PAPER

Selective Preoperative Magnetic Resonance Imaging in Women With Breast Cancer

No Reduction in the Reoperation Rate

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Hypothesis: The use of preoperative magnetic resonance (MR) imaging may have an effect on the reoperation rate in women with operable breast cancer.

Design: Retrospective cohort study.

Setting: University medical center.

Patients: Women with operable breast cancer treated by a single surgeon between January 1, 2006, and December 31, 2010.

Intervention: Selective preoperative MR imaging based on breast density and histologic findings.

Main Outcome Measures: Reoperation rate and pathologically avoidable mastectomy at initial operation.

Results: Of 313 patients in the study, 120 underwent preoperative MR imaging. Patients undergoing MR imaging were younger (mean age, 53.6 vs 59.5 years; $P<.001$), were more often of non-Hispanic white race/ethnicity (61.7% vs 52.3%, $P<.05$), and more likely had heterogeneously dense or very dense breasts (68.4% vs 22.3%, $P<.001$). The incidence of lobular carcinoma (8.3% in the MR imaging group vs 5.2% in the no MR imaging group, $P=.27$) and the type of surgery performed (mastectomy vs partial mastectomy, $P=.67$) were similar in both groups. The mean pathological size of the index tumor in the MR imaging group was larger than that in the no MR imaging group (2.02 vs 1.72 cm, $P=.009$), but the extent of disease was comparable (75.8% in the MR imaging group vs 82.9% in the no MR imaging group had pathologically localized disease, $P=.26$). The reoperation rate was similar between the 2 groups (19.1% in the MR imaging group vs 17.6% in the no MR imaging group, $P=.91$) even when stratified by breast density ($P=.76$), pT2 tumor size ($P=.35$), or lobular carcinoma histologic findings ($P=.26$). Pathologically avoidable mastectomy (multifocal or multicentric MR imaging and unifocal histopathological findings) was observed in 12 of 47 patients (25.5%) with preoperative MR imaging who underwent mastectomy.

Conclusion: The selective use of preoperative MR imaging to decrease reoperation in women with breast cancer is not supported by these data. In a considerable number of patients, MR imaging overestimates the extent of disease.

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MAGNETIC RESONANCE (MR) imaging of the breast has emerged as a highly sensitive but costly imaging modality of the breast. Although mammography and ultrasonography remain the standard imaging for the diagnosis of breast cancer, MR imaging is increasingly being used for further evaluation of newly diagnosed breast cancer to rule out multicentric disease that may preclude breast conservation therapy.[1] Substantial evidence indicates that MR imaging is more sensitive than conventional imaging in identifying additional cancer foci that otherwise would not have been detected in the ipsilateral[2] and contralateral[3] breast. However, many suspicious MR images that lead

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to recommendations for biopsy are proven to be benign on further evaluation.[3]

The American College of Radiology and the American Society of Breast Surgeons have practice guidelines that provide current indications for MR imaging of the breast. These include screening of the contralateral breast in patients with a new malignant neoplasm of the breast, as well as

screening in patients with invasive carcinoma and ductal carcinoma in situ to determine the extent of disease and the presence of multifocality and multicentricity.[4,5] In addition, the American Society of Breast Surgeons[5] supports the use of MR imaging in patients with proven breast cancer who have associated conventional imaging difficulties, such as those with invasive lobular carcinoma or dense breasts.

Since 2006, we have selectively used preoperative MR imaging in women with newly diagnosed breast cancer who have difficulties with conventional imaging, in accord with the American Society of Breast Surgeons guidelines. Implicit in the use of preoperative MR imaging is improved surgical planning, leading to a reduction in reexcision surgery and to a more precise determination of the need for mastectomy because of multicentric disease. Herein, we investigate these outcomes from the selective use of preoperative MR imaging in patients most likely to benefit from this imaging modality.

METHODS

PATIENTS

Under institutional review board approval, all women between the ages of 18 and 93 years with newly diagnosed breast cancer (invasive or noninvasive) undergoing primary surgical treatment at East Carolina University, Brody School of Medicine, by a single surgeon (L.S.B.) between January 1, 2006, and December 31, 2010, were analyzed. Demographic data and baseline assessments, including mammography and ultrasonography, were reviewed in the patient population.

BREAST MR IMAGING SELECTION CRITERIA

All patients underwent standard diagnostic breast imaging, including mammography and ultrasonography wherever appropriate. Bilateral breast MR imaging was performed using a dedicated system (Achieva or Intera; Philips Healthcare) with a 1.5-T breast coil and a 1.5-T magnet. Two-dimensional and 3-dimensional spin-echo T1-weighted and T2-weighted fat saturation sagittal and T1-weighted axial images were obtained before the injection of gadolinium (0.1 mmol/kg). Gadobutrol was administered, and dynamic images after contrast administration were obtained using a 3-dimensional gradient-echo technique. Images were viewed using a maximum-intensity projection, subtraction, and parametric analysis technique. Images were reviewed using MR imaging system software (Dyna Cad; Invivo) and were interpreted by board-certified radiologists.

Images were documented using the Breast Imaging Reporting and Data System (BI-RADS; American College of Radiology). A standard breast imaging lexicon was used to describe the breast composition,[6,7] ranging from BI-RADS category 1 (almost entirely fat, <25% glandular) to BI-RADS category 4 (extremely dense, >75% glandular). The selective indications for patients to undergo preoperative MR imaging included candidates for breast conservation therapy based on conventional imaging or clinical examination among those who had difficulties with conventional imaging (heterogeneously dense or extremely dense tissue) and who after review at our multidisciplinary breast tumor board with radiologists specializing in breast imaging were thought to potentially benefit from the increased sensitivity of MR imaging in surgical planning. Invasive lobular histologic findings were considered a potential indication for MR imaging, particularly in patients with conventional imaging difficulties. Magnetic resonance imaging was also used in the assessment of patients before neoadjuvant therapy to assess potential response.

SURGICAL MANAGEMENT AND PATHOLOGICAL ASSESSMENT

Surgical therapy was conducted as deemed appropriate by one of us (L.S.B.). Patients underwent breast conservation surgery who met appropriate criteria on tumor size relative to breast size by the operating surgeon and who had no evidence of multicentric disease on preoperative evaluation. Several of the patients undergoing preoperative MR imaging in our study may have undergone mastectomy by choice. Partial mastectomies were processed in the usual fashion with oriented inked margins as recommended.[8] Histologically clear margins were defined as at least 2 mm from the inked margin in invasive and noninvasive breast cancer. Patients undergoing mastectomy had the breast specimen serially sectioned at approximately 1-cm intervals, with representative sections obtained to assess the primary tumor and for histologic evaluation of the remainder of the specimen. Patients were defined as undergoing a reoperation if they required a second procedure to achieve histologically clear margins (reexcision partial mastectomy or completion mastectomy) or had a pathologically avoidable total mastectomy as an initial surgical procedure.[9]

STATISTICAL ANALYSIS

All statistical analyses were performed using a statistical program (NCSS for Windows; NCSS). Statistical differences were compared by paired t test and χ^2 test where appropriate. Studies in which baseline imaging was interpreted as completely negative other than for the index lesion were included in the analysis. A power analysis indicated that our patient sample size in each group was sufficient to detect a reduction in the reoperation rate from 20% to 10% at a significance level of $P = .05$, corresponding to the single prospectively randomized trial evaluating this specific end point.[9] True- and false-positive results were determined by histologic concordance with MR imaging on needle biopsy or tumor excision. Because focal enhancement less than 5 mm is generally regarded as benign,[10] enhanced lesions identified by MR imaging but determined to be 3 mm or less in the greatest dimension on final pathological analysis were prospectively defined to be false positive.

RESULTS

In total, the medical records of 313 consecutive patients with operable breast cancer were reviewed. The patients ranged in age from 27 to 93 years (mean age, 57.2 years). **Table 1** summarizes the patient characteristics and demographics. One hundred twenty patients underwent preoperative MR imaging. These patients were significantly younger than the patients in the no MR imaging group (mean age, 53.6 vs 59.5 years, $P < .001$), were more often of non-Hispanic white race/ethnicity (61.7% vs 52.3%, $P < .05$), and more likely had heterogeneously dense or very dense breasts (68.4% vs 22.3%, $P < .001$). The racial/ethnic distribution of the patients described herein is similar to that in the general overall racial/ethnic distribution of the region.[11]

Table 2 gives the pathological and operative results. Although the incidences of invasive lobular carci-

Table 1. Patient Characteristics and Demographics

Variable	Total (N = 313)	MR Imaging Group (n = 120)	No MR Imaging Group (n = 193)	*P* Value
Age, mean (range), y	57.2 (27-93)	53.6 (27-82)	59.5 (27-93)	<.001
Race/ethnicity, No. (%)				
Non-Hispanic white	**175** (55.9)	74 (61.7)	101 (52.3)	<.05
Non-Hispanic black	**125** (39.9)	38 (31.7)	87 (45.1)	
Other	**13** (4.2)	8 (6.7)	5 (2.6)	
Mammographic density, No. (%)				
<25% Glandular	**10** (3.2)	1 (0.8)	9 (4.7)	<.001
25%-50% Glandular	**178** (56.9)	37 (30.8)	141 (73.1)	
51%-75% Glandular	**111** (35.5)	68 (56.7)	43 (22.3)	
>75% Glandular	**14** (4.5)	14 (11.7)	0	
Neoadjuvant therapy	**32** (10.2)	12 (10.0)	20 (10.4)	.89
Partial mastectomy	**7** (2.2)	3 (1.7)	4 (2.1)	.65
Mastectomy	**25** (8.0)	9 (7.5)	16 (8.3)	.74

Abbreviation: MR, magnetic resonance.

Table 2. Pathological and Operative Results

Variable	Total (N = 313)	MR Imaging Group (n = 120)	No MR Imaging Group (n = 193)	*P* Value
Histologic findings, No. (%)				
Invasive lobular carcinoma	**20** (6.4)	10 (8.3)	10 (5.2)	.27
Other	**293** (93.6)	110 (91.7)	183 (94.8)	
Extent of disease, No. (%)				
Localized	**251** (80.2)	91 (75.8)	160 (82.9)	.26
Multifocal	**51** (16.3)	23 (19.2)	28 (14.5)	
Multicentric	**11** (3.5)	6 (5.0)	5 (2.6)	
Size of index tumor, mean (range), cm	1.84 (0.0-18.0)	2.02 (0.1-9.0)	1.72 (0-18)	.009
Surgery performed, No. (%)				
Partial mastectomy	**198** (63.3)	72 (60.0)	126 (65.3)	.67
Mastectomy	**112** (35.8)	47 (39.2)	65 (33.7)	
Other or no surgery	**3** (1.0)	1 (0.8)	2 (1.0)	
Reoperation rate, No. (%)				
Completion mastectomy	**26** (8.3)	10 (8.3)	16 (8.3)	.91
Reexcision partial mastectomy	**31** (9.9)	13 (10.8)	18 (9.3)	
No reoperation	**256** (81.8)	97 (80.8)	159 (82.4)	

Abbreviation: MR, magnetic resonance.

noma and multifocal or multicentric disease were higher in the preoperative MR imaging group, these differences did not achieve statistical significance. The mean pathological size of the index tumor in the MR imaging group was significantly larger than that in the no MR imaging group (2.02 vs 1.72 cm, $P=.009$). The type of surgery performed (mastectomy vs partial mastectomy, $P=.67$) was similar in both groups. No statistically significant difference was observed in reoperation rates between the study groups (19.1% in the MR imaging group vs 17.6% in the no MR imaging group, $P=.91$).

To evaluate potential confounding variables due to observed differences between the MR imaging group and the no MR imaging group, we stratified reoperation rates based on the index tumor and breast imaging characteristics. Again, no statistically significant difference was observed in reoperation rates between the study groups when stratified by lobular carcinoma histologic findings ($P=.26$), tumor size ($P=.37$ for pT1 and $P=.35$ for pT2), or breast density ($P=.76$ for BI-RADS category 3 or 4 [>51% glandular]) or when stratified by younger age ($P=.98$ for ≤50 years) (data not shown).

Thirty-two patients underwent neoadjuvant therapy, 12 of whom had preoperative MR imaging. Among patients who underwent neoadjuvant therapy, no significant difference was observed in the mastectomy rates between those who had MR imaging and those who did not (Table 1). Seven patients (3 in the MR imaging group and 4 in the no MR imaging group) had attempted breast conservation. One of 3 patients in the MR imaging group had a reoperation, while 2 of 4 patients in the no MR imaging group had a reoperation performed. Of 9 patients who had neoadjuvant therapy and preoperative MR imaging, pathological findings demonstrated concordant findings in 7 patients. One remaining patient had multiple regions of enhancement that proved to be a localized area of residual disease, while the final patient had a single area of enhancement that proved to be multicentric disease pathologically.

Because preoperative MR imaging demonstrating multiple areas of enhancement even without biopsy confirmation was an indication for mastectomy, we examined the rate of pathologically avoidable initial mastectomy as part of the reoperation rate (**Table 3**). A pathologically avoidable mastectomy, defined as MR imaging showing multifocal or multicentric disease but histopathological results demonstrating only unifocal malignant disease, was observed in 12 of 47 patients (25.5%) with mastectomy who underwent preoperative MR imaging. Of about 58% of patients with mastectomy who had concordant MR imaging and histopathological findings, approximately 70% had unifocal MR imaging with localized disease on histopathological examination. In addition, 17.0% of mastectomy specimens had histopathological evidence of multifocal or multicentric disease not recognized by preoperative MR imaging.

Table 3. Histopathological Results in 47 Patients With Magnetic Resonance (MR) Imaging Who Underwent Mastectomy

Findings on MR Imaging	Histopathological Results	No. (%) (n = 47)
Unifocal disease	Localized disease	19 (40.4)
Multifocal disease	Multifocal, multicentric disease	8 (17.0)
Unifocal disease	Multifocal, multicentric disease	8 (17.0)
Multifocal disease	Localized disease	12 (25.5)

COMMENT

The routine use of MR imaging in the preoperative staging of the affected breast in newly diagnosed breast cancer is controversial, primarily because of its expensive cost, high false-positive rate, and uncertain effect on definable outcomes, such as ipsilateral breast recurrence or reoperation rates.[12-14] This study examined the selective use of preoperative MR imaging in patients with newly diagnosed breast cancer who were eligible for breast conservation surgery. To minimize the potential intersurgeon variability of indications for breast conservation, the study was limited to patients treated by a single experienced breast surgeon (L.S.B.). Our results demonstrate that the selective use of preoperative MR imaging in women did not affect the reoperation rate compared with women who did not have preoperative MR imaging. It is well recognized that MR imaging of the breast is a more sensitive imaging modality than conventional breast imaging in patients with newly diagnosed breast cancer.[13,15,16] The demonstration of additional foci of disease with imaging has led some to argue that MR imaging should be routinely used in the preoperative assessment of patients considered candidates for breast-conserving therapy. Lending support to this viewpoint are the results of several investigations suggesting that MR imaging results in potentially beneficial alterations in surgical management. Conversion from breast conservation to mastectomy based on MR imaging is reported to occur in up to approximately 22% of patients[15,17,18] and wider excision in up to 14% of patients.[15,16,18]

It has been acknowledged that multifocality and multicentricity are common in breast cancer.[19] Detailed pathological mastectomy mapping with MR imaging correlation indicates that MR imaging identifies some but not all foci of the pathologically notable disease and has a significant potential to incorrectly suggest additional foci of disease not confirmed on pathological review.[20] Before preoperative MR imaging came into standard practice, local recurrences of 15% or less at 20-year follow-up periods had been reported in 2 prospective randomized breast-conserving trials.[1,21] These low recurrence rates suggest that disease identified by MR imaging may be controlled by whole-breast irradiation or may be biologically irrelevant. For this reason, the potential incremental benefit of MR imaging on ipsilateral breast recurrences has come into question and is not likely to be defined except in the setting of a clinical trial.

Herein, we addressed the effect of MR imaging on the rates of reexcision and pathologically avoidable mastectomy. Our choice of these primary end points allowed us to avoid interpreting results as beneficial or unnecessary as proposed by other authors.[15] Since 2006, we have selectively used MR imaging in settings where conventional imaging is considered less sensitive, most often in cases of dense, highly glandular breast tissue. Because the sensitivity of breast MR imaging is not limited by the density of the breast, it was anticipated that this would improve surgical planning and treatment in patients who were potential breast conservation candidates.

Mammographically, invasive lobular carcinoma is not associated with microcalcifications[22] and has a tendency to incite less of a desmoplastic reaction than infiltrating ductal carcinoma.[23-25] For these reasons, invasive lobular carcinoma can frequently be missed or underestimated in size with conventional mammography.[26] Several investigators have suggested that MR imaging is the modality of choice for evaluation of invasive lobular carcinoma,[23,27-29] and its use is supported by the American Society of Breast Surgeons[5] for biopsy-proven invasive lobular carcinoma. Although invasive lobular histology was one of the selection criteria we generally used for MR imaging, we were surprised that there was no statistically significant difference in the use of MR imaging among the small subset of patients with invasive lobular carcinoma. This suggests that the principal indication for MR imaging was concern about the sensitivity of conventional imaging in the presence of heterogeneously dense or extremely dense breast tissue and that invasive lobular histology was a nonuniformly applied secondary consideration.

Our finding that preoperative MR imaging did not affect the reoperation rate is consistent with several population investigations that have examined this end point. In a prospective randomized controlled trial in the United Kingdom, Turnbull and coworkers[9] reported reoperation rates of 19% in patients who underwent MR imaging and 20% in patients who did not undergo MR imaging ($P = .77$). Pengel et al[30] reported positive margins in 19.4% of patients not having MR imaging compared with 13.8% of patients having MR imaging ($P = .17$), while Bleicher et al[31] reported positive margins in 13.8% of patients not having preoperative MR imaging and 21.6% of patients

having preoperative MR imaging ($P = .20$). In contrast to the present study, these population-based investigations did not distinguish patients who were more or less likely to benefit from this procedure. Our findings suggest that, even in a well-defined subset of patients, MR imaging fails to improve rates of reoperation.

A substantial body of evidence indicates that the use of MR imaging is associated with increased use of mastectomy as the initial surgical procedure.[13] In contrast to these findings, our mastectomy rate was no different between patients who had preoperative MR imaging and those who did not have preoperative MR imaging. This may reflect the fact that patients who did not have MR imaging were on average significantly older than those who had MR imaging, which has been documented to be a factor associated with increased rates of mastectomy.[32] In addition, mastectomy may have been selected by rural patients, who often have difficulty traveling to the medical center for radiation therapy.[33] Such individuals represented a significant percentage of our patient population.

Special comment is warranted on patients who had MR imaging and underwent pathologically avoidable mastectomy, defined as mastectomy performed in the presence of pathological unifocal disease and MR images of multifocal or multicentric disease. Of the patients with MR imaging who underwent mastectomy in our study, 25.5% had a pathologically avoidable mastectomy (Table 3). These data reconfirm the substantial risk of false-positive interpretations of MR images. In addition, several patients had unifocal MR images and unifocal histopathological results following mastectomy. It is likely that most patients with known unifocal disease on MR imaging opted for a mastectomy based on personal preference or at the recommendation of an experienced breast surgeon who anticipated an unacceptable cosmetic result with a breast conservation approach due to the area of enhancement relative to breast size. Our study did not explore the clinical and personal decision making before mastectomy. However, it is reasonable to presume that, in the absence of a confirmatory preoperative biopsy specimen, most of these patients with a pathologically avoidable mastectomy elected to have a mastectomy based on the multiple areas of enhancement on MR imaging.

A limitation of our study is the retrospective cohort study design, which restricts our ability to demonstrate causation because of the potential introduction of unrecognized selection bias. In particular, the criteria for reexcision can be variable.[34] We attempted to minimize the potential for reexcision bias by examining the reoperation rate of a single surgeon. However, we believe that these results may be applicable to others, with the caveat that the method of specimen processing and the criteria for reexcision are adhered to as outlined in the "Methods" section herein. Perhaps more compelling evidence of the broad applicability of these findings are the results of the Comparative Effectiveness of MRI in Breast Cancer trial,[9] in which defined criteria for reexcision before randomization between MR imaging and conventional imaging (even if they varied between surgeons) demonstrated no statistically significant difference in reoperation rates. Although the use of MR imaging to reduce the rate of reoperation is not supported by our results, MR imaging has a role in the screening of women at increased risk for developing breast cancer, in women who are seen with axillary metastatic disease from an unknown primary tumor and have normal results on conventional breast imaging, and possibly in women with unusual breast subtypes that have historically been associated with difficulties in conventional imaging.[35] In addition, MR imaging may have a role in patients who are undergoing neoadjuvant therapy and may desire breast conservation, although our experience with such patients to date has been limited.

Critical examination of breast cancer imaging and treatment practices is essential to achieve evidence-based patient care. Herein, we investigated the effect of preoperative MR imaging on the rate of reoperation in patients most likely to benefit from this imaging modality. Despite the increased sensitivity of MR imaging, its preoperative use exhibited low specificity in this study and did not significantly change the reoperation rate. We did not address whether MR imaging has a role in other specific clinical settings such as in very young women with a newly diagnosed breast cancer and a deleterious *BRCA* mutation who are considering a breast conservation approach to local therapy or in patients who are contemplating partial breast irradiation. Our findings do not support even the selective use of preoperative MR imaging to reduce the reoperation rate in operable breast cancer.

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INVITED CRITIQUE

Preoperative Breast Magnetic Resonance Imaging: A Solution Looking for a Problem

Because breast magnetic resonance (MR) imaging has repeatedly been shown to detect occult cancer in patients with newly diagnosed breast cancer, the modality has increasingly been used in the initial evaluation of patients with the disease. Breast MR imaging theoretically provides improved ability to localize disease and avoid reexcision or, worse yet, leave occult cancer behind when attempting breast conservation. Magnetic resonance imaging is believed to be especially helpful for women with dense breast tissue, among whom conventional imaging carries the requisite radiologist's disclaimer that "not all cancers will be detected by imaging." For these reasons and despite its high cost, the use of breast MR imaging has become almost routine in the evaluation of patients with newly diagnosed breast cancer.

Weber et al[1] have added to a burgeoning body of literature questioning the usefulness of breast MR imaging with their current review of the effect of preoperative MR imaging on the reoperation rate for women with operable breast cancer. In their study evaluating 313 patients from a single dedicated breast surgeon's practice, they compared patients who received preoperative MR imaging with patients who did not with regard to rates of reoperation (meaning reexcision partial mastectomy or completion total mastectomy) and rates of avoidable total mastectomy performed at initial operation. This second outcome measure is critically important: how many