Indications for Breast MRI in the Patient with Newly Diagnosed Breast Cancer

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Key Words
Breast MRI, breast cancer, extent of disease, management of breast cancer

Abstract
Use of breast MRI in the preoperative evaluation of patients recently diagnosed with breast cancer has increased significantly over the past 10 years because of its well-documented high sensitivity for detecting otherwise occult breast cancer in the affected and contralateral breasts. However, published research reports on the impact of this improved cancer detection are limited. Equally important are growing concerns that the quality of breast MRI may vary significantly across practice sites, and therefore the published value of MRI may not be achieved for many patients. This article describes the peer-reviewed, published clinical research trials evaluating breast MRI in patients with newly diagnosed breast cancer on which the National Comprehensive Cancer Network (NCCN) practice guidelines are based. The current NCCN guidelines recommend that breast MRI be considered for patients with a newly diagnosed breast cancer to evaluate the extent of ipsilateral disease and to screen the contralateral breast, particularly for women at increased risk for mammographically occult disease. In addition, the guidelines indicate that breast MRI may be used for patients with axillary nodal adenocarcinoma to identify the primary malignancy. The guidelines stress the importance of having proper equipment, imaging technique, and provider training necessary to achieve high-quality breast MRI, and emphasize that MRI practice sites should have the ability to perform MRI-guided biopsy or needle localization. In addition to describing the data regarding use of breast MRI in women with newly diagnosed cancer, this article provides recommendations for the performance of high-quality breast MRI and suggestions for future research. (JNCCN 2009;7:193–201)

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Original Article

Lehman et al.

Although breast imaging of the breast was one of the first attempted clinical applications for MRI, initial evaluations were disappointing. Use of MRI for orthopedic and neurologic applications rapidly advanced in clinical medicine, whereas enthusiasm for this modality as an effective tool for breast imaging waned. In the 1980s, technical improvements and the application of intravenous contrast agents to facilitate the identification of malignant lesions led to a renewed enthusiasm for breast MRI. Clinical studies published since the early 1990s have confirmed the high sensitivity of breast MRI for detecting otherwise occult cancers in women recently diagnosed with breast cancer. These studies have shown that MRI can improve assessment of disease extent in the breast known to be affected with cancer and may detect mammographically occult cancer in the contralateral breast.

No published trials have suggested that breast MRI should be used as a substitute for screening or diagnostic mammography. Studies have evaluated MRI in conjunction with mammographic imaging, with most performing MRI after mammographic evaluation was completed. Thus, the consistent recommendation from all trials is to use MRI as an adjunct to mammography and not in lieu of standard breast imaging with mammography and, when indicated, diagnostic breast ultrasound.

**Preoperative Staging of the Affected and Contralateral Breast in Patients With a Known Cancer**

Among women with a diagnosed breast cancer, MRI provides enhanced cancer detection in both the breast known to be affected by cancer and the contralateral breast. The potential benefit of MRI includes more accurate definition of the extent of the known cancer, detection of additional foci of cancer in the affected breast, and detection of otherwise occult cancer in the contralateral breast.

Numerous studies since the early 1990s have shown the increased sensitivity of MRI compared with standard mammographic or sonographic imaging in determining the true extent of disease in patients newly diagnosed with breast cancer. A recent meta-analysis of 19 published studies of women with breast cancer undergoing preoperative MRI reviewed its staging in the affected breast. This analysis found that preoperative MRI detected additional disease in 16% of women (N = 2610). The review also reported high specificity of MRI, with 66% of suspicious MRI lesions proven to be malignant through biopsy.

Study design and patient selection vary widely across published investigations. Among those that included a broad range of patients with breast cancer, as opposed to studies that restricted patient selection to those with locally advanced disease, dense breast tissue, and/or invasive lobular cancers, MRI was estimated to improve cancer detection in approximately 10% compared with standard breast imaging alone (Table 1). However, to achieve this higher rate of cancer detection, approximately 20% to 30% of patients required additional imaging and tissue sampling before definitive surgical intervention. Given that approximately 30% to 60% of suspicious lesions recommended for biopsy in this setting are benign, suspicious lesions on MRI must be biopsied to confirm true histology before surgical management is modified.

Prior reports have documented that MRI provides improved sensitivity for detecting cancers in the contralateral breast in women with recently diagnosed breast cancer. Published trials indicate that MRI will find mammographically and clinically occult malignancy in the contralateral breast in 3% to 5% of women with a newly diagnosed unilateral breast cancer (Table 2). In these patients, MRI may improve surgical planning when used as part of diagnostic workup before definitive surgical intervention. In the largest prospective multi-institutional study published, MRI detected 30 contralateral cancers among 969 women with negative mammograms. This added cancer yield was achieved with a specificity of 88%. Of these women, 12% underwent biopsy of suspicious contralateral lesions, and 25% of the lesions biopsied proved to be cancer.
Prior study designs almost exclusively performed breast MRI before surgery; however, in some practices, MRI is used for patients with positive margins after surgical excision to assess residual malignancy. Although the intention is to better define the extent of residual disease before returning to the operating room, distinguishing between residual disease and postoperative change can be challenging, and data supporting this practice are sparse. If used in this setting, the goal should be to evaluate possible disease distant from the surgical site.

In patients with newly diagnosed cancer, the specificity of breast MRI has gradually improved, likely because of improved technology and increased reader experience. Compared with studies of MRI performance published in the 1990s, more recent reports show higher and more acceptable specificities of MRI, leading to fewer unnecessary biopsies. Furthermore, similar to lesions detected on mammography and ultrasound, suspicious lesions identified on MRI may be benign. Thus, careful image-guided tissue sampling rather than assumption of histologic diagnosis based on imaging characteristics is essential before discussing appropriate surgical management.

Attention to key elements of adequate study design when evaluating new imaging technology is encouraged. The importance of the reference standard used in assessing diagnostic accuracy was underscored in the recent meta-analysis by Houssami et al. The diagnostic accuracy of MRI varied significantly depending on the reference standard used in the study design, with diagnostic accuracy decreasing from 99% to 86% as the quality of the reference standard increased. The adequacy of the reference standard in each study was assessed according to the extent of histologic verification in all patients.

Of the 19 studies, only 2 were judged to have complete histology data on all patients. At least 8 studies were designed to report outcomes of positive MR examinations only, providing no data on the outcomes of negative MR examinations. This study design essentially assumes that negative MR examinations all represented true negative results, which would imply that MRI has 100% sensitivity for detecting breast cancer. Test accuracy was likely overestimated in the study designs that assumed false-negative rates of 0.

Among the studies that allowed for the measurement of additional unsuspected ipsilateral malignancy, the prevalence of malignancy varied from 10% to 49% (Table 1). The prevalence of malignancy in the contralateral breast was somewhat lower, ranging from 3% to 23% (Table 2). These findings underscore the importance of considering both ipsilateral and contralateral breast malignancy in patients undergoing breast MRI.

### Table 1 MRI Detected Unsuspected Malignancy in the Ipsilateral Breast in Recently Diagnosed Breast Cancer

<table>
<thead>
<tr>
<th>Author</th>
<th>Number of Cases</th>
<th>Number (%) with Additional Ipsilateral MRI Malignancy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Harms and Flamig</td>
<td>29 breasts</td>
<td>10 (34.5%)</td>
</tr>
<tr>
<td>Orel et al.</td>
<td>64 women</td>
<td>13 (20.3%)</td>
</tr>
<tr>
<td>Mumtaz et al.</td>
<td>92 breasts</td>
<td>11 (12.0%)</td>
</tr>
<tr>
<td>Fischer et al.</td>
<td>336 women</td>
<td>54 (16.1%)</td>
</tr>
<tr>
<td>Bedrosian et al.</td>
<td>267 women</td>
<td>49 (18.4%)</td>
</tr>
<tr>
<td>Liberman et al.</td>
<td>70 women</td>
<td>19 (27.1%)</td>
</tr>
<tr>
<td>Schelfout et al.</td>
<td>170 women</td>
<td>33 (19.4%)</td>
</tr>
<tr>
<td>Schnall et al.</td>
<td>423 women</td>
<td>41 (9.7%)</td>
</tr>
<tr>
<td>Tan et al.</td>
<td>83 women</td>
<td>5 (6.0%)</td>
</tr>
<tr>
<td>Tillman et al.</td>
<td>207 women</td>
<td>18 (8.7%)</td>
</tr>
<tr>
<td>Kim do et al.</td>
<td>72 women</td>
<td>8 (11.1%)</td>
</tr>
<tr>
<td>Sardanelli et al.</td>
<td>90 women</td>
<td>31 (34.4%)</td>
</tr>
<tr>
<td>Hiawatsh et al.</td>
<td>101 women</td>
<td>6 (5.9%)</td>
</tr>
<tr>
<td>Bagley</td>
<td>27 women</td>
<td>6 (22.2%)</td>
</tr>
<tr>
<td>Hollingsworth et al</td>
<td>603 women</td>
<td>43 (7.1%)</td>
</tr>
<tr>
<td>Total</td>
<td>2634 women</td>
<td>347 (13.2%)</td>
</tr>
</tbody>
</table>

*Study restricted to women diagnosed with ductal carcinoma in situ.

### Table 2 MRI Detected Unsuspected Malignancy in the Contralateral Breast in Recently Diagnosed Breast Cancer

<table>
<thead>
<tr>
<th>Author</th>
<th>Number of Patients</th>
<th>Number (%) with Contralateral MRI Malignancy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rieber et al.</td>
<td>34</td>
<td>3 (8.8%)</td>
</tr>
<tr>
<td>Fischer et al.</td>
<td>463</td>
<td>15 (3.2%)</td>
</tr>
<tr>
<td>Slanetz et al.</td>
<td>17</td>
<td>4 (23.5%)</td>
</tr>
<tr>
<td>Liberman et al.</td>
<td>223</td>
<td>12 (5.4%)</td>
</tr>
<tr>
<td>Lee et al.</td>
<td>182</td>
<td>7 (3.9%)</td>
</tr>
<tr>
<td>Viehweg et al.</td>
<td>119</td>
<td>4 (3.4%)</td>
</tr>
<tr>
<td>Berg et al.</td>
<td>111</td>
<td>3 (2.7%)</td>
</tr>
<tr>
<td>Lehman et al.</td>
<td>103</td>
<td>4 (3.9%)</td>
</tr>
<tr>
<td>Pediconi et al.</td>
<td>118</td>
<td>22 (18.6%)</td>
</tr>
<tr>
<td>Lehman et al.</td>
<td>969</td>
<td>30 (3.1%)</td>
</tr>
<tr>
<td>Hlawatsch et al.</td>
<td>101</td>
<td>2 (2.0%)</td>
</tr>
<tr>
<td>Bagley</td>
<td>27</td>
<td>1 (3.7%)</td>
</tr>
<tr>
<td>Hollingsworth et al</td>
<td>603</td>
<td>22 (3.6%)</td>
</tr>
<tr>
<td>Total</td>
<td>3070</td>
<td>129 (4.2%)</td>
</tr>
</tbody>
</table>

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of false-negative rates, the sensitivity of MRI was approximately 86%, significantly less than prior reports of sensitivities of 99% to 100%.

Impact of Breast MRI on Surgical Management and Recurrence Rates

The improved sensitivity and acceptable specificity in detecting otherwise unsuspected malignancy among patients undergoing imaging at centers with experience in breast MRI are well accepted. However, reports on the impact of breast MRI on surgical management and recurrence rates in patients recently diagnosed with cancer are preliminary and inconclusive. No published randomized, prospective trials have assessed the impact of breast MRI on mastectomy rates, extent of surgery required for clear margins, and impact on outcome as measured by recurrence rates or mortality.

Several studies have assessed the impact of MRI staging of the ipsilateral breast on surgical planning. A subset of 13 studies was included in the meta-analysis by Houssami et al. Overall, 8.1% of women were converted from wide local excision to mastectomy and 11.3% from wide local excision to more extensive surgery (wider/additional excision or mastectomy) based on additional malignancy detected with MRI (true-positive MRI findings). Changes in surgical management were not always beneficial; 1% of women converted to mastectomy and 5.5% converted from wide local excision to more extensive surgery (wider/additional excision or mastectomy) based on false-positive MR examinations. Reports of women undergoing unnecessary mastectomies based on false-positive MR examinations are concerning and emphasize how important it is for women and their clinicians to understand that surgical management decisions should be based on confirmed histology, and not solely on the suspicious appearance of lesions on breast MRI.

Two retrospective studies have investigated the impact of preoperative breast MRI on long-term outcomes. Although Fischer et al. reported that women who had preoperative MRI were significantly less likely to experience recurrence (1.2%) than those who did not (6.8%), the treatment and control groups were not matched, and those who had undergone preoperative MRI had tumors that were less advanced than those who did not. Whether the differences in recurrence rates between groups would persist if the authors had adjusted for tumor size, nodal size, or use of systemic therapy is unclear.

More recently, Solin et al. reported no difference in recurrence rates among women who underwent preoperative MRI compared with those who did not (3% vs. 4% at 8 years). However, this was a retrospective, nonrandomized analysis, and all women with extensive disease identified on MRI and treated with mastectomy were excluded. The study was not powered adequately (n = 756) to identify significant recurrence rate differences in this population, and the MRI group comprised younger women who had smaller tumors than the non-MRI group.

The British Comparative Effectiveness of Magnetic Resonance Imaging in Breast Cancer (COMICE) trial is an ongoing prospective multicenter trial randomizing women with recently diagnosed breast cancer to preoperative evaluation with MRI or no MRI. The study will assess the impact of MRI on preoperative staging, reoperation rates, recurrence rates, quality of life, and cost-effectiveness. Peer-reviewed preliminary reports are expected in 2009.

Impact of Patient Characteristics on Added Yield of Cancer With MRI

Studies of MRI in patients with a newly diagnosed cancer have attempted to determine whether MRI is more useful for staging particular subgroups of patients, such as those with invasive lobular carcinoma (ILC) or mammographically dense breasts. Overall, most studies were retrospective and not adequately powered for the subset analyses of interest. Results of those studies are mixed.

Although some experts suggest that the impact of MRI is greatest in patients with larger tumors, ILC as the index lesion, and mammographically dense breast tissue, many large studies have not shown significant differences in cancer yields based on patient characteristics. For example, in the American College of Radiology Imaging Network (ACRIN) study of 969 women with a recently diagnosed breast cancer, the frequency of contralateral breast cancer detection was equivalent regardless of patient age, index tumor histology, or breast density. Nevertheless, given prior studies indicating that women with ILC and dense breast tissue are at increased risk for mammographically occult cancer, many clinical practice sites may limit use of breast MRI to these at-risk groups.
Axillary Nodal Metastasis With Unknown Primary

Rarely, women present with adenocarcinoma metastases in the axillary lymph nodes without an identified primary source of cancer. If the primary cannot be found through clinical breast examination and standard breast imaging, adenocarcinoma in the axillary lymph nodes is usually presumed to be caused by a primary cancer in the ipsilateral breast. Historically, mastectomy was recommended in this situation. However, more recent studies have suggested that well-selected patients who undergo whole breast radiation without mastectomy, followed by continued mammographic screening of both breasts, can have equivalent outcome as measured by local recurrence in the breast. MRI helps resolve the clinical dilemma about mastectomy in these patients. MRI detects the primary cancer in up to 70% of these patients, changing the staging from T0 (unknown primary) to the defined T1 to T3. Once the primary cancer is detected and histologically proven to be present in the ipsilateral breast, surgical planning can be made using standard criteria for patient management.

In several published series, MRI accurately identified the primary cancer in most patients presenting with axillary adenopathy, an unknown primary, and a negative clinical examination and mammogram. Overall, MRI will identify the primary in approximately 59% of women with this diagnosis, allowing them to pursue more appropriate and focused therapy for the breast malignancy. Therefore, for patients with biopsy-proven adenocarcinoma presenting in the axilla, a normal clinical breast examination, and a negative mammogram (TxN1–3), breast MRI is indicated to identify a primary cancer in the breast.

Technique and Interpretation Considerations

Because MRI is a newer tool for detecting breast cancer, its current use has several challenges because of a lack of standardization in imaging techniques and varied levels of experience among radiologists who perform and interpret breast MRI. No guidelines for image acquisition have been clearly established, and the techniques used for breast MRI differ across practice sites. Many technical parameters are subject to variability, including the pulse sequences, spatial resolution, and timing of postcontrast sequences. To address the current lack of standardization in MRI technique, the American College of Radiology (ACR) is developing a voluntary Breast MRI Accreditation Program, which will include minimum standards for breast MRI.

In the absence of formal guidelines, some general recommendations regarding reasonable, currently achievable techniques can be identified. The ACR Breast Imaging Reporting and Data System (BI-RADS) now includes a section dedicated to breast MRI. This initial iteration is focused on a BI-RADS lesion description lexicon, and the technical guidelines are limited. The only imaging parameters currently specified are that a dedicated breast coil is used and initial enhancement is measured within the first 2 minutes, and delayed enhancement measured more than 2 minutes after contrast administration.

The acquisition methods required for participation in the ACRIN 6667 trial can also provide guidance. This study evaluated MRI of the contralateral breast in women with recently diagnosed breast cancer and had 25 practice sites in the United States, Canada, and Germany. The minimum requirements for contrast-enhanced breast MRI included use of a dedicated breast coil and imaging with 1.5T or greater magnetic field strength. Also specified were a minimum of 2 postcontrast T1-weighted series, with initial postcontrast images within 4 minutes and delayed postcontrast images within 8 minutes after contrast administration. A maximum image slice thickness of 3 mm was required.

Although these standards were developed several years ago and are less than the spatial and temporal resolution now achievable, adherence to these parameters resulted in a sensitivity of 91% for contralateral breast cancer, with 3 missed cancers among all cases of ductal carcinoma in situ measuring less than 5 mm.

More recently, the European Society of Breast Imaging (EUSOBI) published its guidelines for breast MRI. Recommended parameters in common with the ACRIN trial include imaging with a dedicated breast coil at 1.5T field strength or greater, obtaining a minimum of 2 postcontrast T1-weighted series with initial images within 2 minutes of contrast administration, and slice thickness less than 3 mm (2.5 mm).

Breast MRI interpretation should be performed using the BI-RADS MRI lexicon, which provides a common terminology for describing findings. As with mammography, use of a consistent lexicon allows interpreters to communicate findings in a standardized
If a patient must be referred for tissue sampling, breast MRI must be applied in a fashion and facilitates comparison of findings across scientific studies. It is generally acknowledged that evaluation of both morphologic and kinetic features is important when characterizing breast MRI findings. For kinetics, it is specified that the “worst looking” signal intensity curve be described based on the most suspicious initial- and delayed-phase kinetic characteristics. Currently no consensus exists on the kinetic criteria for malignancy, and the enhancement pattern must be considered with the morphology features. Breast MRI interpretation, as with mammography, should include a final assessment of imaging findings with appropriate management recommendations using BI-RADS terminology.

An important final consideration is that sites performing breast MRI should also be able to perform MRI-guided tissue sampling. Suspicious lesions initially identified on breast MRI are frequently clinically, mammographically, and sonographically occult. These lesions require tissue sampling using MRI guidance for needle biopsy or wire localization and excision. Because of a lack of standardization in MRI techniques, many sites performing MRI-guided procedures do not perform tissue sampling based on an outside MR examination. If a patient must be referred for tissue sampling at a different practice site, then a repeat breast MRI is required, resulting in additional cost and time to diagnosis. Recent EUSOBI guidelines specify that sites performing breast MRI also offer MRI-guided procedures, and it is anticipated that this will be a component of the ACR Breast MRI Accreditation Program.

In summary, the NCCN Breast Cancer Guidelines stress the importance of the personnel, facility, and equipment supporting any breast MRI program: “Breast MRI examinations should be performed and interpreted by an expert breast imaging team working in concert with the multidisciplinary treatment team... Breast MRI examinations require a dedicated breast coil and breast imaging radiologists familiar with the optimal timing sequences and other technical details for image interpretation. The imaging center should have the ability to perform MRI-guided needle sampling and/or wire localization of MRI-detected findings.”

**Future Directions**

As with any new technology or approach to breast cancer diagnosis or treatment, breast MRI must be applied carefully to patients recently diagnosed with breast cancer. Peer-reviewed clinical research trials evaluating the performance of breast MRI across diverse practices and its impact on morbidity (surgical outcomes and recurrence) and mortality (either modeled or measured) are encouraged. As approaches to treatment of patients with breast cancer continue to evolve, the potential contribution of MRI to new treatments will require investigation. For example, current and future studies are expected to clarify the role of MRI in patients undergoing neoadjuvant chemotherapy and those considered for partial breast radiotherapy.

Continued development of clear parameters for performing high-quality breast MRI programs and support for auditing outcomes and performance are needed. The ACR has played a central role in the development and support of quality assurance programs in mammography, breast ultrasound, and image-guided biopsies. Extending these programs to breast MRI will continue to ensure a high quality of health care delivery across diverse practice sites.

**Conclusions**

In experienced centers, breast MRI is well documented to provide improved cancer detection and diagnosis with acceptable specificity. As its use continues to increase, careful application restricted to appropriate patient populations is urged. Development of clear standards for technical parameters to perform breast MRI is encouraged, as is monitoring of performance measures at clinical sites offering breast MRI. Breast MRI may be considered for patients with a new biopsy-proven breast cancer, and is also recommended for patients with axillary adenopathy unknown primary. In women with a newly diagnosed breast malignancy, MRI may be useful in defining the extent of cancer, presence of multicentric cancer in women with dense breast tissue on mammography, and extent of disease in women with locally advanced breast cancer. Decisions regarding the extent of breast surgery (e.g., breast conservation therapy vs. mastectomy) should not be made solely based on MRI and may require additional tissue sampling of identified areas of concern. As the use and demand for breast MRI increases, randomized studies will be increasingly challenging to conduct. Nevertheless, carefully designed prospective trials are encouraged to further clarify how MRI impacts women with known breast...
cancer. In the meantime, given the complexities of breast MRI performance and interpretation, imaging should be performed at sites with experience performing high-quality breast MRI, and interpreted by imaging teams working with multidisciplinary treatment teams.

References


42. Orel S. Who should have breast magnetic resonance imaging evaluation? J Clin Oncol 2008;26:703–711.


Indications for Breast MRI

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1. Which of the following is not likely to be a benefit of preoperative staging of breast cancer with MRI?
   A. Better definition of the extent of known cancer
   B. Reduction in the number of invasive procedures performed
   C. Detection of additional foci of cancer in the affected breast
   D. Detection of occult cancer in the contralateral breast

2. On the basis of clinical research, breast MRI may be most helpful in which of the following women?
   A. A woman with axillary node metastasis but unknown primary tumor
   B. A woman with very dense breasts
   C. A woman suspected of having invasive lobular carcinoma
   D. A woman with a large breast tumor

3. All of the following elements are part of the ACR Breast Imaging Reporting and Data System (BI-RADS) technical guidelines for breast MRI, except:
   A. A dedicated breast coil should be used
   B. The initial enhancement should be measured within 2 minutes of contrast administration
   C. Delayed enhancement should be measured 2 minutes after contrast administration
   D. Only 3-dimensional pulse sequences should be used

4. All of the following elements are part of the European Society of Breast Imaging (EUSOBI) technical guidelines for breast MRI, except:
   A. A dedicated breast coil at 1.5T field strength or greater
   B. At least 1 postcontrast T1-weighted image
   C. Initial postcontrast images should be captured within 2 minutes of contrast administration
   D. Slice thickness less than 3 mm

Activity Evaluation

| 1. The activity supported the learning objectives. | 3. The content learned from this activity will impact my practice. |
| Strongly Disagree | Strongly Agree | Strongly Disagree | Strongly Agree |
| 1 2 3 | 4 5 | 1 2 3 | 4 5 |

| 2. The material was organized clearly for learning to occur. | 4. The activity was presented objectively and free of commercial bias. |
| Strongly Disagree | Strongly Agree | Strongly Disagree | Strongly Agree |
| 1 2 3 | 4 5 | 1 2 3 | 4 5 |

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