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Improvement in Self-Reported Physical Health Predicts Longer Survival Among Women with a History of Breast Cancer

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Abstract

Purpose—Physical health-related quality of life scores have been, inconsistently, associated with breast cancer prognosis. This analysis examined whether *change* in physical health scores were related to outcomes in women with a history of breast cancer.

Methods—2343 breast cancer survivors in a randomized diet trial provided self-reported assessment of physical health-related quality of life at baseline and year 1. Based on change in physical health score, participants were grouped into subpopulations of decreased physical health, no/minimal changes, and increased physical health. Cox regression analysis assessed whether change in physical health (from baseline to year 1) predicted disease-free and overall survival; hazard ratio (HR) was the measure of association.

Results—There were 294 additional breast cancer events and 162 deaths among women followed for 7.3 years. Improvements in physical health were associated with younger age, lower BMI, being employed, not receiving tamoxifen, lower physical activity, and lower baseline physical and mental health. There was no association of change in physical health with additional breast cancer events or mortality among women diagnosed ≤ 2 years before study enrollment. However, among women who entered the study >2 years post diagnosis, the HR for increased compared to decreased physical health was 0.38 (95% CI, 0.16 to 0.85) for all-cause mortality.

Conclusions—These results appear to support testing an intervention to improve physical health in breast cancer patients among patients after the acute stage of treatment.

Keywords

breast cancer; physical health; survival; mortality

INTRODUCTION

Worldwide, approximately 1.3 million women will be diagnosed with breast cancer annually and about 465,000 will die from the disease [1]. Improvements in diagnosis and treatment have led to longer survival of these patients and motivated intense research on factors that predict recurrence and mortality.

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CONFLICT OF INTEREST

All of the authors declare that there are no conflicts of interest for this paper.

Patient-reported measures, such as health-related quality of life (QOL), are important outcomes of treatment and are also prognostic factors for clinical outcomes [2]. Of the two health-related quality of life domains (mental health and physical health), research suggests that physical health may be more important for cancer prognosis. In the EPIC-Norfolk study of 10,000 female participants, a 142 % higher death rate was reported for women in the lowest, compared to the highest, quintile of physical functioning (a subscale of physical health) [3]. Kroenke et al found that among 40,337 healthy women from the Nurses Health Study aged 46–71 years, change in physical functioning predicted mortality. Specifically, in comparison to no change, severe decline in physical health was associated with a relative risk of mortality of 3.32 (95% CI 2.45, 4.50) whereas severe decline in mental health was associated with a relative risk of mortality of 1.86 (95% CI 1.17, 1.65)[4]. However, much less is known with regards to the association of physical health and breast cancer prognosis. One relatively small (n<275) study of breast cancer survivors reported that baseline health-related QOL did not predict survival [5]. Another a study of 275 women with newly diagnosed locoregional breast cancer found that physical health at baseline or one-year later was not associated with medical outcomes [6]. However, Kenne Sarenmalm et al. reported that deteriorating physical well-being was associated with increased risk of breast cancer recurrence (n=141) [7]. Among 2000 women with node-positive breast cancer, Coates et al. found that disease-free survival was not predicted by health-related QOL scores at baseline, 1 month or 18 months later; or by changes in these scores. The authors concluded that any prognostic significance of health-related QOL scores was either minimal or obscured by chemotherapy [8], which may be associated with transient declines in physical health related quality of life [9]. These inconsistent findings may be explained by inadequately powered studies, varying effects during different stages of breast cancer, or limitations in measures of physical health.

The Women's Healthy Eating and Living (WHEL) Study provided an opportunity to assess whether physical health predicted additional breast cancer events or all-cause mortality in a large sample of breast cancer survivors who were enrolled up to 4 years post diagnosis. An analysis of baseline patient ratings of QOL physical health scores on 2967 women with early stage breast cancer reported that the hazard ratios comparing persons with low (bottom two quintiles) to high (top three quintiles) physical health were 1.42 (95% CI, 1.16 to 1.75) for additional breast cancer events and 1.37 (95% CI, 1.08 to 1.74) for all-cause mortality [10]. Inference from this study is limited because it only examined prevalent physical health score at study enrollment and therefore it was not possible to examine cause and effect among factors correlated with physical health. Therefore, the hypothesis of an association between lower self-reported physical health score and study outcomes would be strengthened if it could be demonstrated that change in physical health scores were associated with health outcomes.

This report is a follow-up analysis in the WHEL Study to examine whether *change* in self-reported physical health predicts additional breast cancer events or mortality. As most studies to date are based on cross-sectional measurements, this manuscript capitalizes on an opportunity to prospectively assess change in the physical health component of quality of life. In addition, the possibility of confounding from chemotherapy treatment can be addressed because half of women were enrolled between 2–4 years post diagnosis, beyond chemotherapy-induced declines in physical health scores.

SUBJECTS AND METHODS

Study design and sample

Details of eligibility criteria, data collection, and assessment of outcomes in the WHEL trial have been reported [11]. Briefly, 3088 trial participants were enrolled at 7 study sites

between 1995 and 2000. Major eligibility criteria included diagnosis within past 4 years of primary operable invasive stage I (≥ 1 cm), II, or IIIA breast carcinoma categorized using American Joint Committee on Cancer (edition IV); age 18–70 years at the time of diagnosis; no current or planned chemotherapy; no evidence of recurrent disease or new breast cancer since completion of initial treatment; and no other cancer in the past 10 years. WHEL Study participants were mailed a series of questionnaires for completion before or at their baseline clinic visit.

At the baseline clinic visit, height and weight were measured, and body mass index (BMI, weight[kg]/height[m²]) was calculated. The Human Subjects Committee of the University of California, San Diego and all participating institutions approved the study procedures. As reported in 2007, among survivors of early stage breast cancer, adoption of a diet that was high in vegetables, fruit, and fiber and low in fat did not reduce additional breast cancer events or mortality during a 7.3-year follow-up period [12].

Physical health assessment

Physical health was assessed using the RAND-36-item Health Survey (SF-36), which summarizes four physical subscales (general health perceptions, physical functioning, bodily pain, role limitations due to physical health problems). The RAND-36 uses the same questions as the SF-36 with only minor scoring differences. All subscales have been shown to be reliable (Cronbach's $\alpha=0.75$ to 0.91) and to have adequate construct validity in a variety of diseased populations [13]. The 4 subscales were summarized into the physical health summary score (range=0–100; higher scores indicate better health). Women were grouped into 5 subpopulations by degree of change in physical health from baseline to Year 1 as follows: decrease of >15 points (11.4% of sample), decrease of 6 to 15 points (15.0%), minimal change of ± 5 points (40.8%), an increase of 6 to 15 points (18.8%), and increase of >15 points (14.0%). This grouping scheme was selected because it has good face validity, is easily interpretable, and is supported by research indicating that a 10-point difference in the SF-36 scores can be considered clinically meaningful [14]. However, in the multivariate model of physical health and outcomes, these 5 categories were collapsed into 3 (increased, minimal, or decreased change) because of insufficient numbers of events per physical health change category.

Other assessments

Standardized questionnaires administered at baseline ascertained age, race/ethnicity, educational achievement, employment and marital status, menopausal status, presence of hot flashes, smoking and alcohol intake. Mental health was assessed using the SF-36. Physical activity was assessed using a 9-item measure of physical activity from the Personal Habits Questionnaire [15], adapted from the Women's Health Initiative. Responses were converted to metabolic equivalent tasks (METs) in minutes per week. This scale was validated in the WHEL Study against a standard physical activity recall and accelerometer reading [16]. Data on the original tumor characteristics and treatment were abstracted from medical records. Specific variables include chemotherapy use (yes, no), anti-estrogen use (yes, no), tumor type (either or both lobular and ductal invasive, neither), tumor differentiation (well, moderate, poor), and cancer stage (I, IIA, IIB, IIIA, and IIIC).

Outcome ascertainment

The outcomes of interest were disease-free survival and overall survival. Disease-free survival is the time from WHEL Study enrollment (1995–2000) to development of an additional breast cancer event or the end of follow-up. An additional breast cancer event is defined as a recurrence from the original cancer or developing a new invasive breast cancer. Overall survival is the time from enrollment to reported/confirmed death from all causes

(i.e., mortality). Follow-up time was censored at the time of an additional breast cancer event, a participant's death, the last documented staff contact date, or study completion (June 1, 2006). New breast cancer events or death were confirmed by medical record review.

Statistical analyses

We used a cohort analysis after verifying that change in physical health did not vary by intervention group.¹ Univariate associations with change in physical health were examined for the following variables known to affect disease-free and overall survival: (1) patient characteristics (age, BMI, race/ethnicity, educational achievement, marital, employment, and menopausal status), (2) lifestyle (physical activity, smoking and alcohol consumption), (3) tumor characteristics (grade and stage), (4) treatment (radiotherapy, chemotherapy, and tamoxifen use), (5) baseline mental and physical health, and (6) years from diagnosis to study enrollment. Variables were included in the proportional hazards models if they were significantly associated with change in physical health.

Cox proportional hazard regression was used to determine the association of change in physical health with disease free survival and overall survival, after adjustment for age at randomization, menopausal status, employment status, chemotherapy, tamoxifen therapy, and baseline body weight, physical activity, mental and physical health score. The hazard ratio (HR) and the associated 95% confidence intervals were the measure of association. Interactions between change in physical health score and time from diagnosis to study entry were examined using likelihood ratio tests to test the hypothesis of confounding effects of recent breast cancer treatment (e.g., chemotherapy) on the association between physical health and breast cancer outcomes. All tests were two-sided and analyses were conducted in SAS version 9.2 (Cary, NC).

RESULTS

The final sample for this analysis was composed of women with physical health scores at baseline and year 1 (n=2343). Of the total WHEL sample (n=3088), 113 participants either had a cancer recurrence or died between baseline and year 1 and therefore are not included here. In addition, 632 participants had missing physical health scores at baseline and/or year 1. We conducted a sensitivity analysis including 581 participants who had either their baseline or 1 year scores missing (51 had missing physical health score at both time points), under the conservative assumption that their physical health scores did not change between these two time points. This analysis did not change the results or conclusions presented below.

In this sample of 2343 women, the mean (SD) baseline age of participants was 53.8 (8.8) years and BMI was 27.1 (5.9) kg/m²; 55.2% were college graduates and 86.6% were non-Hispanic white. The original tumors were Stage I (40.5%) or Stage IIA (32.8%) and poorly (33.7%) or moderately (41.4%) differentiated. Most women received some form of adjuvant therapy as part of their post-surgical treatment (68.4% tamoxifen; 68.3% chemotherapy, and 61.5% radiation therapy). Finally, 75.4% of tumors were ER-positive. At the end of the trial (June 01, 2006), there were 294 (12.5%) additional invasive breast cancer events and 162 (6.9%) deaths from all causes. Among the deaths, 125 (77.1%) were caused by breast cancer.

Overall, the physical health mean score statistically significantly increased from baseline (mean score 76.3) to Year 1 (mean score 77.2). Among the subscales of the physical health

¹The WHEL intervention group experienced a modest, but non-statistically significant increase in physical health in comparison to the control group (p=0.60).

summary score, the largest increases were seen for role limitation and general health (Figure 1).

As shown in Table 1, improvements in physical health were associated with the following baseline characteristics: younger age, lower BMI, being employed, not receiving tamoxifen, lower physical activity, lower baseline physical and mental health, and fewer years from diagnosis to study enrollment.

Investigation revealed that there was an interaction of change in physical health with years since the original cancer diagnosis and study enrollment. Specifically, in a model predicting mortality, the effect of change in physical health (adjusted for baseline physical health) was statistically significantly different among women diagnosed ≤ 2 years before study enrollment and women diagnosed > 2 years before enrollment (p-value 0.01 for interaction). Therefore, the model of change in physical health and cancer outcomes was stratified by years between cancer diagnosis and study enrollment.

As shown in Table 2, there was no association of change in physical health with additional breast cancer events or mortality among women diagnosed relatively soon before study enrollment (i.e., ≤ 2 years). However, among women who entered the WHEL study > 2 years post diagnosis, there was an approximate 60% reduction in risk of mortality for women who reported an increase compared to a decrease in physical health.

DISCUSSION

In this analysis of a large cohort of breast cancer survivors who were > 2 years post-diagnosis from their original breast cancer, increased physical health, as assessed by the SF-36 quality of life measure, was statistically significantly associated with decreased risk of death from all causes. Given that the multivariate model adjusted for baseline physical health, increases in physical health were associated with improvements in mortality regardless of a woman's baseline status. These results are consistent with two studies of change in health-related quality of life and mortality in middle-aged and older women [4] and older Spanish adults [17]. However, there are novel findings related to studying self-reported physical health in breast cancer survivors, as follows.

The finding that change in patient-rated physical health did not predict outcomes among women who had been diagnosed relatively recently (< 2 years before study enrollment) suggests that other cancer-related factors, such as systemic adjuvant therapy, overwhelmed any effect of change in physical health. Consistent with the literature, systemic therapy (chemotherapy or tamoxifen) was associated with decreased physical health [9, 18] and was controlled for in the analysis. Women who did not receive systemic therapy most likely had small tumors with favorable histology. Therefore the association between systemic therapy and decreased patient-rated physical health may reflect either self-report of symptoms associated with treatment or a poorer cancer prognosis (although we observed no association of physical health with cancer stage or grade). This information may be useful to clinicians and patients in discussing the risks of benefits of systemic adjuvant therapy, which is life-saving treatment that improves cancer survival. Note that among the 113 women who were excluded from the analysis because they had an event in the first year of the study, the mean (SD) time since diagnosis was only 0.50 (0.28) years compared with 7.11 (1.96) years for this study sample (n=2443). Therefore survivorship bias does not explain the findings regarding lag between diagnosis and change in physical health with reduced risk of mortality.

The mechanism by which self-reported physical health influences clinical outcomes is not known. It might be hypothesized that patients with declining self-reported physical health

reflects underlying systemic disease even when not yet diagnosed, given that there are limited data on the impact of micrometastases or tumor burden on physical well-being [7–8]. Poor physical health is correlated with other factors such as low levels of physical activity and increased pain that are associated with poor outcomes [19–22]. However, statistical adjustment for these variables produced only slight changes in the HRs reported here, which suggests that changes in self-reported physical health provides unique information enabling prediction of disease.

The vast majority of studies of physical health and breast cancer reported only on the global measure of physical health from the SF-36. However, in this study sample, the greatest change in physical health was seen for the role limitation subscale, which is composed of 4 questions regarding problems with work or other regular daily activities. Our data do not include objective measures of physical health and/or function, but rather rely on patient ratings of physical health. Whether objective measures of physical health are associated with breast cancer outcomes overall or specifically in women taking tamoxifen in our sample is unknown. Future studies should examine whether this self-reported domain is a more sensitive predictor of breast cancer outcomes than other subscales and explore objective measures of physical function/physical health.

This analysis has several strengths, including the use of a broad range of validated and standardized scales for mental and physical health and objective measures of height and weight. Treatment and tumor characteristics variables were obtained from patients' medical reports and charts and verified by an oncologist. Study outcomes triggered a medical record request and the diagnosis was confirmed by oncologist review. Reported deaths were verified by death certificates and vital status was checked with the Social Security Death Index. Outcome data were available on 96% of all those enrolled in the study [12]. This analysis included a large sample size of women with invasive early stage breast cancer and 7.3 years of follow-up. Nonetheless, after stratifying by change in physical health and years between cancer diagnosis and study enrollment, there was limited power in certain subgroups. We only observed change in physical health over a relatively short time frame (1 year) because of insufficient events over longer time frames. Future research should prospectively evaluate change in physical health over longer time frames such as 4 or 6 years.

In summary, self-reported improvement in physical health predicted longer survival among women diagnosed with early stage breast cancer only after the acute stage of treatment. In the recently reported RENEW trial, Morey et al. demonstrated that a diet and physical activity intervention can be effective in reducing the rate of decline of the physical health score in a population of elderly individuals with a history of cancer [21]. These results support testing an intervention to improve physical health in breast cancer patients after the acute treatment phase.

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P-values are from paired t-test between mean values from baseline and year 1

Figure 1. Mean physical health summary score and four sub-scales at baseline and at year 1 of follow-up in a cohort of breast cancer survivors from the Women's Healthy Eating and Living (WHEL) Study (N=2343).

Baseline characteristics associated with change in physical health (baseline to year 1) in a cohort of breast cancer survivors from the Women's Healthy Eating and Living Study (N=2343).

Table 1

Baseline Variable	Physical Health Change (baseline to year 1)					p-trend
	Decreased		Minimal Change		Increased	
	≤15 N = 266	-6 to -15 N = 352	-5 to +5 N = 955	+6 to 15 N = 441	>15 N = 329	
	Mean					
Age, years	55.7	54.9	53.5	53.2	53.2	0.0001
BMI ^a	28.7	27.6	26.4	27.0	27.3	<0.0001
Physical activity ^b	848	856	984	847	773	0.009
Physical health ^c	76.6	79.0	83.5	73.2	56.1	<0.0001
Mental health ^c	74.0	78.4	81.0	74.9	68.1	<0.0001
Years from diagnosis to study enrollment	2.03	2.01	2.05	1.84	1.73	<0.0001
	Percent					
White, Non-Hispanic	85.3	87.8	86.6	85.9	86.9	0.92
Post-menopausal	83.8	82.4	79.8	80.7	78.1	0.08
Obese	36.1	28.7	20.5	23.1	26.7	0.005
College graduate	50.7	51.4	58.7	56.2	51.4	0.56
Married	70.7	73.1	71.1	68.7	71.7	0.68
Employed	67.1	63.6	72.5	72.1	72.2	0.02
Never smoked	54.1	53.4	58.2	53.7	49.8	0.29
No alcohol use	33.2	34.1	27.1	32.5	32.6	0.86
Radiotherapy	57.1	63.1	61.6	59.0	66.8	0.13
Chemotherapy	65.8	64.1	69.4	68.0	71.7	0.06
Tamoxifen	71.3	73.4	66.8	71.8	60.6	0.009
Tumor stage I	40.6	44.9	39.1	41.3	38.6	0.36
High tumor grade	36.1	28.7	34.4	30.8	38.6	0.35

^a Body mass index (kg/m²)

^b metabolic equivalent tasks (METs) per week

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Adjusted associations^a of change in physical health (baseline to year 1) with breast cancer outcomes in a cohort of breast cancer survivors from the Women’s Healthy Eating and Living Study (N=2343).

Table 2

Physical Health Change	Mean Score (SD)	Time from Diagnosis to Study Enrollment					
		≤ 2 years			> 2 years		
		N (event)	HR	95% CI	N (event)	HR	95% CI
Additional breast cancer events							
Decrease (<-5)	-16.8 (10.8)	321 (35)	Reference	-----	297 (37)	Reference	-----
Minimal change (-5 to +5)	0.06 (7.9)	485 (59)	1.07	0.70, 1.65	470 (66)	1.22	0.81, 1.85
Increase (>5)	17.1 (10.9)	474 (66)	1.24	0.80, 1.91	296 (31)	0.66	0.40, 1.10
All-cause mortality							
Decrease (<-5)	-16.8 (10.8)	321 (21)	Reference	-----	297 (20)	Reference	-----
Minimal change (-5 to +5)	0.06 (7.9)	485 (34)	1.12	0.64, 1.95	470 (29)	1.10	0.61, 1.98
Increase (>5)	17.1 (10.9)	474 (48)	1.53	0.89, 2.61	296 (10)	0.38	0.16, 0.85

^aModels adjusted for age at randomization, menopausal status, employment status, chemotherapy, tamoxifen use, body mass index (kg/m²), physical activity (METs per week), and mental health and physical health score at baseline (SF-36)