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ORIGINAL ARTICLE – BREAST ONCOLOGY

Is Clinical Exam of the Axilla Sufficient to Select Node-Positive Patients Who Downstage After NAC for SLNB? A Comparison of the Accuracy of Clinical Exam Versus MRI

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ABSTRACT

Background. The National Comprehensive Cancer Network (NCCN) endorses sentinel lymph node biopsy (SLNB) in patients with clinically positive axillary nodes who downstage after neoadjuvant chemotherapy (NAC). In this study, we compared the accuracy of post-NAC MRI to clinical exam alone in predicting pathologic status of sentinel lymph nodes in cN1 patients.

Methods. We identified patients with T0-3, N1 breast cancer who underwent NAC and subsequent SLNB from March 2014 to July 2017. Patients were grouped based on whether a post-NAC MRI was done. MRI accuracy in predicting SLN status was assessed versus clinical exam alone.

Results. A total of 450 patients met initial study criteria; 269 were analyzed after excluding patients without biopsy-confirmed nodal disease, palpable disease after NAC, and failed SLN mapping. Median age was 49 years. Post-NAC MRI was done in 68% (182/269). Patients undergoing lumpectomy vs mastectomy more frequently received a post-NAC MRI (88 vs 54%, $p < 0.001$). All other clinicopathologic parameters were comparable between those who did and did not have a post-NAC MRI. Thirty percent (55/182) had abnormal lymph nodes on MRI. Among these, 58% (32/55) had a positive SLN on final pathology versus 42% (53/127) of patients with no abnormal lymph nodes on MRI and 52% (45/87) of patients who had clinical exam alone ($p = 0.09$). MRI sensitivity was 38%, specificity was 76%, and overall SLN status prediction accuracy was 58%.

Conclusions. Post-NAC MRI is no more accurate than clinical exam alone in predicting SLN pathology in patients presenting with cN1 disease. Abnormal lymph nodes on MRI should not preclude SLNB.

Historically, all patients with clinically positive axillary lymph nodes treated with neoadjuvant chemotherapy (NAC) had an axillary dissection, regardless of treatment response. A high rate of nodal pathologic complete response after NAC led to clinical trials examining the feasibility and accuracy of sentinel lymph node biopsy (SLNB) in node-positive patients who downstage following NAC.[1] These trials demonstrated that the false-negative rate of SLNB was less than 10% for patients who were node-positive at presentation and had retrieval of three or more sentinel nodes after NAC.[2–4] SLNB in clinically node-positive patients who downstage following NAC is now endorsed by National Comprehensive Cancer Network (NCCN) guidelines.[5] However, the optimal method to select patients for axillary staging with SLNB after NAC is unclear, and practice is variable. In patients with palpable disease on clinical exam after neoadjuvant chemotherapy, the sentinel node biopsy procedure is inappropriate, because it has a false-negative rate of 19.2%.[3] Prospective trials also have shown that palpable disease on clinical exam after NAC has a positive predictive value of 65–89%

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for the presence of residual axillary disease.[4,6] In a previous study from our institution, we also found that among cN1 patients with palpable axillary disease after NAC who underwent axillary dissection, 78% had positive nodes on final pathology.[7] These data support axillary dissection as the appropriate procedure for patients with palpable disease on clinical exam after NAC. Among patients with a negative axillary clinical exam, approximately 47% will have residual nodal disease.[6,7] Although evidence supporting evaluation beyond a clinical exam of the axilla for selection for SLNB is limited, clinical exam combined with axillary imaging has been proposed.[5] MRI has been shown to be the most sensitive imaging modality for assessing residual disease in the breast following NAC and is widely utilized to assess treatment response after NAC.[8,9] In patients with a negative clinical exam, the finding of abnormal-appearing lymph nodes on post-NAC MRI may prompt further workup or lead to axillary dissection. The purpose of this study was to assess the accuracy of clinical exam alone compared with clinical exam combined with MRI in determining the status of axillary sentinel lymph nodes in cN1 patients who have a negative axillary clinical exam following NAC.

METHODS

Upon approval of the Memorial Sloan Kettering Cancer Center Institutional Review Board, we identified patients with clinical T0-3 N1 breast cancer who underwent NAC followed by SLNB between March 2014 and July 2017 from a prospectively maintained NAC database. Demographic, clinicopathologic, and treatment data were retrieved. SLNB in cN1 patients with a negative axillary clinical exam after NAC, without additional axillary imaging, was implemented in 2014. Patients being considered for breast conservation routinely undergo a post-NAC MRI, and in patients electing mastectomy, MRI is performed at the surgeon's discretion. The decision to proceed with SLNB is not changed based on MRI findings. This uniform practice among our surgeons has provided an opportunity to examine the accuracy of MRI in predicting the presence of positive sentinel nodes among a group of patients with known lymph node involvement prior to NAC and a negative axillary clinical exam after treatment. We excluded patients who did not have pathologic confirmation of positive lymph nodes by fine-needle aspiration or core biopsy before NAC, patients who had palpable disease on clinical exam after NAC, and those who had failed sentinel node mapping. The remaining patients were then stratified based upon whether a post-NAC MRI was performed.

A single expert reviewer with 25 years of experience in interpreting breast MRI, who was blinded to the final sentinel node pathology, reviewed post-NAC MRIs for abnormal-appearing lymph nodes. Axillary lymph nodes were considered abnormal on MRI if they had a thickened or irregular cortex (> 4 mm), appeared rounded, or had loss of a fatty hilum. Sentinel lymph nodes were assessed for metastatic disease initially by frozen section, and later confirmed by hematoxylin and eosin stains. Immunohistochemical staining was used only in cases in which a definitive diagnosis could not be made from frozen section or hematoxylin and eosin staining. Sentinel nodes with tumor metastasis of any size, including isolated tumor cells, were considered positive.

MRI accuracy in predicting SLN status was assessed and compared to clinical exam alone. Continuous measures were summarized using the median and range, and categorical measures were summarized using the frequency and percent. The Wilcoxon rank-sum test and Fisher's exact test were used to compare continuous and categorical variables, respectively, according to whether or not a post-NAC MRI was done. Similarly, the Wilcoxon rank-sum test and Fisher's exact test were used to compare continuous and categorical variables, respectively, according to the resulting post-NAC MRI status (post-NAC MRI not done versus positive post-NAC MRI versus negative post-NAC MRI). The sensitivity, specificity, positive predictive value, negative predictive value, and accuracy of MRI for predicting the sentinel lymph node status were calculated. We hypothesized that patients with a higher BMI might have a less-accurate clinical exam and therefore also looked at whether MRI findings differed based on higher versus lower BMI. Patients were stratified based on body mass index (BMI) ≥ 30 or < 30, and the interaction of BMI and MRI finding with respect to final sentinel node pathology was examined. A p value < 0.05 was considered statistically significant. All statistical analyses were conducted using R software version 3.4.4 (R Core Development Team, Vienna, Austria).

RESULTS

A total of 450 patients met our initial study criteria. After excluding patients without biopsy confirmation of a positive node before chemotherapy, patients with palpable disease after NAC, and those with failed sentinel node mapping, our cohort comprised 269 patients. Median patient age was 49 years (range 24–82), and median BMI was 25.8 (range 16.9–48.4). Most tumors were of ductal histology (94%) and classified as high grade (90%). HER2 was overexpressed in 37% of tumors, and 26% were triple negative. Following NAC, 32% (87/269) of patients had

clinical exam alone, and 68% (182/269) had clinical exam and MRI. Patients undergoing lumpectomy versus mastectomy more frequently had a post-NAC MRI (88 vs 54%, $p < 0.001$). Tumor histology, T stage, estrogen receptor status, progesterone receptor status, HER2 status, number of sentinel nodes removed, and number of positive sentinel nodes were comparable between groups (Table 1).

Among those patients who had a post-NAC MRI, 30% (55/182) had abnormal-appearing lymph nodes on MRI. Of 55 patients with abnormal lymph nodes on MRI, 32 (58%) had a positive sentinel node on final pathology compared with 42% (53/127) of patients with no abnormal lymph nodes on MRI. Among patients who had clinical exam alone, 52% (45/87) had a positive sentinel node on final pathology (Fig. 1). There was no difference in the frequency of positive sentinel nodes on final pathology based on whether patients had clinical exam alone, a positive MRI finding, or a negative MRI finding ($p = 0.09$). Comparable proportions of patients among the three groups had BMI ≥ 30, 71% of patients undergoing clinical exam alone, 76% with a positive MRI finding, and 76% with a negative MRI finding ($p = 0.6$). There was no significant interaction effect between BMI and MRI findings with respect to sentinel node status ($p = 0.12$).

We examined measures of accuracy of MRI for predicting the pathologic status of the sentinel node and found a sensitivity of 38% and a specificity of 76%. The overall accuracy of MRI in predicting the sentinel node status was 58%. Post-NAC MRI correctly predicted a positive sentinel node in 32 of 55 patients in whom an abnormal-appearing lymph node was seen on MRI, giving a positive predictive value for MRI of 58%. If an abnormal MRI finding had been used to triage patients to axillary dissection, then 23 of 55 (42%) patients with a suspicious MRI finding and negative final sentinel node pathology would have undergone an unnecessary axillary dissection.

We also looked at whether the addition of MRI response in the breast primary improved MRI prediction of SLN status and found that the highest frequency of having a positive sentinel node occurred when there was residual disease seen in both the breast and axillary nodes. Among patients with no residual disease on MRI in either the breast or lymph nodes, 28% had positive sentinel nodes compared with 37% with abnormal nodes only on MRI, 54% with residual disease in the breast only on MRI, and 71% with residual disease in both the breast and lymph nodes on MRI ($p < 0.001$). The accuracy of MRI in predicting the status of the sentinel node increased to 62% when there was residual disease seen in both the breast and axillary nodes. If this finding had been used to triage patients to axillary dissection, then 10 of 34 (30%) patients would have had an unnecessary axillary dissection.

TABLE 1 Clinicopathologic and treatment characteristics among patients undergoing Post-NAC MRI vs clinical exam alone

Variable	Clinical exam + MRI ($n = 182$)	Clinical exam only ($n = 87$)	p value
Age, median (range)	50 (24–77)	49 (28–82)	0.98
BMI, median (range)	26 (18–48)	26 (17–47)	0.36
Tumor type			0.2
IDC	174 (96%)	80 (92%)	
ILC	2 (1%)	4 (5%)	
Mixed/other	6 (3%)	3(3%)	
Histologic grade			0.2
1	1 (0.5%)	0 (0%)	
2	11 (6%)	10 (11%)	
3	168 (92%)	74 (85%)	
N/A	2 (1%)	3 (3%)	
LVI			0.63
Yes	78 (43%)	42 (48%)	
No	73 (40%)	30 (34%)	
Suspicious	8 (4%)	4 (5%)	
N/A	23 (13%)	11 (13%)	
Clinical T			0.47
Tis/x	1 (0.5%)	2 (2%)	
T1	31 (17%)	15 (17%)	
T2	109 (60%)	47 (54%)	
T3	41 (23%)	23 (26%)	
Subtype			0.14
ER+/HER2–	60 (33%)	40 (46%)	
ER+/HER2+	43 (24%)	14 (16%)	
ER–/HER2+	28 (15%)	15 (17%)	
ER–/HER2–	51 (28%)	18 (21%)	
NAC type			0.75
ACT based	175 (96%)	83 (95%)	
Other	7 (4%)	4 (5%)	
Type of surgery			< 0.001
Lumpectomy	98 (54%)	14 (16%)	
Mastectomy	84 (46%)	73 (84%)	
Number of SLNs removed, median, (range)	4 (1–13)	4 (0–14)	0.4
Sentinel node status			
Positive	85 (47%)	45 (52%)	0.5
Negative	97 (53%)	42 (48%)	

NAC neoadjuvant chemotherapy, *IDC* invasive ductal carcinoma, *ILC* invasive lobular carcinoma, *N/A* not available, *LVI* lymphovascular invasion, *ER* estrogen receptor, *ACT* doxorubicin plus cyclophosphamide followed by weekly paclitaxel, *SLN* sentinel lymph node

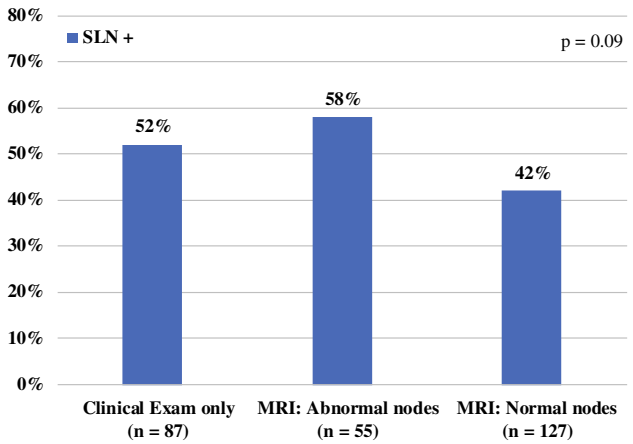

FIG. 1 Frequency of positive sentinel nodes in patients with clinical exam alone compared to positive or negative MRI findings. *SLN* sentinel lymph node

DISCUSSION

In this study, we found that the addition of MRI to a negative clinical exam was of limited utility in predicting the pathologic status of sentinel nodes after NAC, with an accuracy of 58% and the potential to result in an unnecessary axillary dissection in 42% of patients with a positive MRI finding. There is confusion regarding the appropriate method to assess the axilla after NAC and whether or not imaging studies are necessary to select patients as candidates for SLNB. In the four prospective trials examining the accuracy of SLNB in node-positive patients after NAC, selection criteria for axillary staging with SLNB was variable.[2–4,10] The American College of Surgeons Oncology Group (ACOSOG) Z1071 trial enrolled patients with pathologically confirmed N1 or N2 disease before chemotherapy, but did not exclude patients with residual clinically evident (by exam or ultrasound) disease after NAC from SLNB.[3] The SENTINA trial included patients with a positive axilla by clinical exam alone, but required a sonographically negative axilla before sentinel node biopsy (arm C). Patients with residual disease identified by palpation and ultrasound (arm D) underwent axillary dissection.[2] The SN FNAC study recorded axillary clinical exam and ultrasound findings before and after NAC; however, patients were not excluded from SLNB if they had palpable disease or abnormal lymph nodes on ultrasound.[4] The node-positive arm of the GANEA 2 study enrolled patients with T1-4, N1-2 disease, all of whom went on to SLNB.[10] Because there was no uniform selection criteria for SLNB in these trials, defining the patient who is eligible for SLNB can be complicated. The NCCN acknowledges that assessment of nodal response to NAC is "difficult" and recommends clinical exam combined with imaging studies that were abnormal at time of initial staging. These can include mammogram and/or MRI or an imaging study determined by a multidisciplinary group.

To the best of our knowledge, the question of whether findings on MRI should preclude SLNB in cN1 patients who have a negative clinical exam after NAC has not been previously examined. Sixty-eight percent of our study population had a post-NAC MRI. As expected, those choosing breast conservation were more likely to have a post-NAC MRI ($p < 0.001$), because MRI is routinely used for surgical planning. We found that only 58% of patients with abnormal-appearing lymph nodes on post-NAC MRI had a positive SLN on final pathology, suggesting that post-NAC MRI does not accurately predict residual sentinel node disease. Had the decision to procced with SLNB been altered based on abnormal lymph nodes on post-NAC MRI, 42% of patients with a positive MRI finding would have undergone an unnecessary ALND. When residual disease is seen in both the breast and axilla, the accuracy of MRI increased to 62%, but triaging patients to axillary dissection based on these findings would still result in 30% of patients with negative sentinel nodes having an axillary dissection.

While many studies have examined the performance of MRI in assessment of response to NAC and show a high degree of accuracy in assessing disease in the breast, only a few studies have looked at the accuracy of MRI in assessment of axillary lymph node status after NAC, and these report variable accuracy ranging from 48–74% (Table 2).[9,11–20] Most of these studies included a mix of patients who had palpable and non-palpable disease after NAC. Our study is unique in that only patients with a negative axillary clinical exam were included, and we demonstrate an accuracy of only 58% for MRI in determining sentinel node status after NAC. Clinical exam has historically been shown to have poor accuracy in predicting residual disease after NAC in the breast, largely driven by a low negative predictive value.[9,15] In the axilla, similarly low negative predictive values ranging from 38-47% are reported.[4,6] Our results support this finding. In the entire cohort of patients, all of whom had a negative clinical exam, approximately half had residual disease in the SLN. In contrast, clinical exam has been shown to have high positive predictive value for residual disease in both the breast and axilla. Croshaw et al. reported a positive predictive value of 87% in the breast, and the SN FNAC trial demonstrated an 89% positive predictive value in detecting residual axillary disease. And so, while clinical exam cannot be used to predict pathologic complete response, the high positive predictive value makes it a useful modality to select those patients most likely to have residual axillary disease who are not candidates for SLNB. This is supported by findings of the Z1071 trial which demonstrated that in

TABLE 2 Accuracy of post-NAC axillary exam, ultrasound, and MRI in detecting residual nodal disease in cN+ patients

	Clinical exam			MRI			Ultrasound		
	PPV (%)	NPV (%)	Accuracy (%)	PPV (%)	NPV (%)	Accuracy (%)	PPV (%)	NPV (%)	Accuracy (%)
Javid (2010)[19] $n = 38$	–	–	–	80.9	92.3	–	–	–	–
Hieken (2013)[17] $n = 154$ (MRI 88, US 106)	–	–	–	75	42.5	60	71	56.8	65
*Boileau (2014)[4] $n = 153$	89	38	45	–	–	–	81	48	62
Steiman (2016)[16] $n = 135$	–	–	–	93	26	48	–	–	–
Hyun (2016)[20] $n = 115$	–	–	–	96.8	65.5	74	–	–	–
*Schwentner (2017)[6] $n = 651$ (US 299, CE 352)	65.3	46.6	–	–	–	–	77.5	50.3	
Weber (2017)[14] $n = 65$	–	–	–	67	66	–	–	–	–

PPV positive predictive value, *NPV* negative predictive value, *US* ultrasound, *CE* clinical exam

All studies include patients with both positive and negative axillary clinical exam

*Analyses of prospective trial data

patients with palpable disease after NAC, the false-negative rate of SLNB was 19.2%, making it an unsuitable procedure for these patients.[3]

Ultrasound, although extensively used, has an accuracy of 62–65% for determining the status of axillary nodes after NAC.[4,17] In the SN FNAC study, ultrasound had a positive predictive value of 81%, a negative predictive value of 48%, and an accuracy of 62%. Similarly, a comparison of the accuracy of axillary clinical exam and ultrasound from the SENTINA trial showed comparable results, with a positive predictive value and negative predictive value for ultrasound of 77.5% and 50%, respectively, compared to 65.3% and 47%, respectively, for clinical exam.[4,6] Boughey et al. in an analysis of the Z1071 trial data, found that if patients with suspicious ultrasound findings had been assigned to ALND, 28% would have had no residual axillary nodal disease.[21] In aggregate, these data underscore the inability of both ultrasound and MRI to predict with high accuracy the pathologic status of axillary lymph nodes after NAC.

To our knowledge, this is the largest study examining the accuracy of MRI in predicating residual axillary lymph node disease after NAC and the only one to perform a comparison with clinical exam. Our analysis included only patients with biopsy-proven lymph node metastasis, all of whom had a negative clinical exam of the axilla after NAC. A strength of this study is that all MRIs underwent review by a single expert radiologist, eliminating inter-reviewer variability. A limitation is that we could not assess how addition of ultrasound to MRI might increase the accuracy of predicting the sentinel node status in the post-NAC setting, because this is not routinely done at our institution.

Our results show that in cN1 patients with a negative axillary clinical exam after NAC, MRI assessment of axillary lymph nodes does not accurately predict the pathologic status of sentinel nodes. In this setting, a negative clinical exam alone is sufficient to determine SLNB eligibility, and abnormal lymph nodes on MRI should not alter surgical planning.

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