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THE IMPACT OF BREAST MRI ON SURGICAL DECISION- MAKING: ARE PATIENTS AT RISK FOR MASTECTOMY?

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Abstract

Background and Objectives—The goal of the current study was to determine whether MRI impacts multidisciplinary treatment planning and if it leads to increased mastectomy rates.

Methods—A retrospective review was conducted of 441 patients treated for breast cancer between January 2005 and May 2008 who underwent breast MRI. Data included number of additional findings and their imaging and pathologic work-up. This was analyzed to determine impact of MRI on treatment planning.

Results—Of 441 patients, 45% had 1 additional finding on MRI. Of 410 patients with complete records, 29% had changes in the treatment plan, including 36 patients who were initially considered for breast conservation but proceeded directly to mastectomy based on MRI findings of suspected multicentricity. Twenty-three of those patients did not have a biopsy of the MRI lesion, with 87% having unicentric disease on final pathology. Overall, the mastectomy rate was 44%, which was significantly increased compared to patients not undergoing MRI (32%, $p < 0.05$).

Conclusions—Breast MRI alters the treatment planning for many patients with newly-diagnosed breast cancer. Mastectomy rates are increased when MRI results alone direct surgical planning. Biopsy of MRI-identified lesions should be performed to avoid over-treatment.

Keywords

Breast cancer; Breast-conserving therapy; Surgery; Staging

INTRODUCTION

Breast magnetic resonance imaging (MRI) has become a frequently used imaging modality in the evaluation of local extent of disease in patients with a known diagnosis of breast cancer. The sensitivity and specificity have been shown to be 93–100% and 26–91%, respectively [1–3]. While specific guidelines exist regarding the utility of screening breast

MRI for high-risk patients [4], no such guidelines are available for patients with newly diagnosed breast cancer. As a result, the inclusion of a breast MRI as part of the diagnostic work-up of patients with breast cancer occurs at variable rates and for variable indications. Most commonly, MRI is being used both to define the extent of disease in the ipsilateral breast and to determine the presence of contralateral disease. Hollingsworth et al. [1] demonstrated a 7.7% rate of multicentric disease and a 3.7% rate of contralateral disease not detected by routine imaging in a retrospective study of 603 patients, which is consistent with other large prospective studies, showing a 1.8% to 3.1% rate of undetected contralateral disease [2, 5]. Such authors have concluded from this data that all women with newly diagnosed breast cancers should undergo pre-operative evaluation with MRI.

Although the sensitivity of breast MRI is quite high, there is also significant potential for false positives. Concern has been raised that such false positive findings may prompt a higher utilization of mastectomy without any clear survival benefit [2, 6–8]. Solin et al. [8] retrospectively reviewed 756 women undergoing treatment for breast cancer and compared recurrence rates between the patients who underwent pre-operative breast MRI versus those who did not. They found that there was no significant difference in the recurrence rates between the two groups (3% vs. 4%). Further, Berg et al. [2] demonstrated that 12% of women with likely benign lesions on MRI elected to proceed with mastectomy rather than breast conservation therapy (BCT) or interval follow-up MRI based on these imaging findings alone. The reasons for these decisions are likely attributed to the breast cancer patient's fear of additional cancer lesions, fear of future failure of BCT, and fear of delay in treatment that would be necessary in order to fully investigate and/or biopsy the additional observed MRI abnormalities. These studies have raised the question as to the benefit of breast MRI at all, especially when one considers data from the NSABP B-06 study [9] demonstrating equivalent outcomes when comparing BCT with mastectomy in the pre-MRI era. In theory, if the addition of MRI to standard imaging was detecting clinically significant disease, the patients randomized to mastectomy should have had an improved outcome due to patients with missed multicentric disease in the BCT arm.

Because of the low rates of local recurrence following both BCT and mastectomy and the lack of randomized trials, it may be difficult to ever demonstrate a breast cancer-specific mortality benefit from the additional use of breast MRI. However, it is possible to determine whether breast MRI led to a change in surgical decision-making and treatment. Previous studies have alluded to this with mixed results [2, 3, 10–14]. While these studies report changes in surgical decision-making ranging from 11–26%, none has focused specifically on the work-up of suspected additional disease and how that can lead to a change in the surgical plan. The goal of the current study was to determine how breast MRI imaging affected our surgical decision-making. We hypothesized that the rate of mastectomy would be significantly increased in patients undergoing MRI, and that the final pathology would confirm surgical over-treatment in patients not completing work-up of these areas with pathologic confirmation prior to surgical treatment.

METHODS

Institutional review board approval was obtained prior to the commencement of this retrospective study. Written informed consent of patients was not required. The surgical, radiology, and pathology databases at Washington University/Barnes Jewish Hospital were queried from January 1, 2005 to May 31, 2008 to identify all consecutive patients with a diagnosis of Stage 0-III invasive breast cancer who underwent surgical treatment of their cancer at our institution and who underwent breast contrast-enhanced magnetic resonance imaging (MRI) during the diagnostic work-up. Patients who had been previously treated for breast cancer and were undergoing MRI for a screening purpose only were excluded.

MRI was performed using either a Siemens 1.5T Sonata or Espree magnetic resonance imaging unit. Patients were placed in the prone position and both breasts were imaged using a dedicated breast coil. Imaging sequences obtained included a pre-contrast axial 3-dimensional gradient echo with fat suppression. All patients received an intravenous dose of gadolinium at 0.2 mmol/kg administered as a bolus dose with a power injector followed by a saline flush. Three post-contrast scans were performed and images were viewed on a dedicated workstation by dedicated breast radiologists. Post-processing included image subtraction, maximum intensity projection, 3-dimensional reconstruction, signal-intensity analysis, and computer-assisted diagnosis. In patients requiring MRI-guided biopsies, a Suros 9-gauge vacuum-assisted device was utilized.

Patient and imaging data collected included age of the patient, mammographic findings, ultrasonography findings, initial biopsy pathology, timing of MRI relative to diagnostic biopsy, and results of the MRI (size of index lesion, contrast kinetics of the index lesion, and number and characteristics of additional lesions in the ipsilateral or contralateral breast). Criteria for suspicious lesions on MRI included size, morphology, and contrast kinetics. Patients with suspicious lesions on MRI were recommended to undergo second-look ultrasonography of the suspicious area. If lesions were visible on second-look ultrasound and remained suspicious, then an ultrasound-guided biopsy was performed. If the lesion was not visible and the index of suspicion was high based on MRI, an MRI-guided biopsy was performed. A subset of patients had a second-look ultrasound for an indeterminate MRI lesion that was not visible on ultrasonography with recommendation for a follow-up MRI in 6 months to document stability.

Final pathology was examined and compared to estimated MRI size of the lesions. Size of the lesion on MRI was reported as total extent of disease, whereas final pathology size was reported as the extent of an invasive component. The correlation of non-mass like enhancement on MRI, which may represent ductal carcinoma in situ (DCIS), was not able to be directly correlated with extent of DCIS on final pathology.

Surgical data collected included the use of neoadjuvant therapy, presence of DCIS in the specimen, type of surgical procedure performed, and presence of contralateral pathologies and surgical interventions. Determination of a change in management of the patient was made based on a retrospective review of patient records, clinic notes, and multidisciplinary breast conference notes. We define a change in management as a change in the multidisciplinary treatment plan based on MRI findings compared with the treatment plan prior to MRI. Such changes included administration of neoadjuvant chemotherapy prior to attempted BCT, conversion from BCT to mastectomy with or without the administration of neoadjuvant chemotherapy, or management of an MRI-identified contralateral breast cancer. The use of neoadjuvant chemotherapy in patients ultimately having a mastectomy was due to either a failed attempt to make a patient a candidate for BCT or as a way to initiate therapy while coordinating care in patients interested in immediate reconstruction. Reasons for conversion from BCT to mastectomy after MRI included confirmed or suspected multifocal disease, or a presumed increase in the extent of disease.

All data were transferred to a single spreadsheet (Excel; Microsoft, Redmond, WA). Data analysis for this study was descriptive in nature. The associations between patient and tumor characteristics and changes in the treatment plan based on MRI results were summarized using contingency tables and assessed by Fisher's exact test. Statistical analyses were performed using a statistical package SAS (SAS Institutes, Cary, NC). A p-value under 0.05 was taken to indicate significance and all statistical tests were two-sided.

RESULTS

Patients

A total of 1009 consecutive breast contrast-enhanced MRIs were performed at our institution between January 1, 2005 and May 31, 2008. Of these, 517 were performed for screening purposes in high-risk patients and were not included in the analysis. During the study period, a total of 1444 newly diagnosed breast cancer patients were cared for at our facility. Of the total patients treated for breast cancer, 492 patients underwent MRI as part of their diagnostic imaging evaluation and 952 patients did not. Patient selection for breast MRI at our institution is selected on a case-by-case basis, depending on the difficulty of determining the extent of disease by conventional imaging. The rationale for performing MRI is difficult to assess retrospectively, though we did note that patients with difficult mammograms (as described by our breast radiologists), dense breasts, younger age at diagnosis, or with a diagnosis of invasive lobular cancer were more likely to be advised to have an MRI.

Of 492 patients with a known diagnosis of breast cancer who underwent breast MRI as part of their diagnostic imaging evaluation, an additional 51 patients were excluded after initial data collection for the following reasons: diagnosis of high risk lesion only (7); diagnosis was not adenocarcinoma (5); MRI performed to find primary for metastatic disease already diagnosed (16); prior history of treated ipsilateral breast cancer (18); diagnosis of inflammatory breast cancer (3); and MRI was not interpretable due to technical reasons (2). The patient and tumor characteristics of the remaining 441 patients included in the analysis are shown in Table I.

MRI findings

Of the 441 patients included in the analysis, 200 (45%) had an additional lesion seen that was not categorized as benign. Overall, in the total cohort, the average number of additional lesions seen on MRI was 0.7. Of the 200 patients who had an additional lesion identified, the average number of additional lesions was 1.5. All 200 patients with additional lesions identified were recommended to have a second-look ultrasound and 131 (66%) completed the additional imaging. Of those patients undergoing second-look ultrasound, 23 (18%) had lesions with benign characteristics and no biopsy was recommended, 5 (4%) were categorized as probably benign, and 62 (47%) were determined to be suspicious on ultrasound and a biopsy was recommended. Forty-one patients (31%) undergoing second-look ultrasound did not have a correlative lesion seen, and 14 underwent either MRI-guided biopsy or MRI-guided wire localization excisional biopsy. The remaining 27 patients without a correlative lesion were recommended to undergo a 6 month follow-up MRI. Therefore, a total of 15% (67 of 441) of patients underwent additional preoperative biopsies. Twenty-eight (42% of those biopsied or 6% of the total cohort) identified an additional malignancy or a high risk lesion. Figure 1 shows the outcome for all 441 patients undergoing MRI.

Of the 200 patients who had an additional lesion identified, 69 (34%) were recommended to undergo second-look ultrasound, but this imaging was not performed (Figure 2). Twenty-eight of these patients underwent neoadjuvant therapy prior to definitive surgical therapy and pathological correlation of the MRI-identified abnormalities is not feasible. In the 23 patients who proceeded directly to mastectomy, only 4 had multicentric disease on final pathology. An additional 13 patients did have a follow-up ultrasound confirming a suspicious lesion, but did not have it confirmed by preoperative biopsy (Figure 3). Of those patients, 5 went directly to mastectomy with only 1 patient having multicentric disease on final pathology. Of note, an additional 4 patients who had a follow-up ultrasound confirming

a suspicious lesion but no biopsy had neoadjuvant therapy prior to mastectomy, and pathological correlation of multicentricity is not feasible.

Surgical decision-making

Of the 441 patients included in the analysis, 31 of them had incomplete charts and therefore we were unable to determine if the MRI had any impact on decision making. Of the 410 patients that were evaluable, 117 (29%) had a change in the surgical plan based on the MRI (Figure 4). Changes included: 9 (8%) patients who were given neoadjuvant chemotherapy prior to breast-conserving therapy; 51 (44%) patients who underwent mastectomy based on the size of the primary lesion on MRI or the presence of additional lesions; 37 (32%) patients who were given neoadjuvant chemotherapy prior to mastectomy; 10 (8%) patients who required contralateral procedures (4 (40%) of these ultimately showed malignancy); and 2 (2%) patients who underwent re-excisions of their excisional biopsy cavity based on MRI alone. In 8 (7%) patients, our surgical plan changed, but the patient ultimately did not have surgery performed at our institution.

In the 51 patients who were initially planning breast-conserving therapy and then migrated to mastectomy following MRI evaluation, 36 patients had additional lesions seen on MRI that were “suspicious” for multicentric disease. However, only 10 of those patients underwent pre-mastectomy work-up and biopsy which confirmed multicentricity. Of the 23 patients who did not have a pre-mastectomy biopsy to confirm multicentricity, 15 (65%) had unicentric disease on final pathology, consistent with routine imaging. The 3 remaining patients had biopsies which were benign and concordant, but they elected to proceed with mastectomy despite the additional benign pathology.

Patient age, histologic subtype of the breast cancer, and previous excisional biopsy did not significantly alter the decision-making process. Size of the lesion on MRI ($p=0.006$) and the presence of new lesions on MRI ($p<0.00001$) did lead to an increased likelihood of altering the surgical plan (Table II). After controlling for all potential confounders in univariate analyses, multivariate logistic regression demonstrated that size of the lesion on MRI and the presence of new lesions on MRI were the only independent predictors leading to a change in the surgical plan. Compared to patients without any new lesions seen on MRI, those with 1 (OR=4.1) or >1 (OR=4.4) new lesions were more likely to have a surgical treatment plan change ($p<0.0001$). The relationship between MRI size and change of plan is not linear. Those patients with lesion size on MRI of 2–5cm had the highest likelihood to undergo a change in plan.

Patient age, histologic subtype of the breast cancer, previous excisional biopsy, and use of neoadjuvant therapy did not significantly predict the use of mastectomy (Table III). The only significant factor associated with the use of mastectomy compared to BCT was the addition of MRI in the diagnostic work-up. Overall, the rate of mastectomy in the study population was 44% (192 of 441), which was significantly increased compared to patients not undergoing MRI during the same time period (305 of 952, 32%, $p<0.05$).

DISCUSSION

Although there have been previous papers investigating the impact of MRI on surgical decision-making and management [2, 3, 10–14], this series is the largest to date, and only one other has considered the use of neoadjuvant chemotherapy as a change in surgical plan for their analysis [14]. Correlation of MRI results with final pathology in patients undergoing neoadjuvant chemotherapy is not feasible, and therefore, the impact on surgical over-treatment is difficult to ascertain. Despite the inclusion of these patients, the results from our data suggest that MRI does have an impact on surgical decision-making, changing

the plan in 29% of our patients. This is consistent with previously published reports demonstrating a change in 14–35% of patients [2, 3, 10–14]. Current numbers also vary widely with regards to the potential increase in mastectomy rates following the use of MRI, ranging from 3–25% [2, 10]. Overall, the rate of mastectomy in our study population was 44% (192 of 441), which was significantly increased compared to patients who did not undergo MRI during the same time period (32%, $p < 0.05$). This 12% differential falls well within the range of data already published. Some have questioned whether the use of MRI is driving the increase in mastectomy rates in the United States [15]. It is difficult to determine whether MRI alone is responsible for this change. The finding is likely to be a result of multifactorial issues, including increased knowledge of high-risk patients and genetic susceptibilities as well.

The fact that mastectomy rates were higher in our study population than in patients who did not undergo MRI during the same time period, does suggest that MRI may be a significant risk factor for the use of mastectomy. Based on our data it does appear that some of these mastectomies represent surgical over-treatment. The most concerning aspect of our study was the identification of a subset of patients who had suspicious MRI findings, but proceeded to mastectomy without a tissue confirmation of multicentricity. It was difficult to determine in a retrospective fashion whether these mastectomies were performed based on the surgeon's feeling that the disease was too extensive for BCT or whether the patient's preference changed toward mastectomy, perhaps due to the time delay of further work-up and anxiety over the additional areas seen. This would be best determined in a prospective fashion.

In a prospective study by Schelfout et al. [12], breast MRI changed the therapeutic approach in 30.6% of breast cancer patients, with no reported cases of unnecessary mastectomy. However, all patients in their study had the MRI performed prior to a tissue diagnosis of cancer and all patients had full imaging and tissue evaluation of all suspicious lesions. At our institution, we prefer to have a tissue diagnosis prior to the use of MRI. The current study demonstrates that a significant number of women undergoing preoperative MRI for evaluation of extent of disease will have at least one additional lesion seen on MRI which needs to be evaluated further (45% in the current study). Further, our results support the finding that lack of characterization by ultrasound and omission of biopsy of suspicious lesions may potentially lead to unnecessary mastectomies. These findings corroborate previous reports by authors who caution surgical management changes based on MRI findings alone [11, 16, 17].

To date, there is insufficient data to determine whether the use of MRI will impact the outcome (in terms of recurrence rates, disease-free survival and overall survival) in patients who have multifocal or multicentric lesions seen on MRI [8, 18]. Solin et al. [8] compared women who underwent preoperative breast MRI versus those who did not and found that there were no significant differences between the two groups with respect to local recurrence, overall survival, cause-specific survival, freedom from distant metastases, or contralateral breast cancer. In contrast, Fischer et al. [18] found that patients undergoing preoperative MRI had a significantly decreased rate of in-breast local recurrence (1.2%) compared to those patients who did not have a preoperative MRI (6.8%). It is difficult to interpret these retrospective results as it is unclear whether the patients undergoing preoperative MRI may have been pre-selected to have additional imaging due to factors placing them at higher risk for recurrence based on tumor biology and other patient and/or tumor characteristics.

The lack of a clear survival benefit for MRI is unlikely to be seen, in part, due to the current high overall survival rates and low local recurrence rates. In addition, the efficacy of

adjuvant systemic therapy and radiation therapy may obviate the need to surgically remove small multifocal or multicentric lesions that are being identified on MRI. However, as adjuvant systemic therapy becomes more tailored to individual patients and the use of partial breast irradiation increases, identifying occult multicentricity may have more of an impact on outcomes. The local recurrence rate for whole breast versus partial breast radiation is equivalent, though long term follow-up studies have not yet been published [19].

Limitations of this study include its retrospective nature and the heterogeneous group of patients included. The standard practice at our institution is to perform the diagnostic MRI after the diagnosis of cancer has been confirmed by biopsy, but prior to any surgical intervention. However, a significant number of our patients are referred from outside facilities, and may have previously had an excision of the primary tumor. In addition, many of our patients underwent neoadjuvant chemotherapy prior to definitive surgical intervention making pathologic correlation with MRI findings impossible. Finally, the determination of tumor size by MRI versus final pathology is limited by the ability to delineate invasive versus *in situ* disease on MRI and difficulty in estimating extent of DCIS size in final pathology specimens.

CONCLUSION

Despite these limitations, the current study highlights the significant implications of performing MRI for evaluation of extent of breast cancer disease. Although MRI may demonstrate suspected multifocal, multicentric, or contralateral disease, its low specificity mandates tissue confirmation prior to definitive surgical intervention. If MRI is utilized in the preoperative planning, patients must be counseled that the MRI will lead to identification of additional lesions approximately 50% of the time, and that additional work-up and biopsies are necessary to resolve the importance of such findings. In the absence of a rigorous imaging and pathological analysis, patients are at risk for surgical over-treatment and decreased breast conservation. Prospective studies are necessary to determine if the MRI identification of multifocal, multicentric, or contralateral disease impacts recurrence rates, disease-specific survival, or overall survival.

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SYNOPSIS

A review of 441 patients with newly-diagnosed breast cancer who also underwent breast MRI demonstrated that treatment planning was altered for 29% of patients. Mastectomy rates were increased when MRI results alone directed surgical planning. Biopsy of MRI-identified lesions should be performed to avoid over-treatment.

Figure 1. Radiologic interpretation and outcome of 441 patients with newly diagnosed breast cancer undergoing MRI for diagnostic work-up.

Figure 2.

Final outcome for 69 patients with newly diagnosed breast cancer who had an additional abnormality identified on pre-operative MRI and who were recommended to undergo second-look ultrasound, but did not complete the additional imaging.

Figure 3.

Final outcome for a subset of 13 patients with newly diagnosed breast cancer who had an additional lesion seen on MRI and categorized as suspicious on second-look ultrasound, but did not undergo biopsy of the lesion prior to definitive surgical intervention.

Figure 4.

Final outcome for 117 patients with newly diagnosed breast cancer who underwent MRI and had a surgical treatment plan change.

Table I

Patient and tumor characteristics in 441 patients with newly diagnosed breast cancer undergoing breast MRI.

Variable	N	%
Age		
<40	64	14.5%
40–60	282	63.9%
>60	95	21.5%
Pathology		
DCIS	51	11.6%
IDC	273	61.9%
ILC	74	16.8%
Other	36	8.2%
Unknown	7	1.6%
T size*		
p0	51	11.6%
p1	144	32.7%
p2	74	16.7%
p3	17	3.9%
yp0	27	6.1%
yp1	69	15.6%
yp2	33	7.5%
Unknown	26	5.9%
Neoadjuvant therapy		
yes	129	29.3%
no	312	70.7%
Previous excision		
yes	83	18.8%
no	358	81.2%
MRI extent of disease		
<2 cm	200	45.4%
2–5 cm	160	36.3%
>5 cm	64	14.5%
Unknown	17	3.9%
# new lesions on MRI		
0	241	54.6%
1	133	30.2%
>1	67	15.2%
Surgical management		
BCT	202	45.8%
Mastectomy	192	43.5%
Unknown	47	10.7%

DCIS = ductal carcinoma in situ; IDC = invasive ductal carcinoma; ILC = invasive lobular carcinoma; MRI = magnetic resonance imaging; BCT = breast-conserving therapy

*
"y" denotes previous neoadjuvant therapy

Table II

Characteristics of 117 patients with newly diagnosed breast cancer who underwent MRI and had a change in surgical decision-making.

Variable	N	%	P value
Age			p = 0.314
<40	12	10.3%	
40–60	77	65.8%	
>60	28	23.9%	
Histology			p = 0.392
DCIS	9	7.7%	
IDC	80	68.4%	
ILC	18	15.4%	
Other/unknown	10	8.5%	
Previous excision			p = 0.618
Yes	30	25.6%	
No	87	74.4%	
MRI extent of disease			p = 0.006
<2 cm	42	35.9%	
2–5 cm	58	49.6%	
>5 cm	15	12.8%	
Unknown	2	1.7%	
# of new lesions on MRI			p < 0.00001
0	38	32.5%	
1	46	39.3%	
>1	33	28.2%	

DCIS = ductal carcinoma in situ; IDC = invasive ductal carcinoma; ILC = invasive lobular carcinoma; MRI = magnetic resonance imaging

The reference group equals the 324 patients who did not have a change in surgical decision-making.

Table III

Characteristics of 192 patients with newly diagnosed breast cancer who underwent pre-operative MRI followed by mastectomy.

Variable	N	%	P value
Age			p = 0.388
<40	26	13.5%	
40–60	118	61.5%	
>60	48	25.0%	
Histology			p = 0.317
DCIS	28	14.6%	
IDC	123	64.1%	
ILC	32	16.6%	
Other/unknown	9	4.7%	
Previous excision			p = 0.628
Yes	33	17.2%	
No	159	82.8%	
Neoadjuvant therapy			p = 0.819
Yes	46	24.0%	
No	146	76.0%	

DCIS = ductal carcinoma in situ; IDC = invasive ductal carcinoma; ILC = invasive lobular carcinoma; MRI = magnetic resonance imaging

The reference group equals the 249 patients who underwent breast-conserving therapy or unknown surgical therapy.