

# Quality of Life at the End of Primary Treatment of Breast Cancer: First Results From the Moving Beyond Cancer Randomized Trial

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**Background:** During the last decade, survival rates for breast cancer have increased as a result of earlier detection and increased use of adjuvant therapy. Limited data exist on the psychosocial aspects of the transitional period between the end of primary treatment and survivorship. We investigated the baseline psychosocial status of women enrolled in a randomized trial testing two psychosocial interventions for women at the end of primary treatment. **Methods:** Participants, identified within 1 month after surgery (registration), provided demographic information and limited measures of quality of life. They were followed until they finished primary treatment (enrollment), at which time they completed a mailed baseline survey that included standardized measures of quality of life (including standardized scales of physical and emotional functioning), mood, symptoms, and sexual functioning. A total of 558 patients (mean age = 56.9 years) were enrolled in the study between July 1, 1999, and June 30, 2002. Health outcomes were examined according to treatment received: mastectomy with and without chemotherapy, and lumpectomy with and without chemotherapy. All statistical tests were two-sided. **Results:** Among all treatment groups, patients who had a mastectomy had the poorest physical functioning at registration ( $P < .001$ ) and at enrollment ( $P = .05$ ). At enrollment, mood and emotional functioning were similar among all patients, with no differences by type of treatment received. At enrollment, symptoms, including muscle stiffness, breast sensitivity, aches and pains, tendency to take naps, and difficulty concentrating, were common among patients in all groups and were statistically significantly associated with poor physical functioning and emotional well-being. Sexual functioning was worse for women who received chemotherapy than for those who did not, regardless of type of surgery ( $P < .001$ ). **Conclusions:** At the end of primary treatment for breast cancer, women in all treatment groups report good emotional functioning but report decreased physical functioning, particularly among women who have a mastectomy or receive chemotherapy. Clinical interventions to address common symptoms associated with treatment should be considered to improve physical and emotional functioning at the end of primary treatment for breast cancer. [J Natl Cancer Inst 2004;96:376–87]

More than 215 000 women will be diagnosed with breast cancer in the United States in 2003 (1). Over the last two decades, psychosocial research has explored the experience of women newly diagnosed with breast cancer (2–8) and, more recently, the experience of survivors (i.e., women who are well beyond the acute phase of treatment) (9–15). However, limited data exist on the experiences of women during the critical transitional period between the end of primary treatment and

survivorship—the time when women must move beyond cancer to reestablish their normal life patterns. Having a better understanding of how patients navigate this transitional period is increasingly important, given the widespread use of adjuvant chemotherapy and the extension in time and complexity of primary treatments (16). For example, adjuvant chemotherapy treatment, whether given before or after surgery, often lasts more than 6 months. Primary radiation therapy, which is usually deferred until completion of adjuvant chemotherapy, further extends treatment time. Although physicians and patients accept that adjuvant chemotherapy adds short-term toxicity in exchange for the long-term benefit of improved disease-free and overall survival (17), contemporary adjuvant therapy regimens are more toxic and protracted than those used a decade ago (18,19). Consequently, the impact of contemporary primary treatment regimens on short-term quality of life (QOL) is largely unknown.

The end of treatment can be exceedingly stressful for women with breast cancer, especially for those who have received adjuvant chemotherapy and/or radiation treatments (20–24). In one study of 160 lymph node-negative breast cancer survivors (25), women were asked, between 4 and 12 months after the end of treatment, to rate stressful aspects of their cancer experience. Ending radiation therapy and ending chemotherapy were rated as moderately to extremely stressful for 27% and 48% of the women, respectively. A number of variables appear to contribute to the stress of this transition period. First, women often report that their fear of recurrence increases after active treatment is withdrawn. As women move from very frequent to infrequent visits to the oncologist, they miss the ready access to the health care system and the reassurance that this contact can provide, resulting in a sense of greater vulnerability (22). After active medical treatment ends, patients may feel as though a safety net has been lost (20). Second, many survivors report being unpre-

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pared for the lingering side effects of therapy (e.g., fatigue, alopecia, and menopausal symptoms). In one study (23), 16 of 18 patients were surprised to experience chemotherapy-related problems 6 months after ending treatment. Uncertainty about what to expect after treatment, what kind of follow-up is typical, and which symptoms are important to monitor leaves many women feeling out of control.

These problems associated with the end of treatment may be compounded by a withdrawal of and changes in social support. At least one report (26) has suggested that patients are in greatest need of interpersonal support after completing treatment but often find it unavailable. Furthermore, family members may expect that, after treatment is over, the woman will be able to resume all of her usual activities and responsibilities at her pre-cancer level of functioning. Some women are surprised by symptoms of anxiety and depression after treatment, particularly if they feel that they coped well during treatment. This experience can cause a paradoxical response for survivors, who may feel both relief at having completed treatment and heightened anxiety about the future (26).

To address this period of transition, we conducted the “Moving Beyond Cancer (MBC) Study,” a multisite, randomized, controlled, behavioral intervention trial. The MBC Study compared two separate psycho-educational strategies aimed at preparing women for recovery after primary breast cancer treatment with a control strategy. We report on the health status and QOL of women with breast cancer who had completed primary treatment and enrolled in the MBC Study, focusing on the four most frequent groups of patients seen in clinical practice—groups determined on the basis of type of surgery and whether adjuvant chemotherapy was administered. The women had not yet been randomly assigned to arms of the MBC Study or received the intervention.

## STUDY PARTICIPANTS AND METHODS

### Geographic Sites and Recruitment Procedures

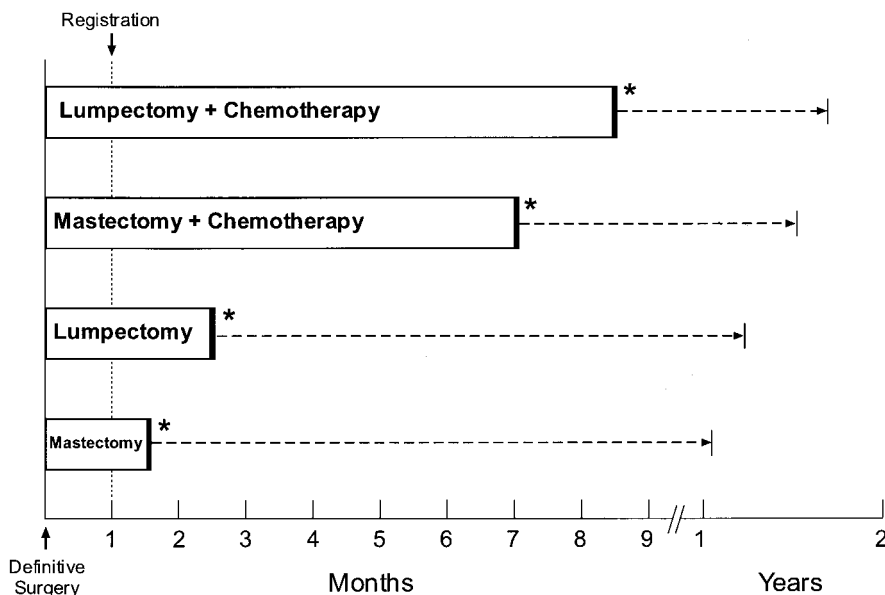
Patients were recruited from three separate geographic sites. After the study received approval from the Institutional Review

Board at each participating university, patients were recruited in Los Angeles (University of California, Los Angeles), Washington, DC (Georgetown University), and Kansas City/Lawrence, Kansas (University of Kansas, Lawrence) from the practices of collaborating surgical and medical oncologists in each community who were willing to identify and refer newly diagnosed breast cancer patients to the study. Potentially eligible patients with stage I or II breast cancer were sent a letter of invitation and a study brochure from their physician. The letter was followed by a telephone call from the research staff who explained the nature of the study. During this telephone call, women were registered on study if they gave permission to be contacted periodically to determine when their primary treatment (i.e., radiation therapy or chemotherapy) for breast cancer was completed, at which time the full study would be described and written consent obtained. Limited demographic data (age, race/ethnicity, marital status, and educational level) and responses to standardized measures of physical and emotional functioning (*see below*) were obtained during the registration telephone call. The frequency of subsequent tracking calls was determined on the basis of the woman’s projected treatment plan (e.g., radiation therapy or chemotherapy). Fig. 1 presents an overview of the full study in timeline format, indicating the projected time intervals between study registration and end of treatment for each of the four primary treatment patterns for early-stage breast cancer. A baseline survey, independent of the information collected during the registration telephone call, was performed for the randomized intervention trial that began after the end of treatment. Data from the baseline survey are the principal source of information for this article. The follow-up assessments in the intervention trial occurred in the year after the baseline survey and are not presented in this article.

### Study Eligibility

Patients were eligible for registration on the study if they met all of the following inclusion criteria: had had definitive primary surgery within the past month and surgery was the initial therapy, had invasive epithelial cancer determined by histology, had a stage I or II cancer of any size and any lymph-node status, and

**Fig. 1.** Overview of “Moving Beyond Cancer” Study Design. A registration telephone call took place between 2 and 5 weeks after definitive surgery. Patients were then tracked until the end of therapy, when they were approached about entry into the randomized trial. **Asterisk** indicates the anticipated end of treatment, at which time the baseline survey was completed. End of treatment was slightly longer for patients who had a lumpectomy due to the inclusion of radiation therapy. The **dashed line** indicates the follow-up period after entry into the randomized trial.



had or were scheduled to have reconstructive surgery that was completed within a defined period of time (e.g., within 6 months of primary surgery). Patients were excluded from the study if they met any of the following criteria: had a prior history of breast cancer; had metastatic disease at diagnosis; had noninvasive breast cancer; had inflammatory breast cancer; planned the use of neoadjuvant chemotherapy; planned the use of high-dose chemotherapy with bone marrow or stem cell rescue; had protracted reconstructive surgery or complications related to surgery; had severe physical, cognitive, or psychiatric illness; were unable to read and/or write in English; or were currently participating in another clinical trial with a QOL intervention.

## Enrollment and Randomization Procedures

Registered subjects were contacted by telephone 2–3 weeks before the anticipated completion of primary treatment to confirm the expected end-of-treatment date, to verbally explain the full study, and to confirm that they did not have any of the exclusion criteria. Women who agreed to participate were asked to provide written informed consent for the study and to complete a baseline enrollment survey within 4 weeks after the end of treatment. For this study, the end of treatment was defined as 1 month after mastectomy or lumpectomy for patients who did not receive chemotherapy; 3 weeks after the last radiation treatment, if radiation was the last component of therapy; and 3 weeks after the last chemotherapy injection, if chemotherapy was the last component of therapy. Upon the timely return of the consent and baseline survey questionnaire, each woman was randomly assigned to one of three study conditions: standard information only (National Cancer Institute booklet, “Facing Forward,” National Institutes of Health Publication No. 99-2424); standard information plus a videotape developed for the MBC Study that modeled effective coping and realistic expectations about the transition period; or standard information and the MBC Study videotape, plus a brief counseling intervention and educational workbook designed for the MBC Study. Each woman received the assigned treatment immediately after random assignment to the non-counseling arms and within 2 weeks of random assignment to the counseling arm. All data reported here (except for some demographic characteristics) were obtained from the mailed survey completed at enrollment. Time elapsed since surgery was calculated using the receipt date of the survey. Enrollment in the study began July 1, 1999, and was completed by June 30, 2002. The final follow-up of subjects in the intervention trial occurred by August 15, 2003.

## Instruments

The 39-page survey booklet included standardized questionnaires and instruments developed specifically for the MBC Study. The following domains were included: demographic and medical information, stressful life events, women’s health history (including treatments for breast cancer and menstrual changes), psychosocial and health-related adjustment, and additional psychological variables. This article focuses on demographic, medical, and QOL data.

QOL was assessed with two generic instruments: health-related QOL from the RAND SF-36 (also known as the Medical Outcomes Study [MOS]-SF-36) (27–29) and global QOL as measured by the Ladder of Life Scale (30). The SF-36 contains

eight individual scales that include physical functioning, role function–physical, bodily pain, social functioning, mental health, role function–emotional, vitality (i.e., energy and fatigue), and general health perceptions (27–29). Each scale is scored from 0 to 100, with 100 being the most favorable score. General population reference scores are available for the SF-36 (28). The full SF-36 was administered as part of the mailed survey; however, only the SF-36 physical and mental health scales were administered during the registration telephone call for the purpose of comparing full study participants with non-participants [see (31)]. The SF-36 also has two summary scales—the Physical Component Summary Scale (PCS) and the Mental Component Summary Scale (MCS) (32). The summary scales have been standardized to a reference normal healthy population, in which the mean score is 50, and a score of 60 or 40 represents one standard deviation (SD) above or below the mean, respectively.

The Ladder of Life scale (30) provides a global subjective rating of QOL. Ratings are made on a 10-point scale, ranging from 10 (best possible life) to 1 (worst possible life). This scale, widely used in epidemiologic and population studies, provides a global rating of life satisfaction (33). In prior studies of patients with cancer, global rating scales of this type were statistically significantly associated with both the physical and psychosocial dimensions of QOL, making them good summary measures of QOL (34).

Depressive symptoms and affect were measured with two instruments. The Center for Epidemiologic Studies–Depression (CES-D) scale, a 20-item self-report scale developed for the general population to measure depressive symptoms over the past week, has excellent reliability and validity (35). Reference scores are available from community-based samples (36,37). Responses to the CES-D are rated on a four-point scale, and the total scores range from 0 to 60. Higher scores on the CES-D indicate greater risk of depression, with scores of 16 or more indicating the possibility of increased risk of clinical depression (35). The CES-D has been used in studies of healthy women (38) and of breast cancer patients and survivors (12,15). We also used the Positive and Negative Affect Schedule (PANAS) (39), a 20-item adjective checklist that measures both the positive and negative dimensions of mood and has excellent reliability and validity. The PANAS uses a five-point Likert-type scale for rating mood over the past 4 weeks.

The Revised Dyadic Adjustment Scale (RDAS) (40) was used to measure the quality of the woman’s partnered relationship. This 14-item scale is a shortened version of the Dyadic Adjustment Scale (41). Scores range from 0 to 69, with a mean value of 48.0 (SD = 9.0) among married couples in the general population, with higher scores representing better adjustment. Sexual functioning was measured by the MOS Sexual Problems Scale (42). Scores range from 0 to 100, with higher scores representing more sexual problems.

We obtained information on symptoms using the Breast Cancer Prevention Trial (BCPT) symptom checklist (43), to which we added two items, one about arm swelling and one about decreased range of motion in the arm on the side of surgery. Respondents indicated “yes” or “no” about the presence of each problem during the past 4 weeks, and if the problem was present, then they rated bother from 0 (not at all) to 4 (extremely bothered).

## Statistical Methods

In this article, we focus on comparisons among health-related QOL outcomes, sexual functioning, and symptoms, considering the three study sites and the four treatment groups (lumpectomy with/without chemotherapy, and mastectomy with/without chemotherapy). In additional analyses, we investigated sexual functioning variables, including separate categorical measures of sexual limitations and composite summary scores, and variables reflecting potential treatment symptoms or menopausal symptoms that women reported. Categorical variables were compared across groups using chi-square or Fisher's exact tests; continuous variables were compared across groups using analysis of variance (ANOVA), with pairwise mean differences evaluated using ANOVA contrasts. In addition, we used SAS PROC GLM (SAS Institute, Cary, NC) to implement analysis of covariance models controlling for site, demographic variables (i.e., age, race/ethnicity, educational level, employment status, and marital status), and treatment-related variables (i.e., time since surgery and whether immediate reconstruction was received). We focused on partial *F* tests across treatment protocols and contrasts for pairwise mean differences between treatment types. Given the descriptive and exploratory nature of this study, there are multiple statistical comparisons across treatment groups, so caution must be used in interpretation of the significance of *P* values. However, to reduce the potential for Type I errors in several of our major analyses, we applied the technique of Benjamini and Hochberg (44) to control for false discovery rates of 5% and 10%. Statistical analyses were conducted using SAS version 8.02 (SAS Institute). All statistical tests were two-sided.

## RESULTS

### Recruitment Results

The flow of subjects and recruitment results for this study are shown in Fig. 2. We received referrals for 2242 women to the study over the 3 years of recruitment at the three sites. Ineligibility for the study could occur during the recruitment, registration, enrollment, or randomization processes and accounted for a loss of 928 (41%) potential participants (31). At each step of

the process, women were given the opportunity to decline participation. Of the 1314 initially eligible women, 756 (58%) refused, either actively or passively [see (31) for details on reasons for refusal], and 558 (42%) participated through completion of the enrollment survey and random assignment (three additional women completed the enrollment survey but were deemed ineligible for random assignment and were excluded from the full study). SF-36 scores for the women who completed the survey did not differ from those for nonparticipants (physical functioning, *P* = .63, and mental health, *P* = .69, respectively); however, study participants tended to be younger than nonparticipants, white, and married (31).

### Subjects

Of the 558 women who completed the survey, 279 were from Los Angeles, 160 were from Washington, DC, and 119 were from Kansas. Demographic and medical characteristics by geographic site are shown in Tables 1 and 2. There were statistically significant site differences in race/ethnicity, marital status, educational level, household income, time elapsed from surgery to survey, type of surgical treatment, and type of therapy (radiation therapy or chemotherapy). Because there were site-related differences in participant characteristics, we controlled for these variables in some analyses.

Site-related differences also emerged in SF-36 physical and mental health scores at registration, which was within 1 month after surgery. The mean physical functioning score was 74.8 (95% confidence interval [CI] = 72.9 to 76.7), with statistically significant differences across the three sites (*P* < .001). Participants from Kansas had the lowest physical functioning score (mean = 68.0, 95% CI = 64.1 to 71.9) and those from Washington, DC, had the highest (mean = 79.1, 95% CI = 75.8 to 82.8). The mean physical functioning score for women from Washington, DC, remained statistically significantly different from mean scores of the other sites, even after adjusting for differences in age, type of surgery, immediate reconstruction, time since surgery, race/ethnicity, educational level, employment status, and marital status. Statistically significant differences were also observed in mental health scores at registration (*P* = .05), with the participants from Kansas having the highest score (mean = 73.4, 95% CI = 70.6 to 76.2) and those from

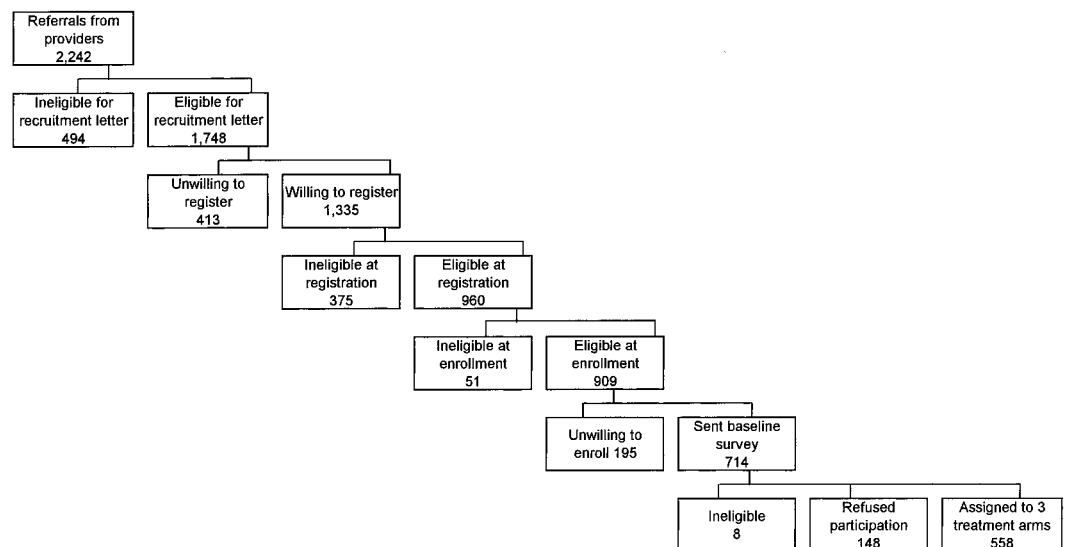


Fig. 2. Flow chart of patient recruitment for the study.

**Table 1.** Demographic characteristics of the study sample by geographic site

	Distribution of study participants by geographic site, No. (%)				<i>P</i> value
	Total N = 558	Los Angeles n = 279	Washington, DC n = 160	Kansas n = 119	
Mean age, y	56.9	56.9	56.3	57.8	.56
Range	26.9–87	26.9–87	30.4–85.1	33.7–81.1	
Age distribution, y*					
<50	146 (26)	81 (29)	41 (26)	24 (20)	.27
50–59	205 (37)	90 (32)	67 (42)	48 (40)	
60–69	126 (22)	64 (23)	31 (19)	31 (26)	
≥70	81 (15)	44 (16)	21 (13)	16 (14)	
Ethnicity*					
White	480 (86)	222 (80)	144 (90)	114 (97)	<.001
African American	37 (7)	23 (8)	11 (7)	3 (2)	
Other	40 (7)	34 (12)	5 (3)	1 (1)	
Marital status					
Married	358 (64)	157 (56)	109 (68)	92 (77)	<.001
Divorced/separated	62 (11)	43 (15)	12 (8)	7 (6)	
Widowed	55 (10)	28 (10)	13 (8)	14 (12)	
Committed relationship	31 (6)	18 (6)	10 (6)	3 (2.5)	
Single	52 (9)	33 (12)	16 (10)	3 (2.5)	
Education level					
Post college	200 (36)	93 (33)	73 (46)	34 (29)	.006
College graduate	153 (27)	78 (28)	41 (26)	34 (29)	
Some or junior college	135 (24)	80 (29)	26 (16)	29 (24)	
High school or less	70 (13)	28 (10)	20 (13)	22 (18)	
Household income†					
<\$30 000	62 (11)	36 (12)	6 (4)	20 (18)	.009
\$30 001–\$60 000	139 (26)	71 (26)	36 (23)	32 (29)	
\$60 001–\$100 000	167 (31)	80 (30)	54 (34)	33 (29)	
≥\$100 001	172 (32)	82 (30)	63 (40)	27 (24)	
Employed, at least part time	314 (57)	155 (56)	92 (58)	67 (57)	.93
Time elapsed from surgery to survey, days					
Mean	173.8	179.4	184.9	145.8	<.001
Range	21–472	33–450	35–472	21–343	

\*Missing data on one subject in Kansas.

†Missing data on 18 subjects (10 from Los Angeles; one from Washington, DC; seven from Kansas).

Washington, DC, having the lowest (mean = 68.2, 95% CI = 65.3 to 71.7). The inverse relationship between physical and mental health scores was not noted for participants from Los Angeles, and after adjustment for age, type of surgery, and time since surgery, no site differences were noted for mental health at registration.

### Sample Characteristics by Treatment Group

To understand the health status, symptoms, mood, and QOL in women at the conclusion of primary treatment for breast cancer, we divided the entire sample into four groups representing the most common clinical treatment patterns: mastectomy

**Table 2.** Medical characteristics of the study sample by geographic site

	Distribution of study participants by geographic site, No. (%)				<i>P</i> value
	Total N = 558	Los Angeles n = 279	Washington, DC n = 160	Kansas n = 119	
Type of surgery					
Mastectomy	183 (33)	88 (32)	42 (26)	53 (45)	.005
Lumpectomy	375 (67)	191 (68)	118 (74)	66 (55)	
Chemotherapy					
Yes	279 (50)	140 (50)	83 (52)	56 (47)	.73
No	279 (50)	139 (50)	77 (48)	63 (53)	
Radiation therapy*					
Yes	380 (69)	193 (69)	120 (76)	67 (58)	.004
No	172 (31)	86 (31)	37 (24)	49 (42)	
Current tamoxifen use	304 (55)	142 (51)	96 (60)	66 (56)	.18
HRT in past†	304 (55)	152 (55)	78 (48)	74 (63)	.07
Postmenopausal at diagnosis‡	364 (67)	184 (66)	99 (64)	81 (74)	.18

\* = Missing data on six patients

† = Missing data on one patient. HRT = hormone replacement therapy.

‡ = Missing data for 16 patients

without chemotherapy, lumpectomy without chemotherapy, mastectomy with chemotherapy, and lumpectomy with chemotherapy. Radiation therapy and endocrine therapy were used across these four groups, depending on other clinical characteristics. Patient characteristics by the four treatment groups are shown in Table 3. Women who received chemotherapy as part of their primary treatment were statistically significantly younger than those who did not ( $P < .001$ ). Women who received surgery without chemotherapy were more often taking tamoxifen than women who received chemotherapy ( $P < .001$ ). There were no differences in educational levels among the four groups ( $P =$

.81), but women who received chemotherapy had a slightly higher household income ( $P = .08$ ).

### Health Status, Mood, QOL, and Symptoms at the End of Primary Treatment

At the time of the study registration telephone call (Table 4), women who had a lumpectomy had statistically significantly better SF-36 physical functioning scores than women who had a mastectomy ( $P = .002$ ), and women who had lumpectomy and chemotherapy had statistically significantly better SF-36 physi-

**Table 3.** Characteristics of patients by treatment strategy (N = 558)\*

	Treatment strategy, No. (%)					P value
	Total N = 558	Mastectomy n = 71	Lumpectomy n = 208	Mastectomy + chemotherapy n = 112	Lumpectomy + chemotherapy n = 167	
Age at survey, y						
Mean $\pm$ SD	56.9 $\pm$ 11.3	61.8 $\pm$ 12.1	61.2 $\pm$ 10.4	51.9 $\pm$ 10.7	52.8 $\pm$ 9.5	<.001
<50	145 (26)	10 (14)	27 (13)	51 (46)	57 (34)	<.001
50-59	205 (37)	21 (30)	70 (34)	33 (30)	81 (49)	
60-69	125 (22)	20 (28)	64 (31)	19 (17)	22 (13)	
$\geq$ 70	81 (15)	19 (27)	46 (22)	8 (7)	7 (4)	
Days from surgery to survey, mean $\pm$ SD	173.8 $\pm$ 84.4	74.2 $\pm$ 41.6	120.3 $\pm$ 29.6	226.8 $\pm$ 79.9	247.8 $\pm$ 49.8	<.001
Race/ethnicity						
White	480 (86)	62 (87)	178 (86)	95 (85)	145 (87)	.99
African American	37 (7)	4 (6)	15 (7)	7 (6)	11 (7)	
Other	39 (7)	5 (7)	13 (6)	10 (9)	11 (7)	
Marital status						
Married or committed relationship	389 (70)	49 (69)	129 (62)	88 (79)	123 (74)	<.001
Divorced/separated	62 (11)	12 (17)	29 (14)	7 (6)	14 (8)	
Widowed	55 (10)	9 (13)	32 (16)	5 (4)	9 (5)	
Never married	52 (9)	1 (1)	18 (9)	12 (11)	21 (13)	
Educational level						
Post college	200 (36)	22 (31)	80 (38)	40 (36)	58 (35)	.81
College graduate	153 (27)	17 (24)	57 (27)	32 (29)	47 (28)	
Some or junior college	135 (24)	18 (26)	50 (24)	26 (23)	41 (25)	
Less than college	70 (13)	14 (20)	21 (10)	14 (13)	21 (13)	
Household income						
<\$30 000	62 (11)	13 (20)	24 (12)	9 (8)	16 (10)	.08
\$30 000-\$60 000	139 (26)	21 (31)	59 (29)	27 (25)	32 (20)	
\$60 000-\$100 000	167 (31)	18 (27)	62 (31)	33 (31)	54 (33)	
$\geq$ \$100 000	172 (32)	15 (22)	56 (28)	40 (37)	61 (37)	
Employed, at least part time	314 (57)	33 (47)	116 (57)	63 (57)	102 (61)	.23
Comorbidities						
None	127 (23)	21 (30)	33 (16)	30 (27)	43 (26)	.02
1 or more	431 (77)	50 (70)	175 (84)	82 (73)	124 (74)	
Currently taking tamoxifen	304 (54)	42 (59)	133 (64)	47 (42)	82 (49)	<.001
Type of chemotherapy*						
MF	1 (0)	—	—	0 (0)	1 (1)	.99
CMF	47 (17)	—	—	7 (6)	40 (24)	.006
CMF + A	2 (1)	—	—	1 (1)	1 (1)	.99
AC	127 (46)	—	—	53 (47)	74 (44)	.62
FAC or CAF	6 (2)	—	—	3 (3)	3 (2)	.69
AC + T	73 (26)	—	—	39 (35)	34 (20)	.007
Other	48 (17)	—	—	22 (20)	26 (16)	.38
Underwent reconstructive surgery	85 (15)	29 (41)	0 (0)	55 (49)	1 (1)	<.001
Underwent radiation therapy	380 (69)	5 (7)	187 (91)	38 (34)	150 (91)	<.001
Geographic site						
Los Angeles	279 (50)	32 (45)	107 (51)	56 (50)	84 (50)	
Washington, DC	160 (29)	14 (20)	63 (30)	28 (25)	55 (33)	.03
Kansas	119 (21)	25 (35)	38 (18)	28 (25)	28 (17)	

\*MF = methotrexate and 5-fluorouracil; CMF = cyclophosphamide, methotrexate, and 5-fluorouracil; CMF-A = cyclophosphamide, methotrexate, and 5-fluorouracil followed by doxorubicin; AC = doxorubicin and cyclophosphamide; FAC or CAF = 5-fluorouracil, doxorubicin, and cyclophosphamide; AC + T = doxorubicin and cyclophosphamide followed by a taxane. Not all numbers and percentages total column headings due to missing data.

**Table 4.** Quality-of-life data by treatment strategy (N = 558)\*

	Treatment strategy, adjusted mean (95% CI)				A v. B F test P value	C v. D F test P value	A v. B F test P value	C v. D F test P value
	Mastectomy only (A) n = 71	Lumpectomy only (B) n = 208	Mastectomy + chemotherapy (C) n = 112	Lumpectomy + chemotherapy (D) n = 167				
	SF-36 scales†							
Physical functioning at registration	66.2 (59.8 to 72.6)	76.7 (73.1 to 80.3)	67.7 (62.9 to 72.4)	81.0 (76.6 to 85.3)	<.001‡	.002‡	<.001‡	
Mental health at registration	71.6 (66.5 to 76.6)	67.7 (64.8 to 70.5)	71.5 (67.7 to 75.2)	73.2 (69.8 to 76.6)	.08	.13	.47	
Physical functioning	70.5 (64.0 to 77.0)	78.7 (75.0 to 82.3)	72.9 (68.1 to 77.8)	78.4 (73.9 to 82.8)	.05‡,§	.02§	.075	
Mental health	77.6 (72.8 to 82.3)	75.0 (72.3 to 77.6)	75.1 (71.6 to 78.7)	76.5 (73.3 to 79.7)	.58	.29	.54	
Role function, physical	42.4 (30.1 to 54.6)	59.3 (52.4 to 66.2)	34.8 (25.6 to 43.9)	52.0 (43.7 to 60.3)	<.001‡	.008‡	.003‡	
Role function, emotional	79.9 (68.3 to 91.4)	68.2 (61.7 to 74.7)	63.8 (55.1 to 72.4)	70.5 (62.6 to 78.3)	.08	.05	.22	
Vitality	53.9 (47.2 to 60.6)	53.4 (49.6 to 57.1)	46.6 (41.6 to 51.5)	51.5 (47.0 to 56.1)	.21	.88	.11	
Pain	63.1 (56.6 to 69.6)	73.3 (69.6 to 76.9)	73.7 (68.8 to 78.5)	74.5 (70.1 to 78.9)	.02§	.002‡	.77	
Social functioning	77.2 (70.4 to 84.0)	82.7 (78.9 to 86.6)	72.6 (67.5 to 77.6)	75.0 (70.3 to 79.6)	.02§	.11	.45	
General health perceptions	70.9 (65.4 to 76.4)	73.0 (69.9 to 76.1)	65.0 (60.9 to 69.1)	72.3 (68.6 to 76.1)	.02§	.45	.005	
MOS PCS	41.2 (38.3 to 44.1)	47.1 (45.4 to 48.7)	42.7 (40.5 to 44.9)	46.0 (44.1 to 48.0)	<.001‡	<.001‡,§	.015§	
MOS MCS	52.3 (49.4 to 55.2)	48.8 (47.2 to 50.5)	47.8 (45.6 to 50.0)	48.6 (46.6 to 50.6)	.07	.02	.55	
Other scales								
CES-D	9.2 (6.6 to 11.8)	10.4 (9.0 to 11.9)	12.1 (10.2 to 14.0)	10.1 (8.3 to 11.8)	.16	.35	.09	
PANAS, positive	34.7 (32.4 to 37.0)	34.1 (32.8 to 35.4)	33.2 (31.5 to 34.9)	33.0 (31.4 to 34.6)	.75	.61	.87	
PANAS, negative	15.9 (14.2 to 17.7)	16.5 (15.5 to 17.5)	17.9 (16.6 to 19.2)	16.3 (15.1 to 17.5)	.14	.51	.052	
RDAS (n = 393)	51.8 (48.7 to 54.9)	47.9 (46.1 to 49.7)	50.3 (48.3 to 52.5)	50.4 (48.3 to 52.4)	.04§	.01‡	.99	
Ladder of Life	7.7 (7.2 to 8.1)	7.7 (7.4 to 7.9)	7.0 (6.6 to 7.3)	7.4 (7.1 to 7.7)	.04§	.98	.04	

\*Adjusted means and 95% confidence intervals (CIs), controlling for site (Los Angeles/Washington, DC/Kansas), age at baseline (years), time since surgery (days), having received immediate reconstruction (yes versus no), and marital status (married versus not married). All data reported are from the survey questionnaire at the end of treatment with the exception of the registration SF-36 Physical Functioning and Mental Health scales that were administered by telephone 1 month after surgery. MOS PCS = Medical Outcomes Study Physical Component Summary Scale; MOS MCS = Medical Outcomes Study Mental Component Summary Scale; CES-D = Center for Epidemiologic Studies–Depression Scale; PANAS = Positive and Negative Affect Schedule; RDAS = Revised Dyadic Adjustment Scale.

†All of the SF-36 scores range from 0 to 100, with 0 being the lowest score and 100 being the highest. For the PCS and MCS scales, a score of 50 equals the mean score for the general population of healthy women, and a score of 10 points higher or lower is equivalent to one standard deviation in the reference population.

‡Remains statistically significant with a false discovery rate of 5%.

§Remains statistically significant with a false discovery rate of 10%.

||CES-D scores range from 0 to 60, with higher scores indicating more depressive symptoms; PANAS positive and negative scores range from 0 to 50, with higher scores indicating higher positive affect and higher negative affect, respectively; RDAS scores range from 0 to 69, with higher scores indicating better adjustment; the Ladder of Life scores range from 1 to 10, with higher scores indicating better quality of life.

cal functioning scores than women who had a mastectomy and chemotherapy ( $P < .001$ ), but there was no statistically significant difference in emotional well-being scores ( $P = .13$  for women who had mastectomy only;  $P = .47$  for women who had mastectomy and chemotherapy). The difference in physical functioning was not seen in earlier studies that compared the two surgical procedures (4,5,45,46) and led us to consider the two surgical groups separately.

At the end of primary treatment, differences in SF-36 scores persisted by surgical group, with PCS scores being statistically significantly lower among women who had a mastectomy than among those who had a lumpectomy ( $P < .001$  for women who had surgery only, and  $P = .015$  for women who had surgery and chemotherapy). Among patients who did not receive chemotherapy, those who had a mastectomy had statistically significantly lower SF-36 physical functioning ( $P = .02$ ), pain ( $P = .002$ ), and role function-physical ( $P = .008$ ) scores than patients who had a lumpectomy, but they had statistically significantly higher MCS scores ( $P = .02$ ). Among patients who received chemotherapy, those who had a mastectomy had statistically significantly lower SF-36 role function-physical ( $P = .003$ ) and general health perceptions ( $P = .005$ ) scores than those who had a lumpectomy. Interestingly, there was no statistically significant difference between vitality scores among patients who received chemotherapy and those of patients who did not;

however, adjusted mean vitality scores for all of the treatment groups are approximately one-half of one standard deviation below scores for age-matched healthy women without cancer, suggesting a decrement in energy associated with cancer treatment (28).

Across all four patient groups at the end of primary therapy, there were no statistically significant differences in any of the mental health scales of the SF-36, consistent with the other measures of depressive mood and affect (Table 4). The percentage of women with CES-D scores of 16 or higher ranged from 16.9% in the mastectomy-without-chemotherapy group to 27.7% in the mastectomy-with-chemotherapy group (chi-square  $P = .41$  for unadjusted scores), with these data being comparable to those of outpatients with other medical illnesses (47). The RDAS scores in all four groups were within the normal range, but those for patients in the lumpectomy-only group were slightly lower than those for patients in the other three groups. In the surgery-only groups, patients who had a mastectomy scored better on the RDAS than those who had a lumpectomy ( $P = .01$ ). Global ratings of QOL were lower for patients who had a mastectomy with chemotherapy than for patients in the other treatment groups ( $P = .04$ ).

### Sexual Functioning

Overall, 60% of the women reported being sexually active at the end of their breast cancer treatments (Table 5); how-

**Table 5.** Sexual activity and problems reported at the end of primary treatment for breast cancer by treatment strategy

	Treatment strategy					P value
	Total sample N = 558	Mastectomy only n = 71	Lumpectomy only n = 208	Mastectomy + chemotherapy n = 112	Lumpectomy + chemotherapy n = 167	
% currently sexually active	60.0	50.0	50.5	66.4	71.5	<.001
% postmenopausal at diagnosis	63.7	77.5	76.4	48.2	52.4	<.001
MOS Sexual Problems score, mean (95% CI)	21.0 (18.5 to 23.5)	16.4 (9.7 to 23.1)	15.4 (11.6 to 19.3)	27.4 (21.2 to 33.6)	25.2 (20.7 to 29.7)	<.001*
Respondents who endorsed items from MOS sexual problems as somewhat or very much a problem, %†						
Lack of sexual interest	23.4	17.2	16.3	33.6	26.9	.002
Inability to relax and enjoy sex	16.7	12.5	12.6	21.5	20.0	.11
Difficulty with arousal	20.5	14.1	16.3	24.1	25.6	.07
Difficulty with orgasm	17.8	14.1	13.1	22.2	21.9	.08
Difficulty with lubrication‡	21.1	12.5	14.2	26.2	29.4	<.001
Impact of breast cancer on sex life, % respondents						<.001
Negative	34.9	25.4	18.2	50.9	48.4	
No impact	57.6	63.5	73.7	40.7	46.6	
Positive	7.6	11.1	8.1	8.3	5	

\*P value for analysis of variance. The Medical Outcomes Study (MOS) Sexual Problems Scale ranges from 0 to 100, with higher scores indicating more problems.

†Each item is a separate question on the MOS Sexual Problems Scale.

‡This is an additional item that was added with the same response format as that used for the MOS Sexual Problems Scale.

ever, this percentage varied among the treatment groups, with those who received chemotherapy being more sexually active than those who did not ( $P < .001$ ). This difference is likely related to the younger age of women in the chemotherapy treatment groups. Respondents were asked to describe the possible reasons for limitations in their sexual activity. More than one-third of the respondents reported no limitations. However, several limitations were reported that ranged from not having a partner (24.4% of respondents overall) to several kinds of partner-associated problems (4.7% reported partner was too tired, 7.2% reported that partner was not interested, and 8.8% reported that partner has physical problem that precludes sexual activity). Patients in the two chemotherapy groups reported more sexual problems than did patients in the non-chemotherapy groups on the MOS Sexual Problems Scale ( $P < .001$ ). The mean score (21.0, 95% CI = 18.5 to 23.5) for the whole patient population was slightly lower (i.e., fewer problems) than the score that has been reported for women with chronic medical conditions (mean  $\pm$  SD = 24.9  $\pm$  32.1) (42); however, our findings are consistent with other work on sexual functioning in breast cancer survivors (12,15,48). Moderate to severe lack of sexual interest was reported by 23.4% of women overall, with greater frequency among women in the two chemotherapy groups ( $P = .002$ ). Vaginal lubrication problems were more severe among women who received chemotherapy than among those who did not ( $P < .001$ ), consistent with previous studies (12,49). Approximately 50% of the women who received chemotherapy reported that breast cancer had a negative effect on their sex life, statistically significantly more than the 18%–25% of the women who had not received chemotherapy ( $P < .001$ ).

We also explored the relationship between sexual problems and a change in menopausal status as a result of breast cancer treatment (data not shown). Before breast cancer, 63.7% of the women overall were postmenopausal. Among

those who were premenopausal at diagnosis, 57.1% reported a change in menstrual periods after the breast cancer diagnosis (12.1% reported that their periods became irregular, 7.6% reported that their periods stopped for >3 months but resumed, and 37.4% reported that their periods stopped and had not resumed). A change in menopausal status was reported more frequently by women who received chemotherapy—who were younger and more often premenopausal at diagnosis—than by those who did not.

Comparing the unadjusted MOS Sexual Problems mean scores of women in the surgery-plus-chemotherapy groups with those of the women in the surgery-only groups, we found that patients in the surgery-only groups had statistically significantly less sexual dysfunction than patients in the surgery-plus-chemotherapy groups ( $P < .001$ ). Regressing the MOS Sexual Problems score onto potential predictors used in previous research (48) (time since surgery, surgery type, menopausal transition status, receiving chemotherapy, currently being on tamoxifen, and having immediate reconstruction), we found that older age at baseline ( $\beta = -0.26$ ), not being currently sexually active ( $\beta = -6.28$ ), and better mental health ( $\beta = -0.20$ ) statistically significantly predicted less sexual dysfunction, whereas greater difficulty with lubrication ( $\beta = 14.27$ ) and a report of a negative impact of breast cancer on sex life ( $\beta = 11.11$ ) statistically significantly predicted much more sexual dysfunction. When limiting the analysis to only those who were currently sexually active, better mental health persisted in the model, predicting less sexual dysfunction, and difficulty with lubrication and a negative impact of breast cancer on sex life predicted more sexual dysfunction. Being unhappy with one's appearance did not predict the MOS Sexual Problems scores in either sub-analysis (data not shown). These findings are consistent with those from our study on sexual functioning in long-term breast cancer survivors (48).



## Symptoms at the End of Primary Treatment

We assessed a wide range of symptoms associated with the end of primary treatment. We found that 61% of patients reported being unhappy with their appearance, 60% reported having hot flashes, 60% reported having aches and pains, 56% reported forgetfulness, 56% reported breast sensitivity, 54% reported joint pains, and 51% reported muscle stiffness. Compared with patients who did not have chemotherapy, patients who had chemotherapy more often reported hot flashes, vaginal dryness, pain with intercourse, forgetfulness, night sweats, swelling in the hands and feet, difficulty concentrating, being easily distracted, and being more excitable. Breast sensitivity was reported more frequently among patients who had a lumpectomy than among patients with mastectomy, and decreased arm motion was reported more frequently among patients who had a mastectomy and who did not receive chemotherapy than among patients with lumpectomy or mastectomy who received chemotherapy (data not shown). Of all patients, those in the lumpectomy-without-chemotherapy group had the lowest reported rate of being unhappy with their appearance.

To explore the extent to which symptoms might be contributing to the assessment of well-being, we examined a correlation matrix between individual symptom severity scores and the SF-36 scales by treatment group. We then selected symptoms whose scores were statistically significantly ( $P < .05$ ) correlated with the PCS and MCS scores and performed a multiple linear regression analysis controlling for treatment group, age at baseline, and site to determine the extent to which the self-reported symptoms statistically significantly predicted either the PCS or MCS scores (Table 6). Breast sensitivity, aches and pains, mus-

cle stiffness, unhappiness with one's appearance, and numbness/tingling were statistically significant predictors for PCS. Forgetfulness, short temper, tendency to take naps, difficulty concentrating, and early awakening were statistically significant predictors for MCS.

For most of these symptoms, the parameter estimates ranged from  $-1$  to  $-2$ , indicating that a one-point increase in severity of the symptom was associated with a one- to two-point decrease ( $0.1$ – $0.2$  SD) in either MCS or PCS. However, some symptoms had larger effects on either MCS or PCS. For example, a one-point increase in the severity of the symptom "difficulty concentrating" was associated with a 3.81-point decrease in MCS; a one-point increase in severity of the symptom "aches and pains" was associated with a 2.41-point decrease in PCS. Thus, the severity of symptoms at the end of primary treatment is statistically significantly associated with a woman's self-assessment of mental and physical health.

## DISCUSSION

In this article, we have described the health status and QOL of a large and diverse sample of women at the end of their primary treatments for breast cancer. We believe that this is one of the largest and most comprehensive assessments of such a patient population to date and that this information will be of value to many patients who currently receive treatment for breast cancer. Although QOL has been extensively studied during the first year after a breast cancer diagnosis ( $2$ – $5$ , $50$ – $52$ ) and has generally focused on the first few months after diagnosis, most studies were done when adjuvant therapy was much less toxic and protracted than therapies used currently. Although our report is descriptive, it provides a window on contemporary

**Table 6.** Regression analysis of baseline Physical Component Score (PCS) and Mental Component Score (MCS) on breast cancer symptoms among women enrolled in the Moving Beyond Cancer randomized trial

Variable	Parameter estimate (95% confidence interval)	<i>P</i> value	Adjusted <i>R</i> <sup>2</sup>
<b>PCS</b>			
Intercept	57.85 (53.17 to 62.55)	<.01	0.34
Treatment (mastectomy only as referent group)			
Lumpectomy only	4.98 (2.71 to 7.25)	<.01	
Mastectomy + chemotherapy	0.52 (–2.02 to 3.06)	.69	
Lumpectomy + chemotherapy	4.47 (2.09 to 6.85)	<.01	
Age at baseline	–0.14 (–0.26 to –0.08)	<.01	
Site (Los Angeles as referent group)			
Washington, DC	–1.64 (–3.23 to –0.06)	.04	
Kansas site	–1.95 (–3.73 to –0.17)	.03	
Breast sensitivity	–1.32 (–1.93 to –0.71)	<.01	
Aches and pains	–2.41 (–3.11 to –1.71)	<.01	
Muscle stiffness	–1.26 (–1.95 to –0.57)	<.01	
Unhappy with appearance	–0.91 (–1.46 to –0.35)	.04	
Numbness, tingling	–0.85 (–1.58 to –0.13)	.02	
<b>MCS</b>			
Intercept	46.67 (41.99 to 51.37)	<.01	0.37
Treatment (mastectomy only as referent group)			
Lumpectomy only	–2.03 (–4.21 to 0.16)	.07	
Mastectomy + chemotherapy	0.61 (–1.89 to 3.11)	.63	
Lumpectomy + chemotherapy	0.52 (–1.80 to 2.84)	.66	
Age at baseline	0.14 (0.08 to 0.21)	<.01	
Site (Los Angeles as referent group)			
Washington, DC	0.48 (–1.09 to 2.06)	.55	
Kansas	0.15 (–1.62 to 1.92)	<.87	
Forgetfulness	0.95 (0.12 to 1.79)	.03	
Short temper	–2.00 (–2.89 to –1.12)	<.01	
Tendency to take naps	–2.05 (–2.68 to –1.42)	<.01	
Difficulty concentrating	–3.81 (–4.70 to –2.92)	<.01	
Early awakening	–0.84 (–1.44 to –0.25)	<.01	

treatments for breast cancer, which for some women did not end until 9–10 months after surgery.

We found that, at the end of treatment, women reported a normal level of mental health, with little evidence of being depressed or having negative affect, despite prolonged and complex treatments. However, they reported a broad range of physical symptoms, including hot flashes, night sweats, aches and pains, and vaginal dryness. By contrast, women, especially those who had a mastectomy, reported physical functioning scores at the end of primary treatment that were much lower (.29 to .88 SD below the mean on the PCS) than scores reported for a general population (32). Although we do not have pretreatment scores for the actual women in our study, these decreases in the PCS scores likely reflect the acute effects of primary treatment, because breast cancer survivors 1–5 years after diagnosis have normal PCS scores, regardless of treatment type (13). Consistent with other research on sexual functioning after breast cancer (5,12,48,53), more sexual problems, specifically difficulties with sexual interest, lubrication, and pain with intercourse, were reported by patients who received adjuvant chemotherapy than by patients who received surgery only. Our work with long-term breast cancer survivors (i.e., those beyond the first year after surgery) demonstrates that these problems persist and may worsen with time and aging (11,48).

What is the clinical significance of these findings? In general, oncology clinicians prepare women for the acute toxicities of breast cancer treatments (e.g., nausea, vomiting, alopecia, and fatigue), but clinicians have had only limited data on the physical and psychosocial sequelae of primary treatments. Indeed, little is known about the pattern of recovery after the end of treatment. Experienced clinicians often tell breast cancer patients that it takes approximately as much time to recover from the effects of treatment as it does to receive the treatments; however, this advice is not based on scientific data. From this study, we now have an accurate description of how women are functioning at the end of primary treatment and, because we have collected longitudinal data on this cohort over 12 months as part of the randomized intervention trial, future results from the MBC Study will provide additional data on the recovery process.

How should these data be used in clinical practice? It is clear that more attention must be paid to the symptoms that women report at the end of treatment because they are associated with poorer physical and emotional well-being. “Aches and pains” and “difficulty concentrating” were two symptoms whose severity contributed substantially to decreased functioning in our population. The etiology of the “aches and pains” is uncertain, but they may be age-related, related to the changes in hormonal status (i.e., stopping hormone replacement, becoming menopausal, or receiving aromatase inhibitor therapy), or associated with particular chemotherapy treatments (i.e., post-chemotherapy rheumatism). More effective management of musculoskeletal complaints in this patient population is clearly needed. “Difficulty concentrating” was noted among patients in both surgery groups who received chemotherapy and among patients who had a lumpectomy only (data not shown). Although this symptom may be related to chemotherapy-associated cognitive dysfunction (54–58), it may also be associated with depressive symptoms or intrusive thoughts regarding the cancer (54). The etiology of cognitive complaints in breast cancer patients is uncertain and is under active investigation (59). Independent of causation,

in our cohort of well-educated and highly functioning women, the perception of having difficulty concentrating statistically significantly contributed to a decrease in emotional functioning. Further research is needed to understand the causal mechanisms of cognitive complaints and to identify who is at risk for changes in cognitive function after breast cancer treatment.

In this study, we observed statistically significant differences in physical functioning within a month after surgery (before radiation therapy or chemotherapy treatments) between women who had a mastectomy and women who had a lumpectomy. To the best of our knowledge, this is the first time a statistically significant difference in physical functioning has been noted for these two surgical procedures [see (2,4,5) for mastectomy versus lumpectomy comparison 1 month after surgery]. At registration, the physical-functioning scores for patients who had a mastectomy were approximately 0.5 standard deviations lower than the population mean for healthy women and statistically significantly lower than the scores for patients who had a lumpectomy. Although Maunsell et al. (51) had previously reported a finding of fewer arm problems in women without an axillary dissection, our results were unexpected and require further explanation. In our study, decreased arm motion was reported frequently in patients who had a mastectomy (data not shown), and we hypothesize that the better physical functioning associated with lumpectomy may relate to earlier detection (small tumors with limited breast surgery), the more widespread use of sentinel lymph node procedures, and limited axillary dissections associated with this surgical procedure. To examine this possibility, we are obtaining detailed information on the specific surgical procedures performed in these women. In our cohort, immediate reconstruction was used more frequently in patients who had a mastectomy than in patients in our earlier studies (5,12); however, there was no statistically significant difference in physical functioning between patients who had a mastectomy with and without immediate reconstruction (data not shown).

At the end of primary treatment for breast cancer, women in this study reported decreased energy and many treatment-associated symptoms, accounting for the substantial decreases in physical and emotional functioning. However, despite these symptoms, women’s emotional functioning was generally in the normal range for healthy women, with little evidence of depressed mood or negative affect. Although this finding was reassuring and contrary to what had been expected from review of the literature, group mean data may mask the experience of those individual women with breast cancer who experience more emotional distress than average and may be less resilient in responding to the diagnosis and treatment than other women with this disease. These issues will be explored in detail in the MBC Study as we examine other data from the baseline survey and the outcomes from the randomized intervention trial during the follow-up year.

## REFERENCES

- (1) Jemal A, Murray T, Samuels A, Ghafoor A, Ward E, Thun MJ. Cancer statistics, 2003. *CA Cancer J Clin* 2003;53:5–26.
- (2) Maunsell E, Brisson J, Deschenes L. Psychological distress after initial treatment for breast cancer: a comparison of partial and total mastectomy. *J Clin Epidemiol* 1989;42:765–71.

- (3) Vinokur AD, Threatt BA, Vinokur-Kaplan D, Satariano WA. The process of recovery from breast cancer for younger and older patients. Changes during the first year. *Cancer* 1990;65:1242–54.
- (4) Ganz PA, Schag CC, Polinsky ML, Heinrich RL, Flack VF. Rehabilitation needs and breast cancer: the first month after primary therapy. *Breast Cancer Res Treat* 1987;10:243–53.
- (5) Ganz PA, Schag AC, Lee JJ, Polinsky ML, Tan SJ. Breast conservation versus mastectomy. Is there a difference in psychological adjustment or quality of life in the year after surgery? *Cancer* 1992;69:1729–38.
- (6) Meyerowitz BE, Sparks FC, Spears IK. Adjuvant chemotherapy for breast carcinoma: psychosocial implications. *Cancer* 1979;43:1613–8.
- (7) Meyerowitz BE. Psychosocial correlates of breast cancer and its treatments. *Psychol Bull* 1980;87:108–31.
- (8) Meyerowitz BE, Watkins IK, Sparks FC. Quality of life for breast cancer patients receiving adjuvant chemotherapy. *Am J Nurs* 1983;83:232–5.
- (9) Andrykowski MA, Curran SL, Studts JL, Cunningham L, Carpenter JS, McGrath PC, et al. Psychosocial adjustment and quality of life in women with breast cancer and benign breast problems: a controlled comparison. *J Clin Epidemiol* 1996;49:827–34.
- (10) Carpenter JS, Andrykowski MA, Sloan P, Cunningham L, Cordova MJ, Studts JL, et al. Postmastectomy/postlumpectomy pain in breast cancer survivors. *J Clin Epidemiol* 1998;51:1285–92.
- (11) Ganz PA, Coscarelli A, Fred C, Kahn B, Polinsky ML, Petersen L. Breast cancer survivors: psychosocial concerns and quality of life. *Breast Cancer Res Treat* 1996;38:183–99.
- (12) Ganz PA, Rowland JH, Desmond K, Meyerowitz BE, Wyatt GE. Life after breast cancer: understanding women's health-related quality of life and sexual functioning. *J Clin Oncol* 1998;16:501–14.
- (13) Ganz PA, Rowland JH, Meyerowitz BE, Desmond KA. Impact of different adjuvant therapy strategies on quality of life in breast cancer survivors. *Recent Results Cancer Res* 1998;152:396–411.
- (14) Bower JE, Ganz PA, Desmond KA, Rowland JH, Meyerowitz BE, Belin TR. Fatigue in breast cancer survivors: occurrence, correlates, and impact on quality of life. *J Clin Oncol* 2000;18:743–53.
- (15) Ganz PA, Desmond KA, Leedham B, Rowland JH, Meyerowitz BE, Belin TR. Quality of life in long-term, disease-free survivors of breast cancer: a follow-up study [published erratum appears in *J Natl Cancer Inst* 2002;94:463]. *J Natl Cancer Inst* 2002;94:39–49.
- (16) Eifel P, Axelson JA, Costa J, Crowley J, Curran WJ Jr, Deshler A, et al. National Institutes of Health Consensus Development Conference Statement: adjuvant therapy for breast cancer, November 1–3, 2000. *J Natl Cancer Inst* 2001;93:979–89.
- (17) Gelber RD, Goldhirsch A. A new endpoint for the assessment of adjuvant therapy in postmenopausal women with operable breast cancer. *J Clin Oncol* 1986;4:1772–9.
- (18) Henderson IC, Berry DA, Demetri GD, Cirrincione CT, Goldstein LJ, Martino S, et al. Improved outcomes from adding sequential Paclitaxel but not from escalating Doxorubicin dose in an adjuvant chemotherapy regimen for patients with node-positive primary breast cancer. *J Clin Oncol* 2003;21:976–83.
- (19) Citron ML, Berry DA, Cirrincione C, Hudis C, Winer EP, Gradishar WJ, et al. Randomized trial of dose-dense versus conventionally scheduled and sequential versus concurrent combination chemotherapy as postoperative adjuvant treatment of node-positive primary breast cancer: first report of Intergroup Trial C9741/Cancer and Leukemia Group B Trial 9741 [published erratum appears in *J Clin Oncol* 2003;21:2226]. *J Clin Oncol* 2003;21:1431–9.
- (20) Ward SE, Viergutz G, Tormey D, deMuth J, Paulen A. Patients' reactions to completion of adjuvant breast cancer therapy. *Nurs Res* 1992;41:362–6.
- (21) Fertig DL. Depression in patients with breast cancer: prevalence, diagnosis, and treatment. *Breast J* 1997;3:292–302.
- (22) Tross S, Holland JC. Psychological sequelae in cancer survivors. In: Holland JC, Rowland JH, editors. *Handbook of psychooncology: psychological care of the patient with cancer*. New York (NY): Oxford University Press; 1989. p. 101–16.
- (23) Beisecker A, Cook MR, Ashworth J, Hayes J, Brecheisen M, Helmig L, et al. Side effects of adjuvant chemotherapy: perceptions of node-negative breast cancer patients. *Psychooncology* 1997;6:85–93.
- (24) Lethborg CE, Kissane D, Burns WI, Snyder R. "Cast adrift": the experience of completing treatment among women with early stage breast cancer. *J Psychosoc Oncol* 2000;18:73–90.
- (25) Green BL, Rowland JH, Krupnick JL, Epstein SA, Stockton P, Stern NM, et al. Prevalence of posttraumatic stress disorder in women with breast cancer. *Psychosomatics* 1998;39:102–11.
- (26) Maher EL. Anomic aspects of recovery from cancer. *Soc Sci Med* 1982;16:907–12.
- (27) Ware JE Jr, Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. *Med Care* 1992;30:473–83.
- (28) Ware JE Jr. SF-36 Health Survey. Manual and interpretation guide. Boston (MA): The Health Institute, New England Medical Center; 1993. p. 10:1–10:38.
- (29) Hays RD, Sherbourne CD, Mazel RM. The RAND 36-Item Health Survey 1.0. *Health Econ* 1993;2:217–27.
- (30) Cantril H. The pattern of human concerns. New Brunswick (NJ): Rutgers University Press; 1965.
- (31) Sears SR, Stanton AL, Kwan L, Krupnick JL, Rowland JH, Meyerowitz BE, et al. Recruitment and retention challenges in breast cancer survivorship research: results from a multisite, randomized intervention trial in women with early stage breast cancer. *Cancer Epidemiol Biomarkers Prev* 2003;12:1087–90.
- (32) Ware JE, Kosinski M, Keller SD. SF-36 physical and mental health summary scales: a user's manual. Boston (MA): The Health Institute; 1994. p. 8:1–8:42.
- (33) McDowell I, Newell C. Measuring health, a guide to rating scales and questionnaires. 2<sup>nd</sup> ed. New York (NY): Oxford University Press; 1996. p. 194–8.
- (34) Schag CA, Heinrich RL, Aadland RL, Ganz PA. Assessing problems of cancer patients: psychometric properties of the cancer inventory of problem situations. *Health Psychol* 1990;9:83–102.
- (35) Radloff LS. The CES-D scale: a self-report depression scale for research in the general population. *Appl Psychol Meas* 1977;1:385–401.
- (36) Roberts RE, Vernon SW. The Center for Epidemiologic Studies Depression Scale: its use in a community sample. *Am J Psychiatry* 1983;140:41–6.
- (37) Myers JK, Weissman MM. Use of a self-report symptom scale to detect depression in a community sample. *Am J Psychiatry* 1980;137:1081–4.
- (38) Day R, Ganz PA, Costantino JP, Cronin WM, Wickerham DL, Fisher B. Health-related quality of life and tamoxifen in breast cancer prevention: a report from the National Surgical Adjuvant Breast and Bowel Project P-1 Study. *J Clin Oncol* 1999;17:2659–69.
- (39) Watson D, Clark LA, Tellegen A. Development and validation of brief measures of positive and negative affect: the PANAS scales. *J Pers Soc Psychol* 1988;54:1063–70.
- (40) Busby DM, Christensen C, Crane DR, Larson JH. A revision of the dyadic adjustment scale for use with distressed and nondistressed couples: construct hierarchy and multidimensional scales. *J Marital Fam Ther* 1995;21:289–308.
- (41) Spanier GB. Measuring dyadic adjustment: new scales for assessing the quality of marriage and similar dyads. *J Marriage Fam* 1976;38:15–28.
- (42) Sherbourne CD. Social functioning: sexual problems measures. In: Stewart AL, Ware JE, editors. *Measuring functioning and well-being: the Medical Outcomes Study approach*. Durham (NC): Duke University Press; 1992. p. 195–204.
- (43) Ganz PA, Day R, Ware JE Jr, Redmond C, Fisher B. Base-line quality-of-life assessment in the National Surgical Adjuvant Breast and Bowel Project Breast Cancer Prevention Trial. *J Natl Cancer Inst* 1995;87:1372–82.
- (44) Benjamini Y, Hochberg Y. Controlling the false discovery rate: a practical and powerful approach to multiple testing. *J Royal Stat Soc Ser B* 1995;57:289–300.
- (45) Kiebert GM, de Haes JC, van de Velde CJ. The impact of breast-conserving treatment and mastectomy on the quality of life of early-stage breast cancer patients: a review. *J Clin Oncol* 1991;9:1059–70.
- (46) Wapnir IL, Cody RP, Greco RS. Subtle differences in quality of life after breast cancer surgery. *Ann Surg Oncol* 1999;6:359–66.
- (47) Coyne JC, Fechner-Bates S, Schwenk TL. Prevalence, nature, and comorbidity of depressive disorders in primary care. *Gen Hosp Psychiatry* 1994;16:267–76.

- (48) Ganz PA, Desmond KA, Belin TR, Meyerowitz BE, Rowland JH. Predictors of sexual health in women after a breast cancer diagnosis. *J Clin Oncol* 1999;17:2371–80.
- (49) Berglund G, Nystedt M, Bolund C, Sjoden PO, Rutquist LE. Effect of endocrine treatment on sexuality in premenopausal breast cancer patients: a prospective randomized study. *J Clin Oncol* 2001;19:2788–96.
- (50) Ganz PA, Schag CA, Cheng HL. Assessing the quality of life—a study in newly-diagnosed breast cancer patients. *J Clin Epidemiol* 1990;43:75–86.
- (51) Maunsell E, Brisson J, Deschenes L. Arm problems and psychological distress after surgery for breast cancer. *Can J Surg* 1993;36:315–20.
- (52) Fallowfield LJ, Hall A. Psychosocial and sexual impact of diagnosis and treatment of breast cancer. *Br Med Bull* 1991;47:388–99.
- (53) Berglund G, Nystedt M, Bolund C, Sjoden PO, Rutquist LE. Effect of endocrine treatment on sexuality in premenopausal breast cancer patients: a prospective randomized study. *J Clin Oncol* 2001;19:2788–96.
- (54) van Dam FS, Schagen SB, Muller MJ, Boogerd W, vd Wall E, Droogeleever Fortuyn ME, et al. Impairment of cognitive function in women receiving adjuvant treatment for high-risk breast cancer: high-dose versus standard-dose chemotherapy. *J Natl Cancer Inst* 1998;90:210–8.
- (55) Ganz PA. Cognitive dysfunction following adjuvant treatment of breast cancer: a new dose-limiting toxic effect? *J Natl Cancer Inst* 1998;90:182–3.
- (56) Brezden CB, Phillips KA, Abdoell M, Bunston T, Tannock IF. Cognitive function in breast cancer patients receiving adjuvant chemotherapy. *J Clin Oncol* 2000;18:2695–701.
- (57) Ahles TA, Saykin AJ, Furstenberg CT, Cole B, Mott LA, Skalla K, et al. Neuropsychologic impact of standard-dose systemic chemotherapy in long-term survivors of breast cancer and lymphoma. *J Clin Oncol* 2002;20:485–93.
- (58) Phillips KA, Bernhard J. Adjuvant breast cancer treatment and cognitive function: current knowledge and research directions. *J Natl Cancer Inst* 2003;95:190–7.
- (59) Tannock IF, Ahles TA, Ganz PA, van Dam FS. Cognitive impairment associated with chemotherapy for cancer: report of a workshop. *J Clin Oncol*. In press 2004.

## NOTES

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