.3) and a larger local excision in 11.3% of women (95% CI 6.8–18.3). In 2012, a systematic review of the literature by Lehman reported 617 (13.7%) of 4500 women undergoing MRI with known breast cancer had additional ipsilateral breast cancer detected, and 151 (3.6%) of 4147 women had additional contralateral cancers detected by MRI.<sup>20</sup> These MRI-detected findings impacted surgical decision-making. A separate meta-analysis by Brennan et al addressed the rate of MRI-detected contralateral breast cancer detection in women with presumed unilateral disease.<sup>4</sup> They reported on 22 studies including 3253 patients. MRI found a synchronous contralateral cancer in 4.1% of patients; 35% were DCIS, and 65% were invasive cancers.

The receipt of MRI in patients with breast cancer is an independent risk factor for the patient receiving mastectomy, even when adjusted for stage and tumor characteristics. In 2013, a meta-analysis by Houssami et al reviewed the outcomes after MRI in 3112 breast cancer patients captured from 7 comparative cohort studies and prospective randomized trials.<sup>19</sup> A significant increase in both the initial and overall mastectomy rates was seen in the MRI group (16.4% and 25.5%, respectively) compared with the no-MRI group (8.1% and 18.2%, respectively), with a consistent increase in mastectomy rates after adjusting for age (initial mastectomy adjusted OR 3.06, 95% CI 2.03–4.62,  $p < .001$ ; overall mastectomy adjusted OR 1.51, 95% CI 1.21–1.89,  $p < .001$ ).

The accuracy of MRI to determine tumor size has been compared to conventional imaging in the neoadjuvant setting. The level of agreement between MRI and pathologic tumor size is better than clinical examination and mammography but similar to ultrasound by meta-analysis.<sup>21</sup>

The comparative effectiveness of breast MRI between patients who had a preoperative MRI and those patients who did not for the outcomes of re-excision rates, ipsilateral breast tumor recurrence (IBTR) and overall survival (OS) were reported in the Houssami meta-analysis (2013) above, and in two randomized trials.<sup>12,18,19</sup> There is no convincing evidence that MRI reduces re-excision lumpectomy rates, local recurrence, or overall survival in patients with invasive breast cancer or ductal carcinoma in situ.<sup>22,23</sup>

The decision to use breast MRI as an adjunct to clinical examination, mammography, and ultrasound in newly diagnosed breast cancer patients should be made by the physician and patient after joint consideration of the benefits as well as the consequences of MRI, such as frequent false-positive findings of the breast, increased ipsilateral and contralateral mastectomy rates and increased time to treatment.<sup>2,4,7,11,17,24,25</sup> The performance of MRI is associated with increased costs of care and may be associated with increased patient anxiety.<sup>7,12,26</sup> Well-informed patients may have less distress when false-positive findings necessitate additional biopsies.

## Screening MRI in the High Risk Patient

In studies comparing the effectiveness of breast MRI to mammography for screening of high-risk women for breast cancer - including patients with BRCA mutations - MRI increased the cancer detection rate. In a 2015 pooled analysis of women at high risk for breast cancer, Phi et al reported that MRI and mammography increased screening sensitivity of cancer compared to mammography alone (94% vs 38%;  $p < .001$ ).<sup>27</sup> In a 2011 study limited to 1,275 BRCA-positive women undergoing screening, Warner et al compared the stage of breast cancer at diagnosis stratified by those screened with MRI and those who had conventional screening alone.<sup>28</sup> On multivariate analysis, the adjusted hazard ratio (HR) for the development of higher-stage (II to IV) breast cancer in the MRI cohort was 0.30 (95% CI 0.12–0.72) compared to screening that did not include MRI.

King et al reported outcomes of 776 women with LCIS, with ( $n = 455$ ) and without MRI screening ( $n = 321$ ) after their diagnosis.<sup>29</sup> After a median follow-up period of 58 months, they were not able to demonstrate any statistical differences in the groups for cancer detection, nodal status, or tumor size. The women who underwent screening with MRI required more biopsies. In women with dense breasts identified on *screening* mammography, the U.S. Preventive Services Task Force's systematic review on *supplemental* MRI screening for cancer detection reported the following: sensitivity 75%-100%, specificity 78%-94%, PPV 3% to 33%, and recall rates 12-24%.<sup>30</sup> Use of MRI detected 3.5 to 28.6 additional cancer cases per 1000 examinations (34% to 86% invasive). They concluded the benefits were "unclear."

## Breast MRI Performance

Diagnostic breast MRI is not recommended until after clinical breast examination and conventional breast imaging are performed and interpreted unless being performed as part of a standard screening program.

Breast MRI requires a high field system (minimum 1.5 Tesla magnet), a dedicated breast surface coil (breast images taken in a body scanner are inadequate) and intravenous gadolinium (or other approved Breast MRI) contrast. "Open" MRI equipment, designed for claustrophobic patients, is not recommended. Breast MRI should be performed by a dedicated imaging team, including radiologists proficient in diagnostic mammography, ultrasound (US), MRI and MRI image- guided biopsy techniques.

Policies for pre-MRI identification of "claustrophobic" and "gadolinium risk" patients should be established. Breast MRI with gadolinium contrast should not be ordered in patients receiving renal dialysis for kidney failure and should be used only with caution and with adequate informed consent in patients with a GFR  $< 30$  mL/min/1.73m<sup>2</sup> due to the risk of nephrogenic systemic fibrosis. Administration of gadolinium contrast is discouraged during pregnancy, as safety of use has not been established. If contrast cannot be used, then breast MRI is not recommended in the screening or diagnostic setting.

Percutaneous MRI-guided biopsy capability is essential for centers performing breast MRI even though some MRI lesions confirmed on second look US are amenable to US-guided core

biopsy. For indeterminate suspicious lesions of the breast identified on MRI that are not amenable to US or MRI guided biopsy, MRI- guided wire localization can be considered.<sup>31</sup>

Radiologic-pathologic correlation is essential for MRI detected indeterminate suspicious lesions diagnosed as histologically benign after minimally invasive breast biopsy (MIBB). The decision to schedule MRI follow-up must be individualized, taking into account the patient's clinical examination, mammography and ultrasound results, level of suspicion, and patient desire. If there is imaging-pathology discordance, then repeat MIBB or surgical excision should be considered.

### **Patient-Centered Policies**

Protocols to optimize patient-centered care should be considered. These include, but are not limited to providing the patient with assistance in MRI scheduling, billing pre-authorization, transparency of anticipated out-of-pocket charges, retrieval of breast imaging studies performed elsewhere, and identification of patients too obese for MRI. Patients should be informed that a contrast agent, such as gadolinium, may be used during the MRI scan to best identify areas of concern. Recent information has shown that when an individual receives gadolinium repeatedly it may collect in the brain. The importance of this information and how it impacts a patient's health is not known.<sup>32</sup> Gadolinium given during pregnancy could cause a still birth or the baby could have skin diseases later in their childhood. Women who are pregnant or could be pregnant should have a pregnancy test prior to a Breast MRI with Gadolinium.

### **Recommendations**

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1. The ASBrS does not recommend routine diagnostic MRI in newly diagnosed breast cancer patients except as part of a scientific study.
2. The ASBrS supports the use of MRI in the following situations:
  - a. To search for occult breast cancer in patients with Paget's disease of the nipple or in patients with axillary node metastasis when clinical examination and conventional breast imaging fail to detect a primary breast cancer. MRI identifies an ipsilateral cancer focus in 60-70% of patients who present with axillary nodal metastases and no cancer identified on clinical examination, mammography, or ultrasound.<sup>33-36</sup>
  - b. For determining the extent of cancer or presence of multi-focal or multi-centric tumor or the presence of contralateral cancer, in patients with a proven breast cancer *and* associated clinical or conventional indeterminate imaging findings suspicious for malignancy. This may include patients with invasive lobular carcinoma or extremely dense breast tissue (limiting mammographic sensitivity), or when there are significant discrepancies in the estimated tumor size as measured on clinical exam, mammogram, and ultrasound. The American College of Radiology Appropriateness Criteria and a recent meta-analysis by Houssami et

al conclude there are no proven criteria for any patient sub-population that benefits the most from routine MRI based on specific patient, tumor, or mammographic characteristics.<sup>37-39</sup>

- c. To aid the assessment for eligibility and response to neoadjuvant endocrine therapy or chemotherapy before, during, or after treatment. MRI can help identify those patients who are candidates for breast conservation, and assist in determining the extent of resection<sup>40,41</sup>. After neoadjuvant chemotherapy (NAC), MRI has a sensitivity of 92% to detect residual disease and a specificity of 60% for pathologic complete response (pCR), based on a meta-analysis of 44 studies including 2050 patients reported by Marinovich et al in 2013.<sup>42</sup> Compared to mammography, MRI was better in assessing response to NAC, but a negative MRI did not always exclude residual microscopic disease. In two updated meta-analyses (2016 and 2017) assessing pCR, Gu et al and Sheikhabaei et al reported pooled sensitivities and specificities of 64%/88% and 92%/55% respectively. MRI is not mandatory in patients undergoing neoadjuvant systemic therapy.<sup>43,44</sup>
- d. For the further evaluation of suspicious clinical or imaging findings that remain indeterminate after complete mammographic and sonographic evaluations. If lesions meet the criteria for biopsy by clinical examination or conventional imaging, then it may be preferable to perform minimally invasive needle biopsy, targeted by mammogram or US, rather than obtain an MRI.
- e. For evaluation of suspected breast implant rupture, especially in patients with silicone implants, if the MRI findings will aid the decision-making for implant removal or aid the diagnostic evaluation of indeterminate clinical or conventional imaging findings in patients with implants. The MRI protocol for detection of silicone leak is different from the protocol for detection of breast cancer. Thus, it is important to clearly define the purpose of the breast MRI if the concern is a silicone leak.

### **MRI Screening of patients at high risk for breast cancer**

1. The ASBrS recommends annual MRI screening in the following patients, compliant with NCCN Guidelines<sup>45-49</sup>:
  - a. Women age 25 or greater with a BRCA gene mutation (Hereditary breast and ovarian cancer syndrome; BRCA1 and BRCA2) and their untested first-degree relatives, unless the patient has limited life expectancy from age and comorbid conditions.
  - b. Women with other germline mutations known to predispose to a high risk of breast cancer: Li-Fraumeni (begin age 20-29), Cowden's disease (PTEN Hamartoma Tumor Syndrome-PT53) (begin age 30-35 or 5-10 years before earliest breast cancer in family), ATM (begin age 40), CDH1 (begin age 30), CHEK2 (begin age 40), NF1 (begin age 30), PALB2 (begin age 30), and STK11, unless the patient has limited life expectancy from age and comorbid conditions. This

recommendation is compliant with the NCCN Guidelines for consideration of screening MRI.

- c. Women with a history of chest irradiation, especially if they received mediastinal radiation for Hodgkins disease between the ages of 10-30.
  - d. Women with a 20%-25% or greater estimated lifetime risk of breast cancer primarily based on mathematical models that are mostly based on family history such as the Claus, BRCAPRO, BOADICEA, and Tyrer-Cuzick models.
2. Screening MRI should be used in addition, not as an alternative, to screening mammography when indicated. The comparative effectiveness of scheduling annual screening MRI and mammography as synchronous versus 6-month metachronous examinations has not been determined.
3. Screening MRI is not recommended in patients with a genetic “variant of unknown significance” (VUS) without other indications for high risk screening.
4. Routine annual MRI is not indicated for screening of women with a prior history of breast cancer unless they have a known genetic or other significant risk factor placing them at high-risk for a new breast cancer as described above.

### **MRI Appropriateness in Special Populations**

1. *Implants*: The ASBrS does not recommend routine MRI screening in asymptomatic patients with silicone or saline implants. The U.S. Food and Drug Administration (2006) recommended that all silicone breast implant recipients undergo serial MRI screening to detect implant rupture. However, a systematic review and meta-analysis by Song et al. identified methodologic biases in prior studies that assessed MRI accuracy in this setting, resulting in overestimation of MRI benefit.<sup>50</sup> Therefore, the FDA recommendations should be interpreted with caution regarding routine screening of patients with silicone implants.
2. *Nipple Discharge*: The NCCN specifies diagnostic MRI as an option to consider in patients with spontaneous unilateral nipple discharge who have normal conventional imaging studies and no palpable mass. However, the sensitivity and specificity of MRI to detect or exclude cancer in the setting of nipple discharge is not well described. We do not recommend its routine use. There is no consensus in the literature on specific sub-populations in which this care pathway is more effective or preferable to care without MRI.<sup>51</sup>
3. *High-risk lesions*: NCCN Guidelines do not include a recommendation for breast MRI after a minimally invasive needle biopsy of the breast identifies LCIS, ADH or other lesions commonly referred to as “high risk.” There is no consensus in the literature on the specific sub-populations in which this care pathway is more effective or preferable to care without MRI.<sup>52</sup> The ASBrS recommends physician discretion regarding the use of

MRI in patients with high risk lesions based on the patient's history and existing conventional imaging.

4. *Breast pain*: NCCN Guidelines and the ASBrS do not recommend breast MRI for evaluation of breast pain.
5. *Inflammatory skin changes*: NCCN Guidelines consider breast MRI as an option for patients presenting with suspicious skin changes consistent with inflammatory breast cancer, if conventional imaging and skin biopsies are first performed and are negative for malignancy.

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**This statement was developed by the Society's Research Committee and on June 22, 2017, was approved by the Board of Directors.**