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ORIGINAL ARTICLE

Correlation of Pathologic and Radiologic Complete Response in the Axilla after Neoadjuvant Chemotherapy for Breast Cancer

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Abstract

Aim: Accurate assessment of locoregional response to neoadjuvant chemotherapy (NAC) is important for surgical planning, particularly in regard to management of the axilla. We evaluated the correlation between radiologic complete response (rCR) in the axilla on magnetic resonance imaging (MRI) and the likelihood of pathologic complete response (pCR) at the time of breast cancer surgery following NAC.

Methods: Our institutional database was queried for patients who underwent NAC from 2010-2016 and had a pre- and post-NAC MRI performed. Clinicopathologic characteristics and MRI findings were recorded and correlated with surgical pathology results. Sensitivity, specificity, predictive values and descriptive statistics were performed.

Results: Of 54 patients identified, 48 (88.9%) had suspicious or positive nodes on pretreatment MRI. Among 41 patients with a pretreatment axillary biopsy, 34 (62.9%) had positive nodes. After treatment, rCR was seen in the breast and axilla in 18.5% and pCR was found in 33.3%. The positive predictive value (PPV) of rCR on MRI was 50%, while negative predictive value (NPV) was 70.5%.

Conclusion: MRI had a PPV of only 50% for a complete response in the axillary nodes. Even in the presence of rCR, surgeons must have a high level of suspicion for residual nodal disease after NAC. We conclude that MRI findings are insufficient to determine the extent of axillary surgery after NAC.

Keywords

Breast cancer, Neoadjuvant chemotherapy, MRI

Abbreviations

ALND: Axillary Lymph Node Dissection; DCIS: Ductal Carcinoma *In Situ*; IRB: Institutional Review Board; MRI: Magnetic Resonance Imaging; NPV: Negative Predictive Value; NAC: Neoadjuvant Chemotherapy; pCR: Pathologic Complete Response; PPV: Positive Predictive Value; rCR: Radiologic Complete Response

Background

Neoadjuvant chemotherapy (NAC) is a critical component of treatment for locally advanced breast cancer and high-risk patients with stage II disease [1]. NAC allows for the assessment of *in vivo* tumor response to treatment and prioritizes systemic treatment in patients at risk for metastatic spread. It also has the potential to downstage the cancer and influence surgical management, either by making the patient a candidate for breast conservation, or by enabling avoidance of complete axillary dissection [2]. Patients who receive NAC may achieve pathologic complete response (pCR), having no evidence of invasive or *in situ* cancer on pathologic examination of the surgical specimen [3]. Studies have shown that the likelihood of achieving a pCR varies by breast cancer subtype and the chemotherapy regimen given [3-5]. The achievement of pCR is predictive of a more favorable outcome for the patient [1,2].

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Accurate prediction of pCR in patients after NAC is challenging. The standard imaging modality to assess response is magnetic resonance imaging (MRI). Breast MRI is used to evaluate response in both the breast and axilla and is the most sensitive and specific modality in comparison to ultrasound, mammography, and physical exam [6-8]. However, MRI has been found to either overestimate or underestimate response to treatment in many cases, and a radiologic complete response (rCR) does not always correlate with a true pCR [8]. MRI accuracy has also been found to vary with tumor biology [9-12]. At this time, the literature suggests that MRI demonstrating rCR cannot completely replace surgical excision and pathologic evaluation of the breast [13]. Data for MRI evaluation of the axilla and ability to accurately predict pCR in the axillary nodes are also mixed [2,13]. As trends in management of the axilla shift towards limiting surgery, in an attempt to avoid the morbidity associated with axillary lymph node dissection (ALND), an understanding of the strengths and weaknesses of MRI as a modality for assessing the axilla after chemotherapy is critically important. In this study, we sought to examine our own institutional experience with rCR by MRI as a predictor of pCR, with specific attention to the axilla.

Methods

After Institutional Review Board (IRB) review, we queried our prospectively maintained institutional database for women who underwent neoadjuvant chemotherapy between 2010-2016. Records were reviewed for the presence of MRI images and/or reports. Patients were required to have an MRI from both before and after neoadjuvant chemotherapy to be included in the study. The study radiologist (LM) reviewed the reports for missing information, specifically pertaining to nodal status and characteristics, and provided this information where needed. We defined "positive" nodes as any MRI report with descriptors such as "enlarged", "suspicious" or "abnormal" or patients with pathologically confirmed positive nodes by pre-treatment biopsy.

A radiologic complete response was defined as no further evidence of a discrete mass or suspicious enhancement in the breast, and resolution of abnormal features in the axillary lymph nodes. A pathologic complete response was defined as no residual *in-situ* or invasive tumor in the breast or axillary nodes. Clinicopathologic characteristics were recorded for each patient. Sensitivity, specificity, and predictive values were calculated according to standard procedures, and descriptive statistics were performed.

MRI technique

All breast MRI examinations were performed on a 3.0-T (TIM Trio, Siemens Medical Solutions) with the patient in prone positioning using a dedicated surface breast coil (7-Channel Breast Biopsy Array, *in vivo* Research, Gainesville, FL). Our standard imaging protocol covers the breasts bilaterally and includes a localizing sequence followed by a sagittal T2-weighted sequence (repetition time, 7220; echo time, 84) and a sagittal T1-weighted non-fat-suppressed three-dimensional fast spoiled gradient-recalled echo sequence (repetition time, 4.01; echo time, 1.52; flip angle, 12°; matrix, 384 × 384; field of view, 270 mm; and section thickness, 1 mm). This procedure was followed by the same sagittal T1-weighted fat-suppressed three-dimensional fast spoiled gradient-recalled echo sequence performed before and four times after a rapid bolus injection of 0.1 mmol/kg of gadopentetate dimeglumine (Magnevist, Bayer Healthcare Pharmaceuticals) per kilogram of body weight at an injection rate of 2.0 mL/s via an intravenous catheter, followed by a saline flush. The first contrast-enhanced dynamic image corresponded to 100 seconds after injection. The total duration of the dynamic study was approximately 7 minutes. After the examination, subtraction images were obtained by subtraction of the precontrast images from the first contrast-enhanced image on a pixel-by-pixel basis.

MRI interpretation

A single blinded radiologist with 17 years of experience interpreting breast MRI examinations retrospectively reviewed the breast MRI. Tumor extent, morphology, and relative enhancement were assessed during initial and late enhancement at baseline MRI and at MRI after completion of NAC. The extent of each tumor was assessed by its largest diameter in three reformatted planes (sagittal, axial, and coronal) at initial and late enhancements. The presence of suspicious axillary lymph nodes was defined as abnormal enhancing lymph nodes, loss of the fatty hilum, enlarged lymph nodes with loss of fatty hilum. These MRI results were correlated with pathology.

Results

We identified fifty-four patients undergoing treatment between January 2011 and December 2016 who met the study criteria. The median age at diagnosis was 48 years (range 29-79 years). There were 48 (88.9%) women who had positive nodes by pre-treatment MRI. Forty-one women in our cohort underwent a pre-treatment axillary nodal biopsy, and thirty-four (62.9%) of these biopsies revealed metastatic disease. The pre-treatment stage was II and above in 96.3% of patients. There were 26.1% of patients who had a triple negative phenotype and 50% were HER2 enriched. After neoadjuvant chemotherapy, 13 patients (24.1%) achieved a radiologic complete response in the breast on their follow up MRI, and 10 (18.5%) achieved rCR in the breast and axilla. Among those achieving rCR in the breast and axilla 80% were HER2+, and a further 20% were triple-negative. Seventeen patients (31.5%) in the total cohort

underwent breast conserving surgery while the remaining 37 (68.5%) underwent mastectomy. Thirteen patients (24.1%) underwent sentinel lymph node biopsy alone, 15 (27.8%) had completion ALND, and 26 (48.1%) underwent up front ALND. Pathologic complete response was achieved in 18 patients (33.3%). Among those achieving pCR, 70.6% were HER2+ and 23.5% were triple-negative (Table 1). The positive

Table 1: Clinicopathologic variables.

Variable	Outcome (n = 54)
Age at diagnosis, years (median; range)	48 (29-79)
Tumor size prior to treatment, cm (median; range)	2.9 (0-13)
Tumor size post treatment, cm (median; range)	0.3 (0-9.9)
Pre-treatment MRI	
Negative nodes	6 (11.1%)
Positive (enlarged/suspicious/abnormal) nodes	48 (88.9%)
Post-treatment MRI	
Negative nodes	51 (94.4%)
Positive (enlarged/suspicious/abnormal) nodes	3 (5.6%)
Pre-treatment Axillary Biopsy	
None	13 (24.1%)
Negative	7 (13.0%)
Positive	34 (62.9%)
Pre-treatment Stage	
I	2 (3.7%)
II	30 (55.6%)
III	22 (40.7%)
Final Pathology Stage	
No residual carcinoma	18 (33.3%)
0	6 (11.1%)
I	8 (14.8%)
II	13 (24.1%)
III	9 (16.7%)
Breast surgery	
Breast conserving surgery	17 (31.5%)
Mastectomy	37 (68.5%)
Axillary surgery	
SLND	13 (24.1%)
SLND + ALND	15 (27.8%)
ALND	26 (48.1%)
Receptor status	
ER+/PR+/HER2-	11 (23.9%)
ER+/PR+/HER2+	8 (17.4%)
ER-/PR-/HER2+	15 (32.6%)
ER-/PR-/HER2-	12 (26.1%)
Radiologic complete response (rCR) for breast only	13 (24.1%)
Receptor status of patients with rCR for breast only	
ER+/PR+/HER2-	1 (8.3%)
ER+/PR+/HER2+	4 (33.3%)
ER-/PR-/HER2+	5 (41.7%)
ER-/PR-/HER2-	2 (16.7%)

Radiologic complete response (rCR) for breast & axilla	10 (18.5%)
Receptor status of patients with rCR for breast & axilla	
ER+/PR+/HER2-	0 (0.0%)
ER+/PR+/HER2+	3 (30.0%)
ER-/PR-/HER2+	5 (50.0%)
ER-/PR-/HER2-	2 (20.0%)
Pathologic complete response (pCR)	18 (33.3%)
Receptor status of patients with pCR	
ER+/PR+/HER2-	1 (5.9%)
ER+/PR+/HER2+	4 (23.5%)
ER-/PR-/HER2+	8 (47.1%)
ER-/PR-/HER2-	4 (23.5%)

Table 2: Post-treatment imaging and pathology findings.

Radiologic complete response (rCR) for breast only†	**pCR**	**No pCR**
Breast imaging findings		
rCR	7 (53.8%)*	6 (46.2%)
No rCR	11 (26.8%)	30 (73.2%)**
Radiologic complete response (rCR) for breast & axilla††	**pCR**	**No pCR**
Breast and axilla imaging findings		
rCR	5 (50.0%)*	5 (50.0%)
No rCR	13 (29.5%)	31 (70.5%)**
*Positive Predictive Value (PPV); **Negative Predictive Value (NPV).		
†Sensitivity = 38.9%, Specificity = 83.3%		
††Sensitivity = 27.8%, Specificity = 86.1%		

Table 3: Overall radiological burden and axillary status.

	Post-treatment Pathologic Negative Axillary Nodes	**Post-treatment Pathologic Positive Axillary Nodes**
Post-treatment Radiological Axillary Node Change		
Stable	6 (18.7%)	3 (13.6%)
Decreased	21 (41.2%)	1 (33.3%)
Resolved	23 (45.1%)	0 (0.0%)

predictive value (PPV) of rCR in the breast and axilla on MRI was 50%, while negative predictive value (NPV) was 70.5% (Table 2). Patients with resolved axillary nodal disease by MRI had a 36.4% chance of having positive nodes at the time of surgery (Table 3).

Discussion

MRI is widely used for the pretreatment assessment of patients undergoing neoadjuvant chemotherapy for treatment of breast cancer. In particular, MRI is used to describe the extent of disease at the time of diagnosis and comparison of pre and post-treatment studies is critical for objective assessment of response to therapy. Accurate preoperative determination of the status of the axilla is important for surgical planning. MRI imaging is recognized as the best modality for evaluating the breast post-chemotherapy and has been shown to have the best overall agreement with physical exam and final pathology [8,13,14]. Contrast-enhanced MRI has a greater accuracy than ultrasound (US) and mammography for identifying residual disease [2,15,16]. However, MRI also has limitations, including an imperfect ability to visualize the axilla completely in some patients, due to factors such as positioning or body habitus [7,17]. Post-treatment, patients may also have interruption or blockage of the lymphatic pathways by fibrosis, which may change the appearance of the nodes on contrast-enhanced MRI [6]. In addition, changed vascularity in the breast and axilla may alter the appearance of contrast flow and decrease the ability of the imaging to accurately reflect the nodal status [6]. Other confounding factors that have been proposed include inflammation due to tumor response to che-

motherapy, the presence of multiple lesions, and the presence of extensive ductal carcinoma *in situ* (DCIS), which may cause over or under estimation of tumor extent on imaging [16]. In a meta-analysis of studies of MRI in the neoadjuvant population, Gu, et al. found that diffusion weighted MRI had a pooled sensitivity of 0.93 and specificity of 0.85 compared to standard contrast enhanced MRI which had a sensitivity of 0.64 and specificity of 0.92 [15,16]. However, despite the accuracy of diffusion weighted MRI, especially for axillary imaging, it remains investigational and is not standard of care at this time.

Studies of rCR and pCR in the axilla on MRI are also limited by a lack of standardized definitions for what constitutes an abnormal node on imaging, as well as variable definitions of what is a pCR in the breast [14,15]. Some studies define pCR as resolution of invasive disease, but allow for residual *in-situ* disease at final pathology, others define pCR as absence of any disease in the breast, but allow for pathologically positive lymph node involvement [9]. For our analysis, we defined pCR by the strictest criteria, to include resolution of all disease in both the breast and axilla. We also chose to present both rCR and pCR in the breast alone compared to breast and axilla, in order to highlight this important distinction.

In our study, the majority of patients had a good response to neoadjuvant chemotherapy, with a significant number of patients becoming down-staged from pre-treatment clinical stage to final pathologic stage. In addition, 33.3% of patients achieved a pCR. This is in line with previously published results [7,13,17,18]. Only 18.5% of patients in our study demonstrated a radiologic complete response. The positive predictive value of rCR in the breast and axilla for a corresponding pCR was 50%, while the negative predictive value for residual disease on imaging and a corresponding residual disease at final pathology was 70.5%. De Los Santos, et al. have reported a PPV of 47% and NPV of 83% and 74% accuracy, while Hieken, et al. have noted accuracy of imaging in predicting pCR at 60-72% and Weber, et al. noted a PPV of 63.4% and NPV of 84.1%, all of which are comparable to our results [7,11,13]. In a systematic review of the utility of MRI in the neoadjuvant population, Lobbes, et al. found that median PPV and NPV among 25 studies was 64% and 87% for MRI [16]. All of these studies confirm that while MRI is a powerful tool for the assessment of breast cancer patients, it is still somewhat lacking when it comes to assessing response to chemotherapy.

Of patients with pathologically negative axillary nodes in our study, 46.9% had demonstrated "resolved" axillary nodal abnormality by post-treatment MRI (nodal pCR). However, among those with positive nodes at final pathology, 36.4% were among the group with "resolved" axillary lymph nodes on MRI prior to surgery. Our findings demonstrate that the ability of MRI to accurately predict pCR in the axilla after neoadjuvant chemotherapy is still lacking. Similar findings have been reported by other authors, including Weber, et al. who noted a PPV of 66.7% and NPV of 65.6% for nodal rCR and pCR comparisons [13,17]. Mamtani, et al. noted a nodal pCR of 49%, which is also similar to our findings [19]. Dialani, et al. reported persistently positive axillary nodes in 16-41% of patients undergoing NAC for locally advanced breast cancer [20]. Conversely, Javid, et al. noted a 92% positive predictive value and 80.9% negative predictive value of MRI for prediction of axillary nodal status [14].

Patients with either HER2+ or triple-negative receptor status were significantly more likely to exhibit rCR or pCR in our study. This is also in line with previous reports [2,11,13]. Patients with the poorest prognostic factors tend to have the most benefit from neoadjuvant chemotherapy, and may be the most likely to achieve pCR [3]. Cancer subtypes have also been noted to influence MRI accuracy, with multiple authors reporting either the best accuracy or the best NPV in patients who are triple negative and/or HER2 positive compared to other subtypes [2,11,13,20].

While sentinel node biopsy alone is the accepted standard of care for clinically node negative patients, management of patients who are clinically node positive and undertake neoadjuvant chemotherapy is more complicated. Several studies have attempted to address management of the post-neoadjuvant axilla, and specifically the option to avoid complete axillary dissection in patients with a clinically negative axilla prior to surgery. The ability to successfully perform sentinel node biopsy after neoadjuvant chemotherapy was examined in the ACOSOG Z1071 trial. The investigators noted a nodal pCR of 41%, similar to our findings. The axilla was examined with physical exam and ultrasound after the completion of chemotherapy. They found a false negative rate of 12.6% for sentinel node biopsy in the post-neoadjuvant setting. The false negative rate was reduced by using dual mapping and taking at least two lymph nodes in the sentinel node biopsy [18]. In the SENTINA study, which also examined sentinel node biopsy in patients after neoadjuvant treatment, in patients who converted from node positive before chemotherapy to node negative, the false negative rate was 14.2%, and node detection rate was 80.1%, in comparison to a detection rate of 99.1% for patients who underwent sentinel node biopsy prior to chemotherapy [21]. The axilla in this study was examined with ultrasound only, and the investigators found an improved yield with dual mapping and removal of at least two sentinel nodes. These findings were confirmed by Mamtani, et al. who found that in patients who were clin-

ically node negative after NAC, retrieval of three or more sentinel nodes was possible in 86% of patients. All of the patients with three pathologically negative SLN were spared an ALND, and the ability of SLNB to adequately stage the axilla was reliable in this setting [19]. It is accepted that patients with biopsy proven metastatic nodes that remain persistently abnormal after chemotherapy should be managed with axillary lymph node dissection. However, the management of patients with abnormal nodes that appear to have resolved on post-chemotherapy imaging is more challenging given the lack of accuracy in relying on MRI to consistently predict the pathologic status of the nodes. Postoperatively, the pathologic status of the axilla is important for planning further adjuvant treatment, including radiation therapy. In addition, the status of the axilla is an important prognostic factor for potential recurrence as well as the likelihood of disease-free survival and overall survival [7,13]. However, in order to limit the extent of axillary surgery while providing accurate information, a significantly higher PPV by MRI would be required. Until the accuracy of our current imaging modalities improves, surgical staging will continue to be required for reliable assessment of the presence or absence of residual disease.

Our study is limited by its retrospective nature and relatively small sample size. Additionally, not all imaging studies were carried out at our institution, which introduces the potential for discrepancies in the imaging acquisition methodology used at different clinical sites.

Conclusions

In our study, MRI had a PPV of only 50% for a complete response in the breast and axilla. Even in the presence of rCR, surgeons must have a high level of suspicion for residual nodal disease after NAC. We conclude that MRI findings are currently insufficient to determine the extent of axillary surgery after NAC.

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