Magnetic Resonance Imaging (MRI) of the Breast

Medical Policy

Section
Radiology

Original Policy Date
12:2013

Last Review Status/Date
Reviewed with literature search
12:2013

Issue
12:2013

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Description

Magnetic resonance imaging (MRI) of the breast is performed using MRI scanners and intravenous MRI contrast agents, together with specialized breast coils. This policy addresses the use of breast MRI for breast cancer imaging.

MRI of the breast can be used for screening, detection, and/or diagnosis of breast cancer. It can be used as a replacement for mammography screening, or can be used as an additional imaging test alone or in combination with other imaging modalities.

Screening Uses

- detection of breast cancer in patients who are at high genetic risk for breast cancer
- detection of breast cancer in patients who have breast characteristics limiting the sensitivity of mammography (i.e., dense breasts, implants, scarring after treatment for breast cancer)

Magnetic resonance imaging (MRI) of the breast has been investigated as a screening tool in specific higher risk subgroups of patients. First, it has been studied in patients considered to be at high genetic risk of breast cancer, such as those with known BRCA1 or BRCA2 genetic mutations or with a family history consistent with a hereditary pattern of inheritance of breast cancer. Screening for breast cancer often begins at an earlier age in these patients, and mammography is considered less sensitive in younger patients due to the prevalence of dense breast tissue. In addition, the use of screening MRI has also been suggested for patients who may or may not be at increased risk but who have breast tissue characteristics that limit the sensitivity for mammographic screening. These characteristics are dense breast tissues, breast implants, or scarring after breast-conserving therapy (BCT). BCT consists of breast-conserving surgery (BCS) followed by radiation therapy.
Other Detection Uses

- detection of a suspected occult breast primary tumor in patients with axillary nodal adenocarcinoma and negative mammography and clinical breast exam

Breast MRI has been advocated to help detect suspected occult primary breast cancer in patients with adenocarcinoma in the axillary lymph nodes after mammography and physical exam have failed to reveal a breast tumor. Localization of a breast primary might permit BCT instead of presumptive mastectomy.

- detection of breast cancer in the contralateral breast of patients with breast cancer

Patients with a diagnosed breast cancer are at higher risk for a synchronous or subsequent breast cancer in the contralateral breast, and the use of breast MRI has been suggested as a more sensitive screening test compared with mammography.

Diagnostic Uses

- diagnosis of low-suspicion findings on conventional testing not indicated for immediate biopsy but referred for short-interval follow-up
- diagnosis of a suspicious breast lesion to avoid biopsy
- preoperative tumor mapping (e.g., detection of multicentric disease) in patients with clinically localized breast cancer who are considered candidates for BCS followed by radiation therapy (RT)
- preoperative tumor mapping in patients with locally advanced breast cancer before and after completion of neoadjuvant chemotherapy
- evaluation of response during neoadjuvant chemotherapy in patients with locally advanced breast cancer
- diagnosis of suspected chest wall involvement in posteriorly located tumors
- evaluation of residual tumor after lumpectomy with positive surgical margins

Patients with abnormal findings on mammography are categorized according to the level of suspicion of the findings. Those with low-suspicion findings are often recommended to undergo short-interval follow-up after 3–6 months instead of immediate biopsy. This follow-up may continue for a period of 2 years to demonstrate stability of benign findings or to detect progression, indicating the need for biopsy. MRI of the breast has been investigated as a technique to further characterize low-suspicion breast lesions, so that patients with MRI-negative lesions may be reassured and avoid the need for prolonged follow-up and those with MRI-positive lesions may be referred for early biopsy, possibly leading to earlier diagnosis and treatment.

Breast lesions considered suspicious that are detected by clinical exam or mammography are frequently referred for biopsy; however, only a minority of such biopsies reveal breast cancer due to the relatively low specificity of clinical and radiologic exams. MRI of the breast has been investigated as a technique to further characterize suspicious breast lesions, so that patients with benign lesions may be spared a biopsy procedure. One infrequent situation (niche use), in which MRI of the breast may be helpful and improve health outcomes is in the management of patients who have a suspicious lesion seen on only one mammographic view that is...
recommended for biopsy; however, the lesion cannot be seen in other views or on ultrasound, so percutaneous biopsy localization cannot be performed. MRI would be used, in this situation, to localize the suspicious lesion and permit biopsy and would presumably lead to earlier diagnosis of breast cancer compared to waiting until the lesion was visible on 2 mammographic views or on ultrasound. This is an infrequent occurrence, so the evidence base addressing this use is mainly anecdotal, but the rationale supporting this use is good.

The primary technology for conducting MRI-guided biopsies appears to be vacuum-assisted biopsy. In a study by Perlet et al., (1) 578 patients with 649 lesions visible on MRI alone or that could be localized in 3 dimensions on MRI only were considered for MRI-guided, vacuum-assisted biopsy. A total of 538 lesions underwent biopsy; the rest were excluded because the lesions could not be reproduced during the pre-biopsy planning or because of technical difficulties with the procedure (e.g., breast too small, could not access lesion, motion). Of the remaining 538 lesions, 96% of the biopsies were successful (517 of the original 649 or about 80%). The yield of malignant lesions varied with the type of patient, from 20% among patients with lesions visible only on 1 mammographic view and not on ultrasound to 27% among women screened because of a family history suggesting a high genetic risk of breast cancer to 50% among 10 women with axillary metastases of suspected breast origin. The group of patients was diverse, and the method of selection was not described. Therefore, it is not possible to generalize these results to other populations. Some of the women were also evaluated for multifocal or multicentric disease, and the issues in this group are different because of the possibility that these lesions will be treated successfully by radiation or chemotherapy, as discussed here. Multifocal disease refers to having additional malignant lesions in the same breast quadrant as the primary tumor; multicentric disease refers to having additional malignant lesions outside of the breast quadrant where the primary tumor is located.

Patients with localized breast cancer are considered candidates for BCS followed by radiation therapy. However, mastectomy may be considered in patients with multicentric disease. MRI has been investigated as a technique to assess the extent of tumor in the breast and specifically to detect multicentric disease as an aid to surgical planning.

Patients with locally advanced breast cancer are generally offered neoadjuvant chemotherapy in the hopes of reducing tumor size to permit BCT. Evaluation of tumor size and extent with conventional techniques (i.e., mammography, clinical examination, ultrasonography) is suboptimal, and breast MRI has been proposed as a more accurate means of determining tumor size for surgical planning. The MRI scan before chemotherapy is used to demonstrate tumor location, so that the tumor can be optimally evaluated after chemotherapy, especially if the size and degree of contrast enhancement are greatly reduced. In addition, tumors that respond to chemotherapy get smaller and may even disappear; however, actual reduction in size is a delayed finding, and earlier changes in tumor vascularity have been observed in tumors responsive to chemotherapy. Reduction in the degree of contrast enhancement on MRI has been noted in tumors relatively early in the course of chemotherapy. The role of this MRI finding as an early predictor of tumor response has been explored as a means to optimize choice of chemotherapeutic agents, e.g., to drop or change chemotherapeutic agents if the tumor appears to be unresponsive. Tumors located near the chest wall may invade the pectoralis major muscle or extend deeper into the chest wall tissues. Typically, modified radical mastectomy removes only the fascia of the pectoralis muscle; however, tumor involvement of the muscle would necessitate removal of the muscle (or a portion of it) as well. In smaller tumors, it is necessary to determine how closely the tumor abuts the pectoralis muscle and whether it invades the muscle to determine whether there is an adequate margin of normal.
breast tissue to permit BCT. Breast MRI has been suggested as a means of determining pectoralis muscle/chest wall involvement for surgical planning and to assist in the decision of whether or not to use neoadjuvant chemotherapy.

BCT includes complete removal of the primary tumor along with a rim of normal surrounding tissue. Pathological assessment of surgical margins is performed on excisional specimens to determine whether tumor extends to the margins of resection. Surgical specimens are generally oriented and marked to direct re-excision if margins are shown to contain tumor; however, when tumor is not grossly visible, the extent of residual tumor within the breast can only be determined through repeat excision and pathological assessment. MRI has been proposed to evaluate the presence and extent of residual tumor as a guide to re-excision when surgical margins are positive for tumor.

**Note:** This policy only addresses the use of breast MRI for clinical indications related to detection or diagnosis of breast cancer. The use of MRI to monitor silicone-gel-filled breast implants for leaks or ruptures, which may be done without contrast enhancement, is addressed in policy No 6.01.50.

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**Policy**

**Note:** All of the following policy statements refer to performing MRI of the breast with a breast coil. MRI of the breast without the use of a breast coil, regardless of the clinical indication, is considered **investigational**. See additional comments in Policy Guidelines about the breast imaging team and the need for breast MR imaging centers to perform MRI-guided biopsy and localization.

MRI of the breast may be considered **medically necessary** for screening for breast cancer in patients:

- with a known BRCA1 or BRCA2 mutation or
- at high risk of BRCA1 or BRCA2 mutation due to a known presence of the mutation in relatives or
- who have Li-Fraumeni syndrome or Cowden syndrome or Bannayan-Riley-Ruvalcaba syndrome or who have a first-degree relative with one of these syndromes or
- at high risk (lifetime risk about 20% to 25% or greater) of developing breast cancer as identified by models that are largely defined by family history or
- who received radiation therapy to the chest between 10 and 30 years of age.

MRI of the breast may be considered **medically necessary** for detection of a suspected occult breast primary tumor in patients with axillary nodal adenocarcinoma (i.e., negative mammography and physical exam).
MRI of the breast may be considered **medically necessary** for presurgical planning in patients with locally advanced breast cancer before and after completion of neoadjuvant chemotherapy to permit tumor localization and characterization.

MRI of the breast may be considered **medically necessary** to determine the presence of pectoralis major muscle/chest wall invasion in patients with posteriorly located tumors.

MRI of the breast may be considered **medically necessary** in those with a new diagnosis of breast cancer to evaluate the contralateral breast when clinical and mammographic findings are normal.

MRI of the breast may be considered **medically necessary** for preoperative tumor mapping of the involved (ipsilateral) breast to evaluate the presence of multicentric disease in patients with clinically localized breast cancer who are candidates for breast-conservation therapy (see Policy Guidelines).

MRI of the breast may be considered **medically necessary** to evaluate a documented abnormality of the breast prior to obtaining an MRI-guided biopsy when there is documentation that other methods, such as palpation or ultrasound, are not able to localize the lesion for biopsy.

MRI of the breast is considered **investigational** as a screening technique in average-risk patients.

MRI of the breast is considered **investigational** as a screening technique for the detection of breast cancer when the sensitivity of mammography is limited (i.e., dense breasts, breast implants, scarring after treatment for breast cancer).

MRI of the breast is considered **investigational** for diagnosis of low-suspicion findings on conventional testing not indicated for immediate biopsy and referred for short-interval follow-up.

MRI of the breast is considered **investigational** for diagnosis of a suspicious breast lesion in order to avoid biopsy.

MRI of the breast is considered **investigational** to determine response during neoadjuvant chemotherapy in patients with locally advanced breast cancer.

MRI of the breast is considered **investigational** for evaluation of residual tumor in patients with positive margins after lumpectomy.

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**Policy Guidelines**

As stated in the Medical Policy Reference Manual (MPRM) policy on genetic testing for inherited BRCA1 or BRCA2 mutations (Policy No. 2.04.02), families at high risk for harboring a BRCA1 or BRCA2 mutation are those in which the incidence of breast or ovarian cancer in first-degree
(i.e., parent, sibling, offspring) or second-degree (i.e., grandparent, grandchild, uncle, aunt, nephew, niece, half-sibling) relatives suggests an autosomal dominant inheritance, i.e., about half the family members are affected.

A number of models can assist practitioners in estimating breast cancer risk using family history, including the Claus, (2) modified Gail, (3) Tyrer, (4) and BRCAPRO (5) models.

Breast MRI exams should be performed and interpreted by an expert breast imaging team working together with the multidisciplinary oncology treatment team.

As noted, breast MRI exams require a dedicated breast coil and radiologists familiar with the optimal timing sequences and other technical aspects of image interpretation. The breast MR imaging center should also have the ability to perform MRI-guided biopsy and/or wire localization of findings detected by MRI.

The use of preoperative MRI in patients with localized disease results in higher rates of mastectomy and lower rates of breast-conserving treatment (BCT). There is uncertainty from the available evidence on whether outcomes are improved by changing to a more extensive operation.

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**Rationale**

This policy was originally created in 2000 and was updated regularly with searches of the MEDLINE database. The most recent literature search was performed for the period January 2011 through January 2012. Following is a summary of the literature to date:

**Screening Uses**

Magnetic resonance imaging (MRI) as a screening tool in patients at high genetic risk for breast cancer

- There is a large body of published evidence on this question. The original policy is based on a 2003 TEC Assessment. (6) This Assessment concluded that for high-risk women, the evidence appears to show at least equivalent performance for MRI in terms of sensitivity in detecting breast cancer compared to mammography. In 2 published studies, however, there were only 15 cases of cancer. (7, 8) In both studies, MRI detected 100% of cancer cases, while mammography detected 33%. Recent abstracts show findings consistent with superior sensitivity of MRI and either equivalent or slightly inferior specificity.

- Other studies since the 2003 TEC Assessment have corroborated the improved sensitivity of MRI compared to mammography in high-risk women. Although direct benefit of MRI screening among this population has not been proven, such a benefit might be inferred by knowledge of the sensitivity and specificity of this test, along with knowledge of the benefits of mammography developed through several lines of evidence including randomized clinical trials.
• This indication also incorporates several American Cancer Society guidelines for use of breast MRI that were based on expert consensus. (9) Two of the indications related to use of MRI in rare genetic syndromes. In these uncommon conditions, the risk of breast cancer, which often occurs in premenopausal women, is as high as 50%. Thus, the given threshold for using MRI in those whose lifetime risk is 20% to 25% or greater is thought to be met by patients with Li-Fraumeni syndrome (mutations of TP53 gene) and their first-degree relatives, and patients with Cowden syndrome, aka Bannayan-Ruvalcaba syndrome (mutations of PTEN gene), and their first-degree relatives. Use of MRI in these situations is also included in NCCN [National Comprehensive Cancer Network] guidelines on genetic/familial high-risk assessment. (10) The third recommendation based on expert consensus is for use of MR in those who received radiation (therapy) to the chest between the ages of 10 and 30 years. The risk of breast cancer in these patients can be quite high but depends on the age at treatment, radiation dose, and concomitant use of chemotherapy. Travis et al. estimates that the cumulative absolute risks of breast cancer for a survivor of Hodgkin’s lymphoma who was treated at age 25 years with chest radiation dose of at least 40 Gy without alkylating agents are 1.4% at age 35, 11.1% at age 45, and 29.0% at age 55. (11) The American Cancer Society (ACS) guidelines also note that more recent treatment approaches using lower doses of radiation and limited fields are associated with lower risks. (9) The NCCN guidelines related to breast cancer screening in those with prior thoracic RT [radiation therapy] recommend clinical examination and then mammography beginning 8 to 10 years following radiation therapy, or starting at age 40, whichever comes first. (12)

• The sensitivity of MRI in detecting breast cancer may vary with the type of lesion. Kuhl et al. reported results for the diagnosis of ductal carcinoma from a prospective series in a single, specialized referral center. (13) Over a 5-year period, 7,319 women who were referred to this center received MRI in addition to mammography for diagnostic assessment and screening. A total of 193 women received a final surgical pathology diagnosis of pure DCIS [ductal carcinoma in situ]. Of those, 167 had undergone both imaging tests preoperatively; 93 (56%) of these cases were diagnosed by mammography and 153 (92%) by MRI (p<0.0001). Of the 89 high-grade DCIS, 43 (48%) were missed by mammography, and all 43 cases missed by mammography were detected by MRI. By contrast, MRI detected 87 (98%) of these lesions. MRI was significantly more sensitive than mammography in detecting high-grade (98% vs. 52%, p<0.0001) and intermediate-grade DCIS (91% vs. 59%, p<0.0127) but not for detecting low-grade DCIS (80% vs. 61%, p<0.13). The authors note that their results are not representative of the typical screening setting. They also indicate that a multi-institutional trial will be needed to further investigate the role of MRI for diagnosing DCIS in a screening population and determining its impact on outcomes such as recurrence rates and mortality. It should be noted that the joint recommendations from the Society of Breast Imaging and the American College of Radiology therefore recommend that high risk women be screened annually with both MRI and mammography. (14)

• **Summary:** MRI is more sensitive than mammography or ultrasonography in detecting malignancy. Because of the high likelihood of malignancy among women at high risk for breast cancer, the benefits of detecting cancer earlier with MRI outweigh the disadvantages of incurring more unnecessary workups and biopsies due to false positive results.
MRI of the breast as a screening test for the detection of breast cancer in patients with average risk, or who have breast characteristics limiting the sensitivity of mammography

- The evidence for this question is based on a 2004 TEC Assessment (15) and a number of more recent articles. The sensitivity of mammography is limited in patients after breast-conserving therapy, therefore, there is the potential for improvement in sensitivity with MRI. However, additional prospective studies are needed to confirm this and to identify the most useful subsets for MRI evaluation given the relatively low incidence of recurrence.

- Discussion continues on the possible use of MRI to screen women with dense breasts. This debate is driven in part by the recognition that women who have dense breasts have an elevated risk of cancer. In three nested case-control studies with 1,112 matched case-control pairs, the authors estimated that the adjusted odds ratio [OR] of detecting breast cancer among women with density in 75% or more of the mammogram versus those with density in less than 10% of the mammogram was 4.7 (95% CI [confidence interval]: 1.0–7.4). These cancers were detected through screening or during a period of less than 12 months after a negative screening examination. In younger women, 26% of all breast cancers were in patients with density evident in 50% or more of the mammogram. (16)

- In a retrospective study, the accuracy of MRI was evaluated among patients with dense breasts and suspected breast cancer or inconclusive evaluations who had a breast MRI at a single institution in Italy. (17) The reference standard was histology of 6- and/or 18-month follow-up. MRI was compared to mammography or ultrasound. About half of the women were found to have breast cancer. Of 238 patients, 97 had all 3 imaging tests. The sensitivity and specificity of MRI was 98.2% and 95.2%, respectively; for mammography, 72.7% and 45.2%; and for ultrasound, 85.5% and 40.5%. In this study, MRI is used to evaluate patients suspected of having breast cancer or with equivocal results from other modalities, including clinical examination. Although the specificity is relatively high and the negative predictive value in this selected population is 97.6%, this study does not provide sufficient evidence to use MRI as a substitute for biopsy in these patients, as the authors themselves state.

- For average-risk women, the benefits of increased detection probably do not outweigh the harms. Because the prevalence of breast cancer is extremely low in average-risk young women, screening with a test such as MRI that has inferior specificity would result in lower positive-predictive values and many more false-positive results. Compared to mammography, there would be greater numbers of workups, biopsies, anxiety, and morbidity if MRI screening were to be applied to young, average-risk women.

- Joint recommendations from the Society of Breast Imaging and the American College of Radiology suggest that the addition of ultrasound to screening mammography “may be useful for incremental cancer detection” for women for whom dense breast is their only risk factor. (14) MRI is not mentioned in this context. However, the authors do mention that the recommendations focus the use of MRI on the highest risk women because of the considerable cost of MRI and the potential for more false positives with a lower cancer yield as the risk of developing cancer declines.

- **Summary:** In the average risk population or among women with breast characteristics limiting the sensitivity of mammography, the incremental effects of adjunctive MRI screening remain uncertain. There is a potential for harm in this patient population given the high cost and limited evidence of benefit for average-risk women.
the low overall prevalence of breast cancer and the larger numbers of false-positive results that may result in unnecessary biopsies.

Other Detection Uses

MRI of the breast for detection of a suspected occult breast primary tumor with axillary nodal adenocarcinoma when there is a negative mammography and physical exam

- The evidence for this question is based on a 2004 TEC Assessment (15) and one subsequent article. In this small subgroup of patients, the adjunctive use of breast MRI allows patients to avoid the morbidity of mastectomy in a substantial portion of patients (approximately 25–61%), while the risk of unnecessary biopsy is estimated to be 8%.

- A meta-analysis of studies on the use of MRI in patients with mammographically occult breast cancer and an axillary metastasis evaluated 8 retrospective studies with a total of 220 patients. (18) In 7 studies, a potential primary lesion was detected in a mean of 72% of cases (range: 36–86%). Pooling individual patient data yielded a sensitivity of 90% (range: 85–100%) in detecting an actual malignant tumor. The specificity, however, was a pooled value of 31% (range: 22–50%).

- Summary: The use of positive MRI findings to guide BCT instead of presumptive mastectomy appears to offer the substantial benefit of breast conservation for those patients in whom the MRI scan detects the primary tumor.

MRI to detect breast cancer in the contralateral breast of patients with established breast cancer

- The evidence for this question consists of observational studies, primarily retrospective. Six studies (total n=667) that have a primary focus on screening the contralateral breast in women with breast cancer were identified. (19-24) Five of the 6 studies reported a 4% to 9% prevalence of cancer in the contralateral breast on MRI, although 1 small study of 17 subjects found a much higher prevalence at 24%. Positive predictive value (PPV) was quite variable, ranging from 20% to 80%, and specificity ranged from 76% to 97%. These studies conducted MRI exams at various times before, during, or after treatment for breast cancer. Most studies reported that contralateral cancers detected on MRI were not detected by conventional testing, whereas, in some cases, MRI was done to evaluate suspicious findings in the contralateral breast.

- Liberman et al. (21) reported on 212 subjects who had negative findings on mammograms of the asymptomatic contralateral breast, and found 12 cancers (prevalence: 5%) on MRI including 6 ductal carcinoma in situ (DCIS) and 6 infiltrating carcinomas. However, the PPV of these findings was only 20%, with a specificity of 76%. Lehman et al. found 4 contralateral cancers in 103 patients; in this study, 10 biopsies were done. (20)

- In 2007, Lehman et al. reported the results of the ACRIN-A6667 trial on “MRI Evaluation of the Contralateral Breast in Women with a Recent Diagnosis of Breast Cancer.” They found that 3% (30 of 969) of women with a recent diagnosis of unilateral breast cancer were found to have contralateral cancer at the time of initial diagnosis using MR imaging. (25) These contralateral lesions were not detected by mammography or physical exam. Eighteen of the 30 were invasive cancer and 12 were DCIS. In this study, 12.5% of the patients (121) had biopsies, with a positive biopsy rate of 24.8%. With 1-year follow-up,
sensitivity of MRI was 91% and specificity was 88%. The results of this study in a diverse group of patients were similar to the findings of others.

- These data concur with the recommendation made by the ACR [American College of Radiology] practice guideline (26) and with the consensus statement from the American Society of Breast Surgeons. (27)

- **Summary:** While the long-term outcome of these findings of cancer in the contralateral breast is not fully known, important changes in management will occur as a result of these findings, which should lead to improved outcomes. That is, in addition to the presumed benefits of early detection of these tumors, simultaneous treatment of synchronous cancers can occur rather than multiple treatments on separate occasions.

**Diagnostic Uses**

**MRI of the breast for the diagnosis of low-suspicion findings on conventional testing not indicated for immediate biopsy**

- The evidence for this question is based on a 2004 TEC Assessment. (15) Available evidence suggests that adjunctive MRI may be very sensitive and specific in patients with low-suspicion findings on conventional testing and may provide a useful method to select patients for biopsy or to avoid prolonged short-interval follow-up. However, none of the available studies uses prospective methods in the appropriate patient population to directly compare the sensitivity and specificity of short-interval mammographic follow-up with MRI and to determine the effects of adjunctive MRI on cancer detection rate and biopsy rate.

- Well-designed prospective confirmatory studies would be necessary to permit conclusions regarding the effect this adjunctive use of breast MRI has on health outcomes.

- **Summary:** Insufficient evidence is available on the use of MRI to diagnose low-suspicion findings on conventional testing not indicated for immediate biopsy.

**MRI of the breast to further characterize suspicious breast lesions**

- The evidence on this question is based on TEC Assessments from 2000, (28) 2001, (29) and 2004. (15) The available studies addressed a group of patients who have breast lesions of sufficient suspicion to warrant recommendation to undergo biopsy for diagnosis. Therefore, MRI results are assumed to have an impact on the decision whether or not to undergo definitive biopsy, considered the gold standard.

- The available evidence did not show that this use of MRI of the breast would improve health outcomes. Considering the relative ease of breast biopsy, the sensitivity of breast MR would have to be virtually 100% to confidently avoid biopsy. While MRI performs well, it is clear that the sensitivity is not 100%. False-negative results tend to occur, particularly in certain subcategories, such as DCIS, but invasive carcinomas may fail to enhance on MRI, leading to false-negative findings as well. The potential harm to health outcomes of failing to diagnose breast cancer or at least of delaying the diagnosis of breast cancer is of significant concern. The TEC Assessment concluded that the potential benefit of sparing a fraction of patients from undergoing an unnecessary biopsy does not outweigh the potential harms considering the current level of diagnostic performance of breast MRI.
A fairly large study by Bluemke et al. addressing this issue was released after the 2004 TEC Assessment but did not change the conclusions. (30) Based on results from 821 patients, it reported a sensitivity of 88.1% and a specificity of 67.7%.

A systematic review published in 2011 (31) analyzed 69 studies including 9,298 women. Pooled sensitivity was 90% (95% CI: 88-92%), and pooled specificity was 75% (95% CI: 70-79%). The PPV of an abnormal MRI for malignancy was 3.64 (95% CI: 3.0-4.2%), and the negative predictive value (NPV) was 0.12 (95% CI: 0.09-0.15). The area under the curve for MRI was 0.91.

Summary: MRI for evaluation of suspicious breast lesions has a relatively high sensitivity and a moderately high specificity. However, the negative predictive value is not sufficient to preclude the need for biopsy. Therefore, the use of MRI for further characterization of suspicious lesions is not likely to change clinical management. In addition, the fairly high rate of false positives will lead to substantial numbers of unnecessary biopsies.

MRI of the breast as a preoperative mapping technique to identify multicentric disease in patients with clinically localized breast cancer

The evidence for this question was originally based on a 2004 TEC Assessment. Since that time, there has been a large amount of research published on this issue, including 2 randomized controlled trials (RCTs). The 2004 TEC Assessment concluded that ipsilateral MR imaging at the time of diagnosis did not meet TEC criteria because there was insufficient evidence to permit conclusions on the effect on the health outcomes of adding MRI to the standard staging workup of early stage invasive breast cancer. (32) However, as noted in the Assessment, long-term recurrence rates for the 2 approaches (modified radical mastectomy compared to breast-conserving surgery [BCS] combined with whole breast radiation) did differ, with lower long-term recurrence rates after mastectomy. For example, the National Cancer Institute (NCI) USA trial (n=247) reported 18-year locoregional recurrence rates of 25.6% for breast-conserving therapy (BCT) versus 9.5% for modified radical mastectomy. (33) The NCI Italy trial (n=701) reported local recurrence rates at 20 years for BCT at 8.8% and for radical mastectomy at 2.3%. (34) These differences were both statistically significant with p values less than 0.01. Studies have shown that from 2% to 15% of women with a new diagnosis of breast cancer would have multicentric disease detected on MRI.

As a result of these findings, there was controversy regarding the use of MRI preoperatively for patients diagnosed with breast cancer. (35-43) While these studies were not sufficient to determine the effect on health outcomes, they suggested a mechanism by which outcomes may be improved. If additional foci of malignancy are detected, then the use of MRI may lead to improved surgical decision making and a reduction in re-excision rates that occur as a result of foci of malignancy that were missed at the initial evaluation. (37)

Numerous observational studies have estimated the frequency of additional findings when pre-operative MRI is performed and the rates of change in clinical and surgical management. Only a few of the observational studies are prospective. A prospective case series of 74 patients who had newly diagnosed invasive breast cancer and had a pre-operative MRI was published by Barchie et al in 2011. (44) The rate of mastectomy was increased from 29 to 53% as a result of MRI scans. In another prospective study of 119 patients from Germany, the use of MRI prior to surgery changed clinical...
management in 40.3%. A total of 17 patients (14.3%) had mastectomies instead of breast-conserving surgery, and 8 (6.8%) had an extended excision. (42)

- A meta-analysis of 19 observational studies published in 2008 reported quantitative estimates of the incremental findings on MRI and the resulting rates of change in clinical management. This study reported that the median prevalence of additional ipsilateral cancer foci detected by preoperative MRI was 16% (n=2,610; interquartile range, 11% to 24%). (38) Conversion from BCT to mastectomy occurred in 8.1% (95% CI: 5.9 to 11.3) of patients, and change to a more extensive local surgery occurred in 11.3% (95% CI: 6.8-18.3%). Of the additional mastectomies, a total of 1.1% may have been clinically inappropriate, as judged by the lack of extensive disease on histopathology. The rate of possibly inappropriate change to a wider local excision was estimated to be 5.5%.

- In 2012, Plana et al. (45) published another systematic review and meta-analysis of 50 publications reporting on 10,811 women. In this analysis, additional disease was detected in the ipsilateral breast in 20% of women and in the contralateral breast in 5.5%. Of the additional lesions detected, approximately 2/3 were malignant and 1/3 benign by final histopathology, for a PPV of 66%. Based on MRI findings, a total of 8.3% of women were appropriately referred for mastectomy rather than BCT, while 1.7% were inappropriately referred for mastectomy.

- There have been 2 RCTs published that evaluate the short-term benefit of preoperative MRI in women with localized breast cancer. A multicenter RCT from the U.K. (the COMICE trial) examined the impact of presurgical MRI on the need for additional treatment within 6 months. This study was an open, parallel group trial conducted at 45 centers in the United Kingdom, (43) and enrolled 1,623 women with biopsy-proven breast cancer who were scheduled for wide local excision BCT. Of the 816 patients in the MRI group, 7% (58/816) underwent mastectomy as a result of MRI results and/or patient choice, compared to 1% (10/787) in the no-MRI group that underwent mastectomy as a result of patient choice. There was no statistically significant reduction in reoperation rates in those who received MRI scans (19% in both groups; OR: 0.96; 95% CI: 0.75, 1.24, p=0.77). In the MRI group, 19 patients (2%) had a “pathologically avoidable” mastectomy, defined as a mastectomy based on MRI results that showed more extensive disease, when the histopathology reported only localized disease. Twelve months after surgery, there was no statistically significant difference in quality of life between the 2 groups.

- A second RCT, the MONET trial, was published by Peters et al. in 2011. (46) This study randomized 463 patients with suspicious, non-palpable breast lesions identified on mammography or ultrasound to either pre-biopsy MRI or usual care. Of 207 evaluable patients in the MRI group, there were 11 additional suspicious lesions identified on MRI that were occult on other imaging studies. All 11 of these additional lesions were biopsied, with 2/11 positive for malignancy. The rate of mastectomy was similar between the 2 groups (32% vs. 34%, p=NS), as was the rate of BCS (68% vs. 66%). The rate of re-excisions due to positive tumor margins was unexpectedly higher in the MRI group compared to the control group (34% vs. 12%, p=0.008).

- Summary: For patients with localized disease on standard pre-operative assessment, MRI will detect additional foci of disease in the ipsilateral or contralateral breast with a frequency in the range of 10-20%. Detection of additional disease can lead to changes in surgical treatment, most importantly a change from breast conserving surgery to
mastectomy. Because of the high false-positive rate, current recommendations state that a biopsy of MRI-identified lesions should be undertaken prior to a decision on the type of surgery, in order to reduce the number of inappropriate mastectomies. If the conversions to mastectomy are appropriate based on extent of disease, then patients in the MRI group are expected to show lower rates of local recurrence and re-operations. Two RCTs have evaluated short-term outcomes of a pre-operative MRI versus no MRI and have not shown that short-term reoperation rates are decreased in the MRI group. Further studies of intermediate to long-term outcomes are needed to determine whether outcomes are improved by pre-operative MRI scanning.

The overall evidence is uncertain on whether MRI may improve outcomes when used as part of a pre-operative assessment for localized disease. If biopsies are performed on all MRI-identified lesions, and if shared patient decision making is used for altering the surgical approach, then the probability of improved outcomes is increased. Therefore, under these circumstances, MRI of the breast may be considered medically necessary for preoperative assessment of women with localized disease on conventional imaging.

MRI for preoperative tumor mapping in patients with locally advanced breast cancer before and after completion of neoadjuvant chemotherapy

- The evidence on this question is based on a 2004 TEC Assessment (47) and more recent publications. Compared with conventional methods of evaluating tumor size and extent (i.e., mammography, clinical exam, or ultrasound), MRI of the breast provides an estimation of tumor size and extent that is at least as good as or better than that based on alternatives. Drew et al. (48) found MRI to be 100% sensitive and specific for defining residual tumor after chemotherapy. Conversely, mammography achieved 90% sensitivity and 57% specificity (mammography results considered equivocal), and clinical exam was only 50% sensitive and 86% specific. Similarly, Partridge et al. (49) reported correlation of residual tumor size on MRI of 0.89 and clinical exam of 0.60.

- MRI results were well-correlated with results of histopathological assessment (reference standard) with correlation coefficients of 0.72 to 0.98; however, MRI is not intended as a replacement for histopathological assessment.

- A study of 51 patients compared MRI determination of tumor response following neoadjuvant therapy with pathological results from BCT or mastectomy. (50) Interestingly, MRI correctly diagnosed 18 of the 19 pCR [polymerase chain reaction] cases among HER2-positive patients versus 8 of 16 pCR cases among HER2-negative patients (p<.005). In other words, MRI’s accuracy in determining complete response to neoadjuvant chemotherapy was higher among HER2-positive patients. The authors note that false negatives were more likely when the residual disease was in the form of scattered cells or small foci, which occurred more often in HER2-negative patients. The accuracy of MRI in detecting complete response also varied by chemotherapeutic regimen used. These conclusions are based on small numbers with "suboptimal" spatial resolution and would need to be replicated in larger studies before being applied to clinical practice.

- In a retrospective study of 208 patients undergoing neoadjuvant therapy, 64 indicated complete response on MRI scans, but 36 of them (56%) had residual disease on pathology. (51) Conversely, 144 indicated residual disease on MRI, but no invasive cancer cells were found on pathology results in 14 of them, of whom 5 had DCIS. So the
sensitivity of MRI to detect residual invasive cancer was 78% (95% CI: 0.71–0.83), and the specificity was 67% (95% CI: 0.51–0.79). Furthermore, in 22% of all patients, the tumor size on MRI differed by more than 20 mm from the pathology results. This could alter the treatment choice from mastectomy to BCT or more rarely, from BCT to mastectomy. MRI appeared to be most accurate in patients with triple-negative tumors, then HER-2 positive tumors, and least accurate in patients with ER-positive tumors. The patients in this study may overlap with participants in the study by Loo et al., (52) described below.

- The ACRIN [American College of Radiology Imaging Network] Protocol A6657 on using MRI to evaluate patients undergoing neoadjuvant therapy has been amended to increase the sample size to 377 and include a component that addresses the use of MR spectroscopy in these patients and an optional diffusion-weighted imaging. As of January 27, 2010, 356 patients were enrolled (more information is available online at: http://www.acrin.org).

- Summary: Using breast MRI instead of conventional methods to guide surgical decision making regarding the use of BCT versus mastectomy following neoadjuvant chemotherapy would be at least as beneficial and may lead more frequently to the appropriate surgical procedure.

MRI of the breast to evaluate response during neoadjuvant chemotherapy in patients with locally advanced breast cancer

- The evidence for this question is based on a 2004 TEC Assessment (47) and later articles. The most important use of MRI would be to reliably identify patients whose tumors are not responding to neoadjuvant chemotherapy to avoid the added morbidity of continued ineffective chemotherapy. Such chemotherapy may be discontinued or changed to an alternative and potentially effective regimen. MRI would be harmful when it falsely suggests a lack of response and leads to premature discontinuation of effective chemotherapy.

- High negative-predictive value (NPV) (i.e., ability to predict a nonresponsive tumor) would be most important in association with high sensitivity for detecting tumor response and high specificity for nonresponsive tumors.

- The 2004 assessment reported a total of 6 studies (N=206) that performed breast MRI during the course of chemotherapy. MRI outcomes for response to chemotherapy were based on either reduction in tumor size or reduction in contrast enhancement. Three studies (22, 53, 54) report NPV results of 38%, 83%, and 100%, respectively; however, the 2 lower estimates were from prospective studies, while the highest estimate was from a retrospective study.

- Another study published since the 2004 Assessment (55) examined whether MRI measurements of tumor volume and diameter predicted response to neoadjuvant chemotherapy and recurrence-free survival, but the results did not change the conclusions reached in the 2004 Assessment. The authors found that initial (pre-chemotherapy) and final volumes were the strongest predictors of recurrence-free survival. Early changes in MRI volume or diameter showed a trend of association (p=0.7 or 0.8) with recurrence-free survival but were not statistically significant. However, of the total 62 subjects, only 32 were included in the analysis of early response. Several other
studies on the ability of MRI to gauge response to neoadjuvant chemotherapy did not include MRIs during chemotherapy, when changes in therapy might be considered.

- A study of 188 women who underwent MRI scans before and during neoadjuvant chemotherapy compared the ability of MRI to detect response to treatment by breast cancer subtype. (52) They concluded that the change in the largest diameter of enhancement on MRI was associated with tumor response among patients with so-called triple negative and HER-2-positive tumors but not among patients with the more commonly found ER-positive/HER-2 negative tumors.

- Summary: There is insufficient evidence to determine whether breast MRI can reliably predict lack of response to neoadjuvant chemotherapy. Furthermore, evidence would be needed that any resulting change in patient management (e.g., discontinuation of chemotherapy or change to a different regimen) would improve outcomes.

MRI to diagnose suspected chest wall involvement in posteriorly located tumors

- Morris et al. (56) prospectively studied 19 subjects with posteriorly located breast tumors suspected to involve the pectoralis major muscle based on either mammography or clinical exam. Thirteen of these tumors were thought to be fixed to the chest wall on clinical exam and 12 appeared to have pectoral muscle involvement on mammography. Results of MRI were compared with surgical and pathological findings. The presence of abnormal enhancement within the pectoralis major muscle on MRI was 100% sensitive and 100% specific for identifying the 5 tumors that actually involved the pectoralis major muscle.

- Two other retrospective studies (57, 58) reported on 4 cases in which MRI was able to determine involvement of the chest wall with 100% accuracy.

- Summary: Given the high level of diagnostic accuracy for MRI, as compared with reference standard and conventional alternative techniques, the evidence is considered sufficient to permit conclusions that breast MRI improves net health outcome.

MRI to evaluate residual tumor after lumpectomy with positive surgical margins

- The evidence for this question consists of a number of observational studies, most of which are retrospective. Seven studies were identified that evaluated the diagnostic performance of MRI to determine the presence of residual disease after prior biopsy or lumpectomy. (59-65) Histopathologic examination on re-excision was used as the reference standard. Most of these studies, including the single prospective study, report poor sensitivity and specificity of MRI for detection of residual disease. The two studies that report more favorable results (60, 64) have methodological concerns that limit the influence of reported results. Three of these studies (59, 63, 65) were conducted at the same institution and accrued patients during similar time periods, so overlap of reported patients may exist.

- Lee et al. (62) prospectively studied 80 patients eligible for BCT who had close or positive margins on lumpectomy and were scheduled for re-excision lumpectomy. In this study, MRI was 61% sensitive and 70% specific for detection of residual tumor. The finding of extensive tumor on MRI led to mastectomy in 6 patients (7.5%), but it is difficult to determine from the publication what proportion of these cases had false-positive MRI results. Bedrosian et al. (59) retrospectively studied 70 subjects prior to re-
excision and found MRI had 57% sensitivity and 60% specificity. MRI prompted wider than initially planned surgical excision in 11 cases, but 10 of these turned out to be false-positive MRI results. Kawashima et al. (61) studied 50 subjects and reported 66% sensitivity and 81% specificity. Orel et al. (63) included 47 patients with questionable or positive margins after biopsy and found that MRI had 54% sensitivity and 62% specificity for residual tumor at the biopsy site. Similarly, sensitivity and specificity were low for identification of residual tumor anywhere in the breast (64% and 58%, respectively). Weinstein et al. (65) reviewed 14 cases of invasive lobular carcinoma that had prior excisional biopsy and found that MRI had 57% sensitivity and 0% specificity for identifying residual disease.

- Frei et al. (60) retrospectively studied 68 patients with positive margins and examined the relationship between when MRI was performed after initial surgery and diagnostic performance of MRI for residual disease. However, this study excluded 3 patients with technically inadequate MRI studies and has discrepancies in reported results in the publication. Sensitivity of MRI ranged from 89% to 95%, with slight improvements noted with longer time intervals after initial surgery. Specificity was initially 52% for MRI performed at least 7 days after lumpectomy; whereas, when analysis was restricted to MRI conducted at least 28 days after lumpectomy, the specificity of MRI increased to 75%. Soderstrom et al. (64) retrospectively examined 19 patients with various indications for MRI, including 11 patients with close or positive margins after surgery, and found MRI was 100% sensitive and 71% specific for identification of residual tumor. The authors note that MRI overestimated the extent of tumor in 1 patient that was counted as a true positive in the results.

- Summary: The available evidence is not sufficient to permit conclusions on whether MRI improves net health outcomes when used to identify the presence and/or extent of residual disease after lumpectomy and prior to re-excision.

Other Suggested Uses for MRI of the Breast

- Some have suggested that MRI might be useful before the use of accelerated partial breast irradiation (APBI), (41) by identifying those patients with multicentric tumors that would not fall within the radiotherapy field. However, neither the equivalence of APBI to whole breast irradiation nor the utility of MRI in this context have been demonstrated. In a consensus statement on APBI, a Task Group from the American Society for Radiation Oncology “agreed that there were insufficient data to justify recommendation of routine breast MRI for patients selected for APBI.” (66)

Guidelines and Other Recommendations

The American College of Radiology (ACR) practice guidelines on MRI of the breast were updated most recently in 2008 (available online at: http://www.acr.org/SecondaryMainMenuCategories/quality_safety/guidelines/breast/mri_breast.aspx). It listed the following indications for breast MRI (although it was noted that there may be others):

- Screening: To screen high-risk patients (greater than 20% lifetime risk of cancer), contralateral breast in patients with newly diagnosed malignancy, and to breast augmentation—postoperative reconstruction and free injections
• Evaluating extent of disease: To determine the extent of disease and the presence of multifocality and multicentricity in patients with invasive carcinoma and DCIS; to evaluate whether there is invasion deep to fascia; to assess potentially positive margins post-lumpectomy; and to determine treatment response and the extent of residual disease prior to surgical treatment before, during, and/or after neoadjuvant chemotherapy.

• Additional evaluation: To search for recurrence of cancer among women with a prior history of breast cancer and suspicion of recurrence, when clinical, mammographic, and/or sonographic findings are inconclusive; to search for the primary tumor when patients present with metastatic disease and/or axillary adenopathy and there are no mammographic or physical findings of primary breast carcinoma; to localize/confirm lesion when other imaging is inconclusive and biopsy is not feasible (e.g., possible distortion on only one mammographic view); to evaluate suspected cancer recurrence in patients with tissue transfer flaps (rectus, latissimus dorsi, and gluteal) after breast reconstruction; to guide interventional procedures such as vacuum-assisted biopsy and preoperative wire localization for lesions that are occult on mammography or sonography.

Recent joint recommendations from the Society of Breast Imaging and the American College of Radiology recommend that high-risk women be screened annually with both MRI and mammography. (14)

The American Society of Clinical Oncology guideline in 2006 recommended against the use of breast MRI for routine breast cancer surveillance (available online at: http://jco.ascopubs.org/content/24/31/5091.full). Furthermore, “The decision to use breast MRI in high-risk patients should be made on an individual basis depending on the complexity of the clinical scenario.”

The National Comprehensive Cancer Network (NCCN) has guidelines on breast cancer that were last updated in 2011. These guidelines list the following indications for breast MRI (available online at: http://www.nccn.org/professionals/physician_gls/pdf/breast.pdf):

• To define extent of cancer of presence of multifocal or multicentric cancer in the ipsilateral breast, or as screening of the contralateral breast cancer at time of initial diagnosis (category 2B). There are no data that demonstrate that use of MRI to affect choice of local therapy improves outcomes (local recurrence rate or survival).

• Before and after neoadjuvant therapy to evaluate extent of disease, response to treatment, and potential for breast-conserving surgery

• May be useful to detect additional disease in women with mammographically dense breasts, but “available data do not show differential detection rates by any subset by breast pattern (breast density) or disease type (e.g., DCIS, invasive ductal cancer, invasive lobular cancer)

• May be useful for identifying primary cancer in women with axillary nodal adenocarcinoma or Paget’s disease of the nipple when the primary tumor cannot be detected through other means

• Falsely positive findings on breast MRI are common. Surgical decisions should not be based solely on MRI findings. Additional tissue sampling of areas of concern identified by breast MRI is recommended.
• Value of MRI to follow-up women with prior breast cancer is undefined. Should generally be limited to women with lifetime risk of a second primary breast cancer greater than 20%.

In its policy on screening for breast cancer (available online at: http://www.uspreventiveservicestaskforce.org/uspstf09/breastcancer/brcanrs.htm), the U.S. Preventive Services Task Force (USPSTF) concludes that “the current evidence is insufficient to assess the additional benefits and harms of either digital mammography or magnetic resonance imaging (MRI) instead of film mammography as screening modalities for breast cancer. Grade: I Statement.”

The American Cancer Society guide on early detection of breast cancer, last revised December 16, 2010, recommends the following regarding the use of MRI of the breast (available online at: http://www.cancer.org/cancer/breastcancer/detailedguide/breast-cancer-detection):

Women at high risk (greater than 20% lifetime risk) should get an MRI and a mammogram every year. Women at moderately increased risk (15% to 20% lifetime risk) should talk with their doctors about the benefits and limitations of adding MRI screening to their yearly mammogram. Yearly MRI screening is not recommended for women whose lifetime risk of breast cancer is less than 15%.

References:


6. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Magnetic resonance imaging of the breast in screening women considered to be at high genetic risk of breast cancer. TEC Assessments 2003; Volume 18, Tab 15.


15. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Breast magnetic resonance imaging (MRI) for detection or diagnosis of primary or recurrent breast cancer TEC Assessments 2004; Volume 19, Tab 1.


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47. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Breast MRI for management of patients with locally advanced breast cancer who are being referred for neoadjuvant chemotherapy. TEC Assessments 2004; Volume19, Tab 7.


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