Evaluating the Impact of Preoperative Breast Magnetic Resonance Imaging on the Surgical Management of Newly Diagnosed Breast Cancers

Karl Y. Bilimoria, MD; Angela Cambic, BA; Nora M. Hansen, MD; Kevin P. Bethke, MD

Hypothesis: Women with newly diagnosed breast cancers may harbor additional ipsilateral or contralateral breast malignancies that are undetected by mammography and ultrasonography. Magnetic resonance imaging (MRI) has demonstrated excellent sensitivity in the detection of breast cancers. However, the impact of routine MRI on the surgical management of new, biopsy-proven breast cancers remains unclear.

Design: Retrospective analysis of a prospective database.

Setting: An academic, tertiary care center in a large metropolitan area.

Patients: A total of 155 women with breast cancer newly diagnosed by mammography, ultrasonography, and needle biopsy underwent preoperative bilateral breast MRI in a single-institution, single-surgeon setting during 1 year.

Main Outcome Measures: Change in surgical management based on breast MRI findings.

Results: The MRI demonstrated 124 additional suspicious lesions in 73 patients. Post-MRI follow-up mammograms or ultrasonograms were required in 65 patients, and 41 patients underwent additional image-guided biopsies. There was a change in surgical management as MRI discovered additional, otherwise undetected malignancies in 36 patients based on radiographic-pathologic correlation. Lumpectomy was converted to mastectomy in 10 patients (8 beneficial), wider excision was performed in 21 patients (10 beneficial), and 5 patients (2 beneficial) underwent contralateral surgery. Larger tumor size was an independent predictor of a beneficial change in surgical management (odds ratio, 1.66; 95% confidence interval, 1.04-2.66).

Conclusions: Breast MRI results in a beneficial change in surgical management in 9.7% of newly diagnosed breast cancers. The detection of additional, otherwise undetected ipsilateral and contralateral breast malignancies with MRI suggests that breast MRI may have a role in the evaluation of new breast cancers.

Arch Surg. 2007;142:441-447

Women with newly diagnosed breast cancer are at risk of harboring an occult, synchronous ipsilateral or contralateral breast cancer that is undetected by mammography or ultrasonography. The rate of multifocality and multicentricity varies widely from 11% to 57%. If these additional foci can be identified preoperatively, the planned surgical management can be altered. Unfortunately, mammograms and ultrasonograms are not sensitive enough to detect some of these synchronous lesions.

Recently, breast magnetic resonance imaging (MRI) has been investigated as a screening modality and found to have a sensitivity of 93% to 100% in detecting breast cancers. Studies have shown that MRI in women with newly diagnosed breast cancers identifies additional, otherwise undetected synchronous tumor foci in 27% to 37% of patients. Thus, MRI has the potential to detect synchronous cancers, multifocality and multicentricity of the primary neoplasm, tumor extent, and early lesions that would otherwise develop into future cancers. Local recurrence rates after breast conservation therapy (BCT) range from 4.3% to 10%. These unrecognized lesions lead to worse local control of the cancer, lead to additional procedures and operations, and may result in worse outcomes.

The purpose of this study was to determine the effect of routine breast MRI on the surgical management of newly diagnosed breast cancers. First, our objective was to determine how often MRI detected an additional lesion that was otherwise undetected by mammography and ultrasonography. Second, we sought to examine the change in preoperative
evaluation as a result of the MRI findings. Third, we aimed to determine whether the change in surgical management was beneficial based on radiographic-pathologic correlation. Finally, we attempted to identify predictors of a beneficial change in surgical management based on preoperative breast MRI.

**METHODS**

A standardized protocol was implemented by a single surgeon (K.P.B.) in the management of all new, biopsy-proven breast cancers starting in April 2005. The study includes patients identified from a prospective database from April 1, 2005, to April 1, 2006. Approval for this study was obtained from the Northwestern University Feinberg School of Medicine’s institutional review board. The study included women 34 to 75 years of age with a new primary breast cancer. Women were excluded if MRI was deemed unnecessary: predominantly fatty breast tissue in cases where mammography was thought to be sufficient, women older than 75 years, insurance refusal of MRI performed at an outside institution.

**IMAGING**

Patients who presented with a possible breast cancer underwent exhaustive mammography and ultrasonography. Biopsies were performed on suspicious lesions, typically with radiographic guidance. If the biopsy specimens were positive for malignancy, the patient was referred to a single surgeon (K.P.B.). A full office evaluation was performed, and a preliminary decision was made about the intended surgical treatment of the patient.

After consultation with the surgeon, bilateral breast MRI was performed at 1.5 T, including bilateral dynamic scanning with axial acquisition. Kinetic analyses were facilitated by an MRI computer-aided detection system. If MRI detected an additional lesion that was not identified on prior imaging, the patient returned for a second-look ultrasonogram (for MRI-detected masses) or mammogram (for MRI-detected calcifications). All patients who underwent a second-look mammogram had an ultrasonogram as well. If the lesion was seen and still appeared suspicious, biopsy with image guidance was performed. If the lesion was not seen on follow-up ultrasonography or mammography, the patient underwent either an MRI-guided biopsy if the lesion was suspicious on initial MRI or 6-month follow-up MRI if the lesion was less concerning on initial MRI in the opinion of the attending breast radiologist.

**CHANGE IN SURGICAL MANAGEMENT**

If the pathologic findings of the MRI-detected lesion biopsy specimen were malignant or suspicious, the patient was reassessed by the same surgeon to determine if the MRI-identified malignancy altered the previously determined surgical management. The change in management was divided into 3 categories. First, MRI could result in a change from lumpectomy to mastectomy when the new lesion resulted in multicentric disease or the lesion appeared to be much more extensive on MRI so that more than a quadrantectomy would be required. Second, MRI could force a wider excision when an adjacent lesion or more extensive primary lesion was detected but lumpectomy was still possible. Finally, a change was also made when MRI discovered an otherwise undetected lesion in the opposite breast that resulted in contralateral surgery. Controversial changes in management based on breast MRI were discussed at the institutional multidisciplinary breast conference.

**RADIOGRAPHIC-PATHOLOGIC CORRELATION**

After surgery, all radiographic and pathologic results were reviewed to evaluate concordance by a single reviewer (K.Y.B.). In patients with a change in surgical treatment, the size of the lesion on mammography, ultrasonography, MRI, and final pathology reports was compared to determine whether the change was beneficial or unnecessary. The pathologists had no knowledge of the radiographic findings. Beneficial changes were those in which the pathologic results correlated with the MRI findings but not with those on mammography or ultrasonography.

**STATISTICAL ANALYSIS**

During the 1-year study period, 242 women with breast cancer were treated, and 190 women underwent bilateral breast MRI. Of the 190 who underwent MRI, 35 were excluded from the analysis because of undergoing MRI evaluation for recurrent breast cancer (n = 14), because of surgery for atypical ductal hyperplasia (ADH) that was subsequently found to be malignant (n = 2), because they were referred from an outside hospital for evaluation of positive margins (n = 8), or because they received neoadjuvant chemotherapy before MRI (n = 11). Of the remaining 155 women, the mean age was 53 years (range, 34-75 years). A total of 90 women (58.1%) presented with mammographic findings, and 64 (41.3%) presented with a palpable mass. Mastectomy was performed for 31 patients (20.0%), and lumpectomy was performed for 124 patients (80.0%). Thirty-three patients (21.3%) had ductal carcinoma in situ on final pathologic evaluation, 100 (64.5%) had invasive ductal carcinoma, 18 (11.6%) had invasive mammary carcinoma (a combination of ductal and lobular), and 4 (2.6%) had invasive lobular carcinoma. Forty patients (32.8%) with invasive cancer had node-positive disease.

A total of 155 women with a newly diagnosed breast cancer underwent breast MRI in concordance with the study protocol. A total of 124 suspicious lesions were detected on MRI in 73 patients (Table 1). Sixty-five of the 73 patients required further imaging (ultrasonography or mammography or both) for additional evaluation as a result of the MRI findings. Sixty-five of the 73 patients (88.4%) had a beneficial change in surgical management based on breast MRI. Of these 65 patients, 20 (30.8%) required a change from lumpectomy to mastectomy and 45 (69.2%) had a change from primary lumpectomy to mastectomy or conservative surgery. The statistical significance level was set at P = .05.
mography) in an attempt to further evaluate the newly discovered MRI lesion. Of the 8 patients who did not undergo further imaging, 2 patients proceeded straight to wider excision and the other 6 had 6-month follow-up MRI recommended. In 24 of the 65 patients, the MRI finding appeared benign with follow-up ultrasonography and mammography. The remaining 41 patients in whom the MRI-detected lesion was still concerning after follow-up imaging underwent image-guided biopsy (ultrasonographically guided, stereotactic, or MRI guided). Nine of those patients had malignancies apparent on biopsy specimens, 4 were found to have ADH or atypical lobular hyperplasia, and the remaining 28 had benign lesions. The false-positive rate for biopsy of an MRI-detected lesion was 78.0% (32/41).

Breast MRI altered the surgical management of patients with newly diagnosed breast cancer in 36 (23.2%) of 155 patients (Table 2). Ten patients who were initially candidates for BCT were upgraded, based on MRI, to a mastectomy. Of the 10, 3 patients had an additional focus of cancer detected on MRI that resulted in multicentric disease, and all of these were biopsy proven. The other 7 patients were borderline candidates for BCT, but the MRI demonstrated that the primary lesion was more than 2.0 cm larger than previously thought by mammography and ultrasonography. Because these patients were borderline candidates for BCT even before the MRI, this larger size as seen on MRI resulted in these women being upgraded to a mastectomy as well.

On the basis of MRI findings, 21 women required a wider excision but were still able to undergo a lumpectomy. In 13 patients there was a separate MRI-detected lesion larger than 2.0 cm from the primary site, which still allowed for a lumpectomy but mandated a wider excision. In 8 women, MRI showed that the primary lesion was larger than its appearance on mammography and ultrasonography, and as such, a wider excision was performed. Of the 21 women who required a wider excision, 19 women had wire-bracketed localization performed to ensure excision of the entire suspicious area, and 2 women had a wider excision at the time of surgery without bracketing assistance.

All patients in the study received bilateral breast MRI, and 7 patients had a suspicious lesion discovered in the contralateral breast. Of these 7 patients, 2 had a biopsy-proven malignancy, and 2 patients had a biopsy specimen that demonstrated ADH. The remaining 3 patients had a suspicious lesion detected on MRI in the contralateral breast and instead chose not to undergo a needle biopsy of the lesion but to have a prophylactic mastectomy.

A radiographic-pathologic correlation was performed to assess whether the change in surgical management based on MRI was beneficial owing to better concordance between MRI and surgical pathologic findings than between mammography or ultrasonography and surgical pathologic findings. Of the 36 women who had a change in surgical management based on MRI findings, 15 were found to have a beneficial change when MRI findings were confirmed on the final pathologic report. Eight of the 10 women who had an initially planned lumpectomy converted to mastectomy based on MRI were converted appropriately. Five of the 21 women who had a wider excision had a beneficial change because the MRI correlated with pathologic findings and the lesion was more than 2 cm larger than the mammogram or ultrasonogram had predicted. In the 7 women with contralateral MRI-detected lesions, the final pathologic report confirmed the 2 biopsy-proven malignancies. A malignancy was not found on the final pathologic report for the 2 patients who underwent contralateral lumpectomy for ADH or the 3 patients who elected to undergo a mastectomy rather than preoperative image-guided biopsy to determine the histologic features of the MRI abnormality.

We analyzed patient demographics, breast cancer risk factors, radiographic data, pathologic features, and staging. On univariate analysis, the only significant factors were that patients with larger tumors on pathologic reports (T2 and T3) had a change in surgical management more often than those with smaller tumors (T0 and T1) (35.7% vs 18.9%; P = .03), and patients with advanced-stage (IIIB, IIC, IIIA, IIB, or IIC) compared with early-stage disease (0, I, or IIA) had a beneficial change in management more often (22.2% vs 7.0%; P = .02). Multivariate analysis using logistic regression could not identify any significant factors that led to a change in surgical man-

<table>
<thead>
<tr>
<th>Evaluation</th>
<th>No. of Patients</th>
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<tr>
<td>Patients with additional lesion detected by MRI</td>
<td>73</td>
</tr>
<tr>
<td>Second-look imaging*</td>
<td>65/73</td>
</tr>
<tr>
<td>Ultrasonogram</td>
<td>59</td>
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<tr>
<td>Mammogram</td>
<td>6</td>
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<tr>
<td>Follow-up MRI in 6 mo</td>
<td>23/73</td>
</tr>
<tr>
<td>Ipsilateral</td>
<td>2</td>
</tr>
<tr>
<td>Contralateral</td>
<td>12</td>
</tr>
<tr>
<td>Bilateral</td>
<td>9</td>
</tr>
<tr>
<td>Biopsy of lesion detected by MRI</td>
<td>41/65</td>
</tr>
<tr>
<td>Ultrasonography guided</td>
<td>25</td>
</tr>
<tr>
<td>Stereotactic</td>
<td>6</td>
</tr>
<tr>
<td>MRI guided</td>
<td>10</td>
</tr>
<tr>
<td>Pathologic biopsy findings</td>
<td></td>
</tr>
<tr>
<td>Malignancy</td>
<td>9/41</td>
</tr>
<tr>
<td>ADH or ALH</td>
<td>4/41</td>
</tr>
<tr>
<td>Benign</td>
<td>28/41</td>
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</tbody>
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Abbreviations: ADH, atypical ductal hyperplasia; ALH, atypical lobular hyperplasia; MRI, magnetic resonance imaging.

*All patients who received a follow-up mammogram underwent a follow-up ultrasonogram as well; however, if patients received a follow-up mammogram, they are listed only in the mammogram category and not in both the ultrasonogram and mammogram categories because the follow-up mammogram confirmed the MRI findings.

<table>
<thead>
<tr>
<th>Treatment Change</th>
<th>Change, No. (%)</th>
<th>Beneficial, No. (%)</th>
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<tbody>
<tr>
<td>Lumpectomy converted to mastectomy</td>
<td>10 (6.5)</td>
<td>8 (5.2)</td>
</tr>
<tr>
<td>Wider excision</td>
<td>21 (13.5)</td>
<td>5 (3.2)</td>
</tr>
<tr>
<td>Contralateral surgery</td>
<td>5 (4.5)</td>
<td>2 (1.3)</td>
</tr>
<tr>
<td>Total</td>
<td>36 (23.2)</td>
<td>15 (9.7)</td>
</tr>
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Abbreviation: MRI, magnetic resonance imaging.
management; however, multivariate analysis showed that patients with larger tumors were more likely to have a beneficial change in surgical management (odds ratio, 1.66; 95% confidence interval, 1.04-2.66).

The effect of our increasing experience with breast MRI during the 1-year course of the study was analyzed. Patients were divided into halves based on the date of initial breast MRI. Breast MRI led to a change in surgical management more frequently during the second half of the study (18.2% [16/88] vs 29.9% [20/67]; P = .08). The ability of breast MRI to prompt a beneficial change in surgical management improved as well (5.7% [5/88] vs 14.9% [10/67]; P = .05). No statistically significant change was found in the rate of recommendations for 6-month follow-up MRI (12.5% [11/88] vs 17.9% [12/67]; P = .49).

This study evaluated the impact of breast MRI on the surgical management of newly diagnosed breast cancers. Patients were treated by a strict protocol in which a single surgeon (K.P.B.) at a single institution assessed all patients before breast MRI. The timing of the MRI in the patient’s workup was standardized. The patient was then reevaluated by the surgeon to determine whether a change in surgical plan was merited. A total of 23.2% of women had a change in management, and that alteration was found to be beneficial in 41.7% of those patients on radiographic-pathologic correlation. Thus, 9.7% of women had a beneficial change in surgical management based on preoperative bilateral breast MRI. Therefore, 10 women must undergo a breast MRI for 1 to have a beneficial change in management.

Prior studies have attempted to retrospectively evaluate the effect of breast MRI on clinical management. Tillman et al10 found that the clinical management of 20% of patients changed with breast MRI; however, this change included the need for additional biopsies and changes in surgical management. Tillman and colleagues also attempted to quantify the benefit of the effect of MRI and found that 8% of those with a change in clinical management had a “strongly favorable effect” using a definition comparable to our definition of a beneficial change in surgical management. Bedrosian et al17 categorized the type of change in surgical management based on breast MRI and found that 4% underwent a wider excision, 5% underwent a separate lumpectomy, and 16.5% were upgraded from lumpectomy to mastectomy. However, these studies had multiple inconsistencies, including the failure to perform ultrasonography routinely, the timing of MRI with respect to surgery, the failure to perform bilateral MRI routinely, the instability of MRI technology owing to lengthy study periods, and the ultimate indication for breast MRI.

Numerous reports16,18,19 have also described the identification of previously undetected lesions in the contralateral breast using MRI in 3.8% to 5.0% of patients. Our rate of detection of a contralateral malignancy was 1.3%, which may be attributable to the routine use of mammography and ultrasonography before MRI in our study and at our institution. Our analysis differs from previous studies in that mammography and ultrasonography were performed exhaustively before the use of breast MRI. Breast ultrasonography has gained acceptance in the management of patients with breast cancer and has been shown to adequately assess tumor size and extent.20 Compared with prior studies, we had a lower rate of identifying previously undetected lesions with MRI. Therefore, the use of ultrasonography before MRI may detect lesions around the primary tumor, thus lowering the apparent yield of subsequent breast MRI.

Unfortunately, breast MRI also has a considerable false-positive rate and results in significant inconvenience and expense in the way of additional biopsies and imaging. In addition to patient anxiety about this additional workup, the costs of biopsies and additional MRIs are significant. Our study had an overall false-positive rate of 79.5% (58/73) in which MRI-detected lesions were ultimately benign. The biopsy false-negative rate was 78.0% (32/41). This is similar to the acceptable false-positive rate for stereotactic core biopsy based on screening mammography.21 Furthermore, 2 women were upgraded from lumpectomy to mastectomy who did not have a beneficial change in surgical management. Both of these women were borderline candidates for BCT, and they declined a biopsy of the area identified by MRI and chose to proceed with a mastectomy. On the final surgical pathologic report, the tumor size correlated with the size on mammography; thus, the MRI findings exaggerated the extent of the tumor, resulting in these women undergoing an unnecessary mastectomy.

The cost of MRI technology has been a significant limitation and deterrent in the routine use of breast MRI. Resistance on the part of insurance companies to cover the cost of the study has also restricted its use; however, the Centers for Medicare and Medicaid Services have broadened their list of indications for breast MRI to include “determination of the extent of disease in patients with known malignancy, prior to treatment (to assure confinement to 1 segment of the breast).”22 Furthermore, the reimbursement of breast MRI has been declining during the past 5 years. In 2006, the combined Medicare professional and hospital reimbursement for bilateral breast MRI (Current Procedural Terminology code 76094) was $1313.23 Cost-effectiveness must also consider follow-up imaging and potential biopsies based on the MRI findings; however, if the specificity of breast MRI continues to improve as it did between the first and second half of our study, these costs should continue to decrease. On the basis of our data, 10 women must undergo breast MRI to result in a benefit to 1 patient. Studies of prophylactic mastectomy in high-risk women have demonstrated a number needed to treat of 6 to avoid 1 case of cancer.24-26 Women with a newly diagnosed breast cancer must be considered high risk, and a number needed to treat of 10 is reasonable in our opinion.

Some argue that that MRI-detected lesions are not clinically relevant.27,28 Women undergoing lumpectomy should receive postoperative external beam radiation, resulting in irradiation of any small ipsilateral lesions that may be missed by mammography and ultrasonography. Thus, MRI may simply be detecting disease that is already being addressed by radiation and could not be detected before the use of MRI. In addition, women with breast cancer


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are aggressively screened with physical examinations and mammography to identify a recurrent or new primary cancer. As a result, a lesion in the contralateral breast that is otherwise undetected by the initial mammography and ultrasonography would be detected early because of these aggressive screening practices. Opponents of routine MRI use often dismiss the significance of MRI-detected 1- to 2-mm lesions as too small, which would theoretically be addressed with postoperative radiotherapy. However, if we believe that it is important to clear lumpectomy margins of microscopic disease to minimize the risk of local recurrence, it would follow that small foci detected on MRI also warrant identification and excision.

Use of MRI results in a beneficial change in surgical management in 9.7% of patients. This percentage is likely to increase with time as MRI technology progresses, the radiologists' experience improves, and the cost of MRI decreases. Additional malignancies are uncovered in 1 patient for every 10 who undergo MRI. These data suggest that breast MRI may have a role in the staging evaluation of newly diagnosed breast cancers.

Accepted for Publication: December 13, 2006.

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Author Contributions: Drs Bilimoria and Bethke had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. Study concept and design: Bilimoria and Bethke. Acquisition of data: Bilimoria and Cambic. Analysis and interpretation of data: Bilimoria and Bethke. Drafting of manuscript: Bilimoria, Hansen, and Bethke. Critical revision of the manuscript: Bilimoria, Cambic, Hansen, and Bethke. Statistical analysis: Bilimoria. Study supervision: Bethke.

Financial Disclosure: None reported.

Funding/Support: Dr Bilimoria is supported by a grant from the Goldberg Family Charitable Trust.

Previous Presentation: This study was presented at the 114th Annual Meeting of the Western Surgical Association; November 13, 2006; Los Cabos, Mexico. The discussions that follow this article are based on the originally submitted manuscript and not the revised manuscript.

Acknowledgment: We acknowledge Jacqueline Jeruss, MD, PhD, for her comments on the manuscript. We also appreciate the assistance of Holly Little, BS, and the Lynn Sage Comprehensive Breast Center Database staff for their help with data collection.

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14. Whelan TJ, Julian J, Wright J, Jadad AR, Levine ML. Does locoregional radia-
total mastectomy for the treatment of invasive breast cancer. With more than 20 years of follow-up, lumpectomy followed by radiotherapy for women with breast cancer continues to be appropriate therapy, provided that the margins of resection are tumor free and the cosmetic outcome is satisfactory. Likewise, the NSABP B-17 trial randomized women with noninvasive carcinoma to lumpectomy with or without radiotherapy and demonstrated a higher local recurrence rate without radiotherapy, but no difference in survival. These trials were initiated in an atmosphere of conflicting knowledge about the biology of breast cancer. Isolated nonrandomized studies showed that there were no significant differences in survival among the women treated with less invasive surgery, if followed by radiotherapy, when compared with more radical procedures. There was, however, knowledge that occult foci of breast cancer cells could be identified in quadrants away from the index lesion in autopsy and mastectomy specimens in 21% to 63% of cases. Despite this knowledge of more extensive multifocal and multicentric disease, local recurrence after breast conservation and radiotherapy was 14% in the NSABP B-06 trial, done in an era of less effective chemotherapies given only for node-positive disease. These data suggest that radiotherapy treats some occult disease and that perhaps some occult disease never manifests itself. Ipsilateral recurrence rates have further improved as the technology of standard low-cost breast imaging has improved, as our attention to and ability to assess margins have become more detailed, as chemotherapeutic regimens have improved, and patients have achieved greater response rates, and as more sophisticated radiotherapy treatment planning protocols have been instituted.

I am going to discuss 3 aspects of the study and ask 3 questions.

1. Breast conservation treatment has been recommended as the preferred treatment by the National Cancer Institute Consensus Conference since the early 1990s in appropriate candidates and according to patient preference. This recommendation was based on the results of randomized studies that enrolled women whose breast cancer had been assessed by standard mammographic imaging and clinical criteria. My first question is, Knowing the results of the NSABP B-06 trial and other similar randomized trials, that breast conserving surgery followed by radiotherapy results in similar survival and low in-breast recurrence and that MRI can detect occult malignant lesions in 10% to 54% of reported studies, what discussion did the authors undertake with patients about their choice to undergo MRI and how the findings on the MRI might affect local therapy in the absence of proven clinical trials? Should the findings of an MRI study now be considered a contraindication to breast conservation without randomized prospective data on the impact on in-breast recurrence? Is this not the same argument that was used in the 1970s by the naysayers for breast conservation and declare that studies of breast conservation were inappropriate?

2. In the manuscript, the authors proposed to test the hypothesis that the routine use of MRI can detect occult lesions that can alter surgical management and that this change in treatment is beneficial. The authors have provided an algorithm for the workup of a new breast cancer. In the center of the algorithm stands MRI evaluation, which dominates the decision tree. In fact, the authors provide thorough, well-analyzed data obtained from a single team of physicians with state-of-the-art imaging and multidisciplinary discussion on the immediate impact of MRI in their patient population. The term the authors use to describe the outcome is beneficial or unnecessary. The authors’ definition of beneficial changes is when the pathology results correlate with MRI findings. As clinicians, the term beneficial should have a broader meaning than correlation of breast pathology with MRIs. It is easy to forget that MRI workup of the ipsilateral breast is unlikely to improve survival. The purpose of the MRI evaluation is to change treatment for the few patients who are destined to have in-breast recurrence and require mastectomy at a later date. More than half of the women in this study underwent a change in surgical management that could be described as “unnecessary.” The MRI data lead to 2 unnecessary ipsilateral mastectomies and 3 unnecessary contralateral prophylactic mastectomies based on MRI findings. This is a high price to pay for preventing a mastectomy at a later date for perhaps 9% of the breast conservation patients treated with current therapies. My second question is, Have the “beneficial” and “problematic” results of the authors’ experience with the use of MRI on all patients diagnosed as having breast cancer altered their use, interpretation, and patient involvement in the decision-making process to even order an MRI been modified? Have the authors instituted quality-of-life questionnaires for women going through these repeat diagnostic studies and for those who have had an undesired change in treatment?

3. Securing clear surgical margins affects local recurrence, but there is not a uniform agreement on what constitutes a negative margin. Planned surgical resection is based on clinical and image-detected findings. The authors suggest that MRI can define extent of disease and delineate the area of resection. My third question: How often did the authors have to go back to reexcise positive margins in the patients evaluated with MRI compared with their previous experience without MRI? Magnetic resonance imaging is a highly sensitive technique with high sensitivity for problems in a surgical margin. Patients have been given unnecessary partial mastectomies and extra biopsies unnecessarily. It can be heard in some surgical circles that all the great surgical questions have been answered in breast cancer. I challenge the authors to continue to be in the forefront of this area of surgical research and design a trial with colleagues in radiation oncology, pathology, and breast imaging that can provide hard data on the role of MRI in selecting the few patients who are not candidates for breast conservation and perhaps define a role for MRI in selecting patients who are good candidates for only partial breast irradiation or no breast radiotherapy at all.

I would also compliment the program committee for selecting this topic and identifying this subject as a critical issue for surgeons to understand, whether to incorporate the use of MRI into practice without randomized prospective data or to challenge the push by our colleagues in breast imaging to change 30 years of breast cancer treatment found on the principles of clinical trial data.

Dr Bethke: The first question was, Should MRI findings be a contraindication to BCT? If the MRI showed additional suspicious findings in our study patients, and a subsequent biopsy confirmed more extensive malignancy than that seen on traditional breast imaging, we proceeded to a mastectomy if a standard lumpectomy or quadrantectomy was no longer possible. As breast surgeons we spend a lot of time and effort clearing margins of microscopic disease, and occasionally we will perform multiple reexcisions on a patient who is very keen on breast conservation. If we feel that it is important to clear the breast of microscopic disease, then it would follow that it is also important to clear the breast of macroscopic disease. The initial NSABP studies had local recurrence rates of 12% to 15%. We now have local recurrence rates of 3% or less. Presumably our aggressive approach to clearing the breast of residual disease plays a role in these improved results. More recently, some would argue that this improved local control translates into a modest improved survival. Most everyone would agree that our goal is to surgically remove as much of the cancer from the breast as possible prior to radiation, using safe, efficient, and cost-effective methods. Magnetic resonance imaging is not yet at the level of usefulness we desire but will continue to evolve and improve.

The second question was, Have our indications for preoperative breast MRI changed based on the results of this study?
Yes. During the study period, nearly everyone with a newly diagnosed breast cancer received a preoperative breast MRI. Our current indications are to perform MRI on patients younger than 40 years or on those whom our radiologists indicate have dense breasts. Patients with multifocal breast cancer involving an entire quadrant are evaluated with MRI to rule out multicentric disease, which would then require a mastectomy. We will also obtain an MRI on women with invasive lobular cancer and patients presenting with occult breast cancer manifested by nodal metastases in the absence of mammographic or sonographic abnormalities. We have not instituted a quality-of-life survey for these patients, but I’m sure it would show a fair amount of anxiety related to MRI’s relatively low specificity and the need for additional testing.

The last question was, What was our margin reexcision rate? Our overall reexcision rate for the entire group of 155 patients was 15.0%. For those patients in whom MRI changed management, the reexcision rate was 28%, and in those in whom it did not change management, 13%. The higher rate of reexcision in those whom MRI changed management probably reflects the more extensive nature of the malignancy and the fact that it was not seen on an ultrasonogram or mammogram, making localization difficult. We do not have an accurate estimate for the reexcision rate before our MRI study, but anecdotally MRI did not appear to lower our overall rate.

Alden H. Harken, MD, Oakland, Calif: I think we tend to look at screening tests by virtue of their sensitivity and specificity. As we do so, I can understand how you can detect more breast cancer, or any kind of cancer, if you add more tests, so I look at the basic biology of breast disease and then the mechanism by which each additional testing technique asks the question. X-rays are actually testing for radiodensity, MRI testing examines some kind of polar molecule like water (or how the hydrogen atom “precesses”), positron emission tomographic scanning assesses how cells use glucose, and maybe ultrasonography explores how sonar dense the cells are. Is there something fundamental about breast cancer, the biology of breast cancer, that would make it uniquely visible by any one of these tests, or are you just adding more tests to increase sensitivity at the expense of specificity and cost?

Dr Bethke: Our current breast imaging techniques, mammography, ultrasonography, and MRI, are not specific for breast cancer because they detect density differences (mammogram and ultrasonography) or changes in vasculature (MRI). Thus, they have difficulty differentiating many benign from malignant changes.

We did this study because we were frustrated by the lack of guidelines for the use of breast MRI. Like you, we were concerned about its low specificity. We had hoped to develop clearer indications for MRI in the evaluation of newly diagnosed breast cancers; however, the only statistically significant predictor of a beneficial change in management was pathologic size, which isn’t clinically useful because it is determined after excision. We are hopeful that breast MRI specificity will continue to improve as equipment and software improve. We were encouraged by the significant improvement in beneficial change noted between the first and second half of the study.

Jose M. Velasco, MD, Skokie, Ill: I believe there are 2 points worth being highlighted: one was, who should have an MRI; and two, once an MRI is obtained, what should we do with the results? I would like to say that we should evaluate the role of MRI in the management of patients with breast disease, instead of just evaluating the role of breast MRI in the surgical management of these patients. In other words, do you think MRI could have a role in identifying patients who may have T2 or T3 lesions? Those patients could benefit from neoadjuvant therapy and thus be eligible for breast-preserving operations. Therefore, one could avoid mastectomy. Did you look at that?

Along those lines, is there a controversy of the role, if any, of MRI for evaluating lymph node status? Is there any known correlation? Did you identify sentinel nodes on those patients?

Finally, what criteria did you use to discern and identify the group of patients who needed a biopsy? Were they only those patients in whom the MRI, ultrasonogram, and mammogram identified positive lesions, or did you perform biopsies on all of them using MRI-guided biopsy?

Dr Bethke: You asked if there might be a role for using MRI to direct breast cancer chemotherapy. The 11 patients who received a breast MRI and underwent neoadjuvant chemotherapy were excluded from our study because of the small number of patients and inconsistencies in their management. Magnetic resonance imaging has the potential to be helpful in following chemotherapy response, but at this time the poor specificity and high cost prohibit its routine use for this purpose. Alternatively, I believe that it may play a future role in optimizing patient selection for partial breast radiation by ruling out multicentricity.

We did not use MRI to evaluate lymph nodes in our study, and there is no literature to support its use for this purpose. Sentinel lymph node biopsy was used to evaluate nodes.

If a lesion was considered suspicious on MRI, a follow-up focused ultrasonogram was used to further evaluate the lesion. If it was visible on the ultrasonogram, an ultrasonography-guided core biopsy was performed. If it was considered suspicious and not seen on the ultrasonogram, an MRI-guided core biopsy was performed.

Financial Disclosure: None reported.