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Surgical Patterns of Care in Patients with Invasive Breast Cancer Treated with Neoadjuvant Systemic Therapy and Breast Magnetic Resonance Imaging: Results of a Secondary Analysis of TBCRC 017

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Abstract

Background—Neoadjuvant chemotherapy (NCT) down-stages advanced primary tumors, with magnetic resonance imaging (MRI) being the most sensitive imaging predictor of response. However, the impact of MRI evaluation on surgical treatment decisions in the neoadjuvant setting

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has not been well described. We report surgical patterns of care across 8 National Cancer Institute comprehensive cancer centers in women receiving both NCT and MRI to evaluate the impact of MRI findings on surgical planning.

Methods—Seven hundred seventy women from 8 institutions received NCT with MRI obtained both before and after systemic treatment. Univariate and multivariate analyses of imaging, patient-, and tumor-related covariates associated with choice of breast surgery were conducted.

Results—MRI and surgical data were available on 759 of 770 patients. A total of 345 of 759 (45 %) patients received breast-conserving surgery and 414 of 759 (55 %) received mastectomy. Mastectomy occurred more commonly in patients with incomplete MRI response versus complete (58 vs. 43 %) ($p = 0.0003$). On multivariate analysis, positive estrogen receptor status ($p = 0.02$), incomplete MRI response ($p = 0.0003$), higher baseline T classification ($p < 0.0001$), younger age ($p < 0.0006$), and institution ($p = 0.003$) were independent predictors of mastectomy. A statistically significant trend toward increasing use of mastectomy with increasing T stage at presentation ($p < 0.0001$) was observed in patients with incomplete response by MRI only. Among women with complete response on MRI, 43 % underwent mastectomy.

Conclusions—Within a multi-institutional cohort of women undergoing neoadjuvant treatment for breast cancer, MRI findings were not clearly associated with extent of surgery. This study shows that receptor status, T stage at diagnosis, young age, and treating institution are more significant determinants of surgical treatment choice than MRI response data.

Breast-conserving surgery (BCS) followed by irradiation in women with early-stage breast cancer has produced equivalent survival to mastectomy in multiple prospective randomized trials and has shifted the surgical standard of care.[1–6] BCS has also resulted in equivalent survival to mastectomy in stage II to III breast cancer patients treated with neoadjuvant chemotherapy (NCT).[7–10]

Up to 30 % of women with breast cancer in the United States present with stage IIb to stage III disease annually, and surgical options for these women can be limited at initial presentation.[11] Although there is no clear survival benefit with NCT compared with adjuvant chemotherapy, NCT offers several advantages for the appropriately selected patient by allowing an in vivo assessment of tumor response and often improving candidacy for breast conservation.[7,8,10,12–14]

Despite the greater ability to offer BCS in the last decade, recent studies suggest an overall increase in mastectomy rates.[15] Some studies documenting the changing patterns of surgical care have identified several variables associated with the trend. A recent study of surgical management of early-stage breast cancer at National Comprehensive Cancer Network institutions showed a 60 % rate of BCS with choice of breast surgery associated with institution, availability of subspecialty care, and patient age.[16] Several factors may be responsible for this trend, including more sensitive imaging of the breast, better understanding of subpopulations at higher risk for second malignancies such as those with *BRCA* mutations, and better options regarding postmastectomy reconstruction.[15,17–21] However, to our knowledge, no large study has evaluated the relative rates of BCS and mastectomy with respect to NCT and imaging response.

This study reports patterns of surgical care and the factors that influence surgical decisions in a group of women with invasive breast cancer treated across 8 National Cancer Institute (NCI) comprehensive cancer centers. All patients received NCT along with both preand posttreatment magnetic resonance imaging (MRI). We sought to determine whether MRI findings either at baseline or after NCT affected definitive breast surgery.

METHODS

Patient Selection

All consecutive patients undergoing NCT for invasive breast cancer who underwent breast MRI before and after NCT were retrospectively identified at 8 NCI-designated cancer centers. A total of 770 women diagnosed between January 2002 and February 2011 fulfilled the study criteria. The institutions that participated in the Translational Breast Cancer Research Consortium study 017 included the following: University of Alabama at Birmingham, Birmingham, AL; University of Pittsburgh Medical Center, Pittsburgh, PA; Dana-Farber/Brigham and Women's Cancer Center, Boston, MA; University of Texas MD Anderson Cancer Center, Houston, TX; Duke University, Durham, NC; University of Chicago, Chicago, IL; University of North Carolina Chapel Hill, Chapel Hill, NC; and University of California San Francisco, San Francisco, CA. Institutional review board approval was obtained at each institution. In addition to pre- and post-NCT MRI, eligible patients were required to have undergone definitive surgery with pathology available for review. Patient-, tumor-, and treatment-related variables were entered into a secure password-protected online database. All documentation of baseline and posttreatment imaging with mammography, ultrasound, computed tomography, or positron emission tomography–computed tomography in the breast and lymph nodes were additionally recorded.

Tumor Classification

Histological tumor types were recorded as follows: invasive ductal carcinoma, invasive lobular carcinoma, invasive mammary carcinoma with ductal and lobular features, and invasive mammary not otherwise specified. Estrogen receptor (ER)/progesterone receptor (PR) status was scored as positive (defined as ≥1 % of cells with receptor overexpression) or negative, HER2 (human epidermal growth factor receptor 2) status was reported according to 2007 ASCO/CAP guidelines.[22] All biomarker assessments were performed at the individual sites. Pathologic response in the breast was categorized as no residual invasive disease or ductal carcinoma-in situ (DCIS; complete response or pathologic complete response); no residual invasive cancer with DCIS present; and residual invasive disease, including microscopic residual invasive disease.[12]

Breast Imaging

All eligible patients underwent baseline and posttreatment breast MRI. Dates of posttreatment MRI, mammogram and ultrasound along with MRI response were recorded. Most (77 %) of posttreatment scans were obtained within 30 days of surgery. Lesion size was defined as the maximal diameter in any single dimension by pretreatment MRI, mammogram, and ultrasound. A radiographic T classification was assigned on the basis of largest imaging size, as defined by the American Joint Committee on Cancer, 6th edition, for breast cancer.[23] Specific parameters for dynamic contrast-enhanced image acquisition were not defined for eligibility; however, institutions included on this study have extensive expertise in breast MRI. Central review of MRIs was not performed because the only response data collected was whether imaging revealed complete or incomplete response to NCT. Complete MRI response in the breast was defined as resolution of all areas of abnormal enhancement.

Definition of Type of Surgery Received

Type of surgery was defined as the final surgical procedure used to treat the breast. If more than one procedure was performed (i.e., lumpectomy followed by completion mastectomy), then the last procedure was listed as type of breast surgery. Types of breast surgery recorded were as follows: lumpectomy, simple mastectomy, and skin-sparing mastectomy with immediate reconstruction. Axillary staging was recorded separately.

Statistical Analysis

Comparisons of subsets of patients were based on the Chi square test for contingency tables. Multivariate logistic regression was used to examine the simultaneous effects of multiple factors on the odds of mastectomy and p values computed. Within MRI response categories (i.e., with or without complete response), the Jonckheere–Terpstra test was used to test for trends in mastectomy rate by baseline T classification and IHC phenotype. SAS software, version 9.2 (SAS Institute, Cary, NC), was used for all analyses.

RESULTS

Patient Characteristics at Presentation

Surgical and MRI data were available for 759 of 770 patients. The distribution of baseline imaging-defined T classification was as follows, T1, 65 (9 %); T2, 430 (57 %); T3, 227 (30 %); and T4, 35 (5 %). Forty-three percent (345 of 759) of patients received lumpectomy and 57 % (416 of 759) mastectomy. The median age of the overall cohort was 49 years (range 20–86 years). Patients undergoing mastectomy were younger than those undergoing lumpectomy (median 48 vs. 51 years, respectively) ($p < 0.0001$). Sixty-one percent of tumors were ER positive, 54 % were PR positive, and 34 % were HER2 positive. A total of 21 % (161 of 751) of patients had triple-negative (ER-/PR-/HER2-) tumors.

Surgical Treatment by Imaging Response

Table 1 lists definitive breast surgery by both MRI imaging response and pretreatment imaging T classification. Fifty-eight percent versus 43 % ($p = 0.0003$) of those with an incomplete versus complete MRI response underwent mastectomy. Use of mastectomy for patients presenting with T1/T2 cancers at baseline imaging was 60 % (39 of 65) for T1 and 45 % (194 of 430) for T2 lesions. This is in comparison to patients presenting with T3/T4 disease, who had mastectomy rates of 69 % (156 of 227) and 66 % (23 of 35), respectively.

Univariate and multivariate logistic regression analyses were performed to assess the association between institution, ER status, type of systemic therapy, age at diagnosis, T stage, and MRI response and likelihood of mastectomy. On univariate analysis, covariates associated with receipt of mastectomy were ER positivity ($p = 0.02$), incomplete MRI response ($p = 0.0003$), higher T stage at diagnosis ($p < 0.0001$), systemic treatment regimen ($p = 0.007$), young age ($p < 0.0001$), and institution ($p = 0.004$) (Table 2). All covariates except systemic treatment and treating institution remained independent predictors of mastectomy on multivariate analysis. Overall, mastectomy was performed in almost half (47 %; 233 of 495) of T1 and T2 patients. Mastectomy rates differed between tumor phenotypes as would be expected from multivariate analysis, with the highest rate in the HR+/HER2- subset (196 of 331; 59 %) and the lowest rate among triple-negative breast cancer (76 of 159; 48 %) (Table 3).

Impact of MRI Response

In contrast to the overall group, there was no observed trend toward increased use of mastectomy with increasing T stage at presentation in those patients achieving complete MRI response. Paradoxically, a high rate of mastectomy (61 %; 14 of 23) was noted in patients who presented with T1 disease and had a complete MRI response. However, this is a small subset, which thus precludes our ability to perform further analyses.

Among those with incomplete response, mastectomy rate was strongly associated with baseline T stage ($p < 0.0001$). Overall, 36 % of patients undergoing mastectomy after complete MRI response had a pathologic complete response, versus 13 % after incomplete response.

Impact of Year of Diagnosis and Institution on Surgical Treatment

In this cohort, there was no trend toward increased mastectomy by year of diagnosis, and relative percentages of BCS to mastectomy remained essentially unchanged between 2003 and 2010 (Table 1). However, we observed striking differences in mastectomy rate by institution, despite comparable rates of MRI complete response among most institutions (Table 4). No regional trends or urban/ rural factors could be identified to explain these differences.

DISCUSSION

One important goal of NCT in breast cancer is to downstage locally advanced tumors to improve candidacy for BCS. In our cohort, overall BCS rate was 45 %, lower than published BCS rates at other tertiary care institutions.[24] However, this does not take into account the receipt of NCT and the patients' eligibility for BCS after chemotherapy (multicentricity, inflammatory breast cancer). When compared to a more analogous population, the rate we observed is similar to other series.[25]

Not surprisingly, some of the factors that predicted for mastectomy in our study also predicted for a poor response to NCT. Logically, a prediction of significant residual disease based on clinicopathologic factors or post-NCT imaging could lead to mastectomy. ER positivity, higher baseline T stage, and incomplete MRI response were all associated in this study with mastectomy and have been associated with higher rates of residual tumor in the breast on final pathology.[24–26]

One factor not associated with worse response to NCT that correlated with higher mastectomy rates was young age at diagnosis. Age has been related to mastectomy (and contralateral prophylactic mastectomy) choice in several other studies. The recently increasing mastectomy rate appears to be most pronounced in younger women.[17,18,21,27] Many authors note that this may be a patient population that is particularly worried about recurrence. They may also more frequently be diagnosed with a deleterious BRCA mutation. BRCA status was not collected for our cohort and thus could not be included in the analysis. Despite no published data to suggest overall survival benefit with mastectomy or contralateral prophylactic mastectomy, age at time of diagnosis, and poorer prognostic factors have been identified as predictive of locoregional recurrence in those undergoing lumpectomy after NCT.[28,29] These findings may lead to provider recommendations or patient choice for mastectomy.

In this study, we specifically evaluated the impact of MRI response on choice of surgery. The use of MRI in preoperative assessment of patients with newly diagnosed invasive breast cancer has increased significantly in the last decade.[30] MRI identifies other areas of enhancement in approximately 15 % of patients, which leads to additional biopsies or change in management in a significant proportion of women.[18,27,31] Many investigators have found that MRI leads to a greater extent of surgical treatment. Furman et al.[32] demonstrated a 13.5 % variance in surgical decision making after MRI evaluation. MRI evaluation has resulted in a wider extent of excision during breast conservation, a change in surgical management of the ipsilateral breast from BCS to mastectomy or even the addition of contralateral prophylactic mastectomy in as many as 13–29 % of cases.[18,21,33–35] This trend is even more pronounced in younger women, who are more likely to undergo MRI. Adkisson et al.[27] found that although the value of MRI did not vary with age, the mastectomy rate increased more for younger women than those age >65 years.

Katipamula et al. correlated their findings of increased use of mastectomy (an increase of 12 % in 3 years) with several patient/treatment variables. MRI and surgical year were the only independent predictors of mastectomy on multivariate analysis. MRI use increased from 10 to 23 % in the same study period, and women who underwent MRI were more likely to undergo mastectomy.[17] Similar results have been found when evaluating the use of MRI for pure DCIS.[36]

The present study demonstrates a correlation between the response as determined by MRI and surgical choice. However, we found that even in those patients who had a complete imaging response by MRI, 43 % of women elected to undergo mastectomy.[24,37–39] Interestingly, the negative predictive value of MRI after NCT among all subtypes in our data set, as previously published, was 43 % (85 of 182).[40] In our analysis of patients with both post-NCT MRI and final pathologic response data available, we found that 77 of 403 (19 %) of patients undergoing mastectomy did so despite MRI suggesting a complete response (rCR). Thirty-six percent of patients choosing mastectomy despite rCR did in fact have a pathologic complete response. The factors that led to a decision for mastectomy in the face of a negative posttreatment MRI are unclear. It is possible these patients were *BRCA* positive or had significant residual calcification on mammogram. However, considering recent trends in mastectomy rates, it is likely that other factors also contributed significantly to surgeon recommendation and patient choice.

Despite the assertion that treatment at a tertiary care center could lead to a higher mastectomy rate, our study demonstrated wide variations in patterns of care among 8 NCI designated cancer centers.[24] These varying practice patterns call into question how the stage of cancer at presentation or the level of patient/disease complexity affect decision making. After controlling for stage of disease at presentation and considering MRI response, significant variations remained between institutions, suggesting that other unmeasured variables may be influencing final surgical choice. MRI use varies between institutions, from routine use in all neoadjuvant cases to highly selective use, which may introduce a selection bias. There are numerous factors that could predict for both choice of surgical therapy and choice of institution at which to receive care, including patient health literacy, patients' overall health including body mass index, primary care physician referral patterns, *BRCA* prevalence, and ethnic makeup of the referring community, as well as access to radiation facilities. In addition, access to immediate, high-quality reconstructive surgery has been suggested as a reason for increased used of mastectomy.[15,17–20] This factor likely contributes to surgical decision making. However, in the present study, all the participating centers had ready access to reconstructive options, and this factor is thus unlikely to have contributed to the difference in mastectomy rates between study sites. Further investigation into surgical decision making among surgical oncologists and between institutions as a whole will be required to better understand the source of surgical treatment differences across institutions because these factors appear to have a greater impact on treatment choice than MRI data.

This retrospective study is strengthened by being a multicenter study with a large number of subjects. However, studying patterns of care only at academic institutions could have biased the results, as discussed above, toward surgical choices made in tertiary care centers under the care of breast oncology specialists. This potentially limits generalizability of findings to all practice settings. A significant limitation related to study design is that all patients had MRI before and after NCT, so we cannot compare those who underwent MRI versus those who did not to assess the effect of simply undergoing MRI as a factor affecting surgical choice. Additional limitations of the study were the lack of data regarding multifocal/multi-centric disease and *BRCA* mutation status. An update to the data for this study is underway and will permit further analyses of these and other variables. Despite the above noted limitations, the study offers insight into how surgical decision making is related to MRI response in the setting of locally advanced breast cancer treated with NCT.

CONCLUSIONS

This large multicenter study supports the growing body of knowledge that despite the ability to improve candidacy for BCS with NCT, there has been a shift in surgical trends for certain populations toward increased use of mastectomy. In particular, we observed a trend toward higher mastectomy rates among younger women, for whom the chose to undergo mastectomy even in the setting of a complete radiographic response by post-NCT MRI. This study shows that receptor status, T stage at diagnosis, young age, and treating institution are more significant determinants of surgical treatment choice than MRI response data. The high variability in mastectomy rates indicates the importance of patient education regarding all surgical options, particularly in those cases for which NCT improves feasibility for breast conservation.

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TABLE 1

Surgical treatment by pretreatment T stage and response to therapy as measured by MRI

T stage at presentation	MRI response								
	Complete			Incomplete			Total		
	Mastectomy rate	%	*p*	Mastectomy rate	%	*p*	Mastectomy rate	%	*p*
T1	17/26	65		22/39	56		39/65	60	
T2	42/115	37		152/315	48		194/430	45	
T3	18/39	46		138/188	73		156/227	69	
T4	2/4	50		21/31	68		23/35	68	
Entire cohort	79/184	43	0.057*	335/575	58	<0.0001*	414/759	55	0.0009*

MRI magnetic resonance imaging

*Comparing T1 versus T2 versus T3 versus T4

TABLE 2

Clinicopathologic variables in relationship to mastectomy rate after NCT

Characteristic	*n*	Mastectomies	%	Univariate *p*	Multivariate *p***
ER status				0.02	0.02
Positive	462	267	57.8		
Negative	296	146	49.3		
HER2 status				0.42	
Positive	257	135	52.5		
Negative	496	276	55.6		
T stage				<0.0001	<0.0001
1	65	39	60.0		
2	430	194	45.1		
3	227	156	68.7		
4	35	23	65.7		
MRI response				0.0003	0.04
Complete	184	79	42.9		
Incomplete	575	335	58.3		
Chemotherapy regimen[a]				0.11	
AC	35	16	45.7		
ACT	366	196	53.6		
TC	63	24	38.1		
FEC or FAC	8	3	37.5		
Institution				0.004	0.08
1	98	53	54.1		
2	122	54	44.3		
3	56	27	48.2		
4	46	30	65.2		
5	94	60	63.8		
6	69	48	69.6		
7	64	39	60.9		
8	210	103	49.0		

NCT neoadjuvant chemotherapy, *ER* estrogen receptor, *HER2* human epidermal growth factor receptor 2, *MRI* magnetic resonance imaging, *AC* adriamycin/cytoxan, *ACT* adriamycin/cytoxan/taxotere, *TC* taxotere/cytoxan, *FEC* 5 fluorouracil/epirubicin/cyclophosphamide, *FAC* 5 fluorouracil/adriamycin/cyclophosphamide

[a]Chemotherapy not used in model

**Excluding 287 with chemotherapy listed as “other” or missing

TABLE 3

Surgical treatment by IHC phenotype and response to therapy as measured by MRI

Histologic subtype at presentation	MRI response								
	Complete			Incomplete			Total		
	Mastectomy rate	**%**	***p***	**Mastectomy rate**	**%**	***p***	**Mastectomy rate**	**%**	***p***
HR+ HER2–	34/60	57		162/271	60		196/331	59	
HR+ HER2+	16/43	37		66/109	61		82/152	54	
HR– HER2+	11/30	37		41/72	57		52/102	51	
TN	16/48	33		60/111	54		76/159	48	
Entire cohort	77/181	43	0.059*	330/563	59	0.718*	407/744	55	0.095*

IHC immunohistochemistry, *MRI* magnetic resonance imaging, *HR* hormone receptor, *HER2* human epidermal growth factor receptor 2, *TN* triple negative

* *p* value for effect of phenotype on surgery by Chi square test

TABLE 4

Odds ratio for mastectomy by institution

Institution	OR	95 % CI	MRI CR rate (%)
1	1.0 (ref)		22
2	1.483	0.869–2.531	18
3	1.265	0.655–2.442	23
4	0.628	0.304–1.297	17
5	0.667	0.374–1.190	19
6	0.515	0.269–0.986	2.9
7	0.755	0.398–1.432	14
8	1.224	0.757–1.979	42

OR odds ratio, *CI* confidence interval, *MRI* magnetic resonance imaging, *CR* complete response