Online Exclusive Article

Relationship Between Severity of Symptoms and Quality of Life in Patients With Breast Cancer Receiving Adjuvant Hormonal Therapy

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Purpose/Objectives: To describe symptoms and quality of life (QOL) of patients with breast cancer receiving adjuvant hormonal therapy and to examine possible relationships between the two measurements.

Design: Descriptive, correlational study.

Setting: An oncology clinic within a tertiary medical center in Israel.

Sample: Convenience sample of 132 patients diagnosed with primary breast cancer receiving hormonal therapy.

Methods: Data collection was conducted through the self-administered Functional Assessment of Cancer Therapy endocrine subscale and a sociodemographic and medical information questionnaire.

Main Research Variables: QOL and symptoms of hormonal therapy.

Findings: Ten symptoms were categorized by more than 20% of the participants as "very much" or "quite a bit." The mean QOL score for the participants was higher than that for a healthy population, although a correlation was found between fewer symptoms and higher QOL. Mood swings and irritability were the symptoms most strongly associated with a decrease in QOL. Patients who exercised had higher QOL scores.

Conclusions: Adjuvant hormonal therapy did not affect the QOL of a majority of patients with primary breast cancer. A reduced number of symptoms indicated a higher QOL. Mood swings and irritability have a negative impact on QOL.

Implications for Nursing: A need exists to design a program to follow up on hormonal symptoms and the QOL of patients receiving hormonal therapy and to encourage patients to engage in regular exercise.

As in many Western countries, breast cancer is the most prevalent cancer among women in Israel. About 4,000 Israeli women are diagnosed yearly with breast cancer. Ninety percent of these cancers could be cured if the disease was detected and treated in the early stages (Israel Cancer Association, 2007).

Hormonal therapy is part of the treatment protocol for patients with breast cancer with hormone-sensitive tumors (Woods, Muss, Solin, & Olopade, 2005). Literature on the topic has noted that the side effects of hormonal treatment may negatively affect patients' quality of life (QOL), but the medical community tends to underestimate the effect of hormone-related symptoms compared to patients' perceptions (Leonard, Lee, & Harrison, 1996; Vigler & Inbar, 2002). The literature describes the symptoms of the patients but does not make a connection between the possible effect of the symptoms and QOL, but rather measures the overall QOL of these women (Fallowfield et al., 2006; Land et al., 2006). The purpose of this study was to identify endocrine therapy–related symptoms and severity, patients' QOL scores, and the possible relationship between the type of symptom and QOL scores in specific categories.

Hormonal Treatment for Breast Cancer

In 1895, George Beatson, MD, a Scottish surgeon, mentioned that after removal of the ovaries (oophorectomy) in premenopausal women with advanced breast cancer, estrogen levels declined, which resulted in an improvement in patients' conditions and survival rates (Fallowfield, 2004; Gabbai & Korem, 2002). With this discovery came the knowledge that the estrogen hormone stimulates breast cancer development and can accelerate the progress of the disease. In the 1950s and 1960s, excision or ablation of the ovaries by irradiation was the accepted treatment offered to women with metastatic breast cancer. After the 1960s, this treatment was replaced with pharmacologic therapy (Fallowfield, 2004; Jonat et al., 2002). About 60%–70% of malignant breast

Quick Facts: Israel

Geography and economy: Israel is a democratic pluralistic country on the east coast of the Mediterranean Sea; it is slightly smaller than New Jersey. As of July 2010, the estimated total population in Israel was 7.4 million people; of them about 5.7 million are Jewish and about 1.7 million are Arabs, mostly Muslim. In 2009, gross domestic product per capita based on purchasing power parities was $28,400. The general Jewish population has an affluent Western lifestyle. About 18% of the Jewish population has less than 10 years of schooling and about 44% have more than 13 years of schooling. Most of the population (90%) lives in metropolitan centers and cities.

Health care: In 1995, a National Health Insurance Law was enacted that provides universal healthcare services to all Israeli citizens. Early detection tests for breast, colon, and skin cancers are provided as part of these services. Life expectancy is 78.7 years for men and 83.1 years for women.

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tumors have estrogen or progesterone receptors. With these conditions, anti-estrogen treatment is part of the treatment for breast cancer (Garreau, Delamelena, Walts, Karamlou, & Johnson, 2006; Palmieri & Perez, 2003). Currently, hormonal treatment is given to patients with metastatic breast cancer or as adjuvant therapy after various surgical and oncologic treatments. Sometimes the hormonal therapy is given as neoadjuvant treatment to reduce the cancerous tumor prior to surgery (Woods et al., 2005).

Adjuvant hormonal treatment is prescribed for at least 5 and up to 10 years (Whelan & Pritchard, 2006). Adjuvant hormonal treatments, currently in use for patients with primary breast cancer, are divided into three groups: selective estrogen receptor modulators (SERMs), aromatase inhibitors (AIs), and leuteinizing hormone-releasing hormone (LHRH) agonists.

SERMs preclude estrogen binding to the receptor, thus preventing hormonal activity. SERMs include tamoxifen (the gold standard), and studies have shown that tamoxifen use reduced recurrence of the disease by 47% over a 10-year period among 30,000 women with positive estrogen-receptor tumors (Grana, 2003; Hallquist-Viale, 2005). Raloxifene is another member of this group (Hallquist-Viale, 2005; Mouridsen, Rose, Brodie, & Smith, 2003), although it is not as commonly prescribed but is sometimes still used as adjuvant therapy in Israel.

AIs are used in postmenopausal women whose source of estrogen is adipose tissue and adrenal glands. The AIs suppress the estrogen synthesis and quantity by repressing the aromatase enzyme. Included in this group are the nonsteroidal AIs, anastrozole and letrozole, and the steroidal AIs, such as exemestane (Harwood, 2004; Hassey-Dow, 2002). LHRH agonists suppress ovarian hormonal activity. This group is prescribed to premenopausal women (Hallquist-Viale, 2005; McGinn & Moore, 2001). Preparations in this group include goserelin and leuprorelin.

Symptoms and Quality of Life Related to Adjuvant Hormonal Treatment

Hormonal treatments are included in the regular protocol treatment of women with breast cancer when the tumor is positive for receptors (Vigler & Inbar, 2002). However, relatively few studies have researched adjuvant therapy symptoms and QOL as compared with the number of studies written on chemotherapy symptoms and QOL (Glaus et al., 2006; Shilling & Jenkins, 2007; Tchen et al., 2003). Treatment such as chemotherapy or hormonal therapy can cause a decline in the QOL of women for as long as 5–10 years after diagnosis (Avis, Crawford, & Manuel, 2005; Biglia et al., 2003; Casso, Buist, & Taplin, 2004; Knobf, 2001). However, Schultz, Klein, Beck, Stava, and Sellin (2005) found that 47% of patients with breast cancer reported an improvement in family relationships after breast cancer and a positive influence of the disease and its treatment on their QOL.

In studies comparing the overall QOL of women receiving different hormonal medications or not receiving hormonal treatment at all, no difference was found in the QOL between the two groups. However, in women receiving hormonal therapy, differences were found between various symptoms experienced by women according to the type of hormone they were given (Day et al., 1999; Fallowfield et al., 2004, 2006; Land et al., 2006; Whelan & Pritchard, 2006).

Hormone-related symptoms can be divided into a number of groups: vasomotor symptoms, vaginal symptoms, weight gain, body-image issues, cognitive or mood changes, urinary incontinence, and joint and muscle pain (Alfano et al., 2006; ATAC Trialists' Group, 2004, 2006; Badger, Braden, & Mishel, 2001; Big 1–98 Collaborative Group, 2005; Buzdar, 2003; Day et al., 1999; Glaus et al., 2006). In many studies, the occurrence of hot flashes is the most prominent symptom that appears in various frequencies (41%–78%). This symptom is particularly evident in women taking tamoxifen (ATAC Trialists' Group, 2006; Land et al., 2006; Wilkinson, 2004). The menopausal symptoms are interrelated and can cause body-image problems, sexual dysfunction, relationship issues, and coping difficulties (Avis et al., 2005; Knobf, 2001).

The literature shows that symptoms of hormonal treatment can negatively affect patients' QOL (Leonard et al., 1996; Vigler & Inbar, 2002). Without accurate symptom measurement and appropriate intervention aimed to reduce their effects, patients may abandon treatments that have the potential to cure (Barron, Connoly, Bennett, Feely, & Kennedy, 2007).

Problematic Nature of Reporting Hormone-Related Symptoms

Reporting and listing symptoms related to hormonal treatment are more common in medical studies wanting to show an advantage of a new treatment over others than in common practice (Fallowfield et al., 2006; Land et al., 2006). Several problems arise when referring to symptoms of hormonal treatment in the literature: Research shows that healthcare professionals do not have enough knowledge of the symptoms of hormonal treatment and their severity (Glaus et al., 2006); hormone-related symptoms are regarded by the providers differently and are considered more bearable by them than by the patients; and a sufficient record of symptoms is not kept in the medical files. These distortions may harm the quality of given treatment and may even cause treatment noncompliance (Blackledge et al., 1998; Fellowes, Fallowfield, Saunders, & Houghton, 2001; McGurk, Fallowfield, & Winters, 2006).

Additional issues exist related to the reporting and communicating of symptoms between patients and healthcare professionals. When reporting, patients do not separate postmenopausal symptoms deriving from menopause, chemotherapy, or adjuvant hormonal treatment symptoms (Carpenter, 2005; Carpenter & Andrykowski, 1999; Carpenter, Johnson, Wagner, & Andrykowski, 2002; Ganz et al., 2000; Ganz, Rowland, Desmond, Meyerowitz, & Wyatt, 1998). Other studies do not distinguish between patients with primary breast cancer and patients with metastatic breast cancer receiving hormonal treatment because the metastatic group may suffer from additional symptoms related to the metastatic disease (Garreau et al., 2006; Glaus et al., 2006).

Another problem with symptom analysis is related to different methodologies that make it impossible to compare studies. Recording of symptoms has been performed by patient self-report (e.g., a symptom checklist), questionnaires on QOL (e.g., the Functional Assessment of Cancer Therapy endocrine subscale [FACT-ES]), or specific questionnaires about hormonal treatment symptoms (e.g., a checklist for patients with endocrine therapy). These variations in measurement systems cause variations in the reporting of related symptoms, the strength of their effect, and the percentage of respondents suffering from specific symptoms (Garreau et al., 2006; Mouridsen, 2006; Winters, Habin, & Gallagher, 2007).

Table 1. Sociodemographic Characteristics

Characteristic	n	%
Country or region of origin		
Israel	74	56
Europe or America	37	28
Asia	12	9
Africa	9	7
Ethnicity		
Ashkenazi	74	56
Middle Eastern	50	40
Mixed Ashkenazi and Middle Eastern	4	2
Not Jewish born	4	2
Religion		
Jewish	129	98
Muslim	2	1
Christian	1	1
Religiosity		
Secular	66	50
Traditional	34	26
Religious	22	17
Ultra Orthodox	10	7
Family status		
Married or permanent partner	91	69
Divorced or separated	16	12
Widowed	14	11
Single	11	8

N = 132

When reviewing the literature, the authors noted a need for a uniform and close follow-up of hormone-related symptoms in view of the extension of treatment for more than five years, according to the recommendations of the American Society of Clinical Oncology (Winer et al., 2005). This follow-up is vital to prevent treatment noncompliance (Buzdar, 2004; Grana, 2003; Viale, 2005). According to Barron et al.'s (2007) cohort study, the rate of patients with breast cancer dropping out of hormonal treatment was 22% after one year of treatment and nearly 35% after 3.5 years. Identifying patients at risk for treatment noncompliance and providing appropriate solutions also are important.

Two main models were used as the theoretical framework of this study. The first model, based on the University of California, San Francisco, School of Nursing Model for Symptom Management (Dodd, Miaskowski, & Paul, 2001; University of California, San Francisco, School of Nursing Symptom Management Faculty Group, 1994), focuses on the interplay among symptom experience, management, and status as they are reflected in the functional, emotional, and overall QOL of the patient. An additional model, Breast Cancer QOL (Ferrell, Grant, Funk, Otis-Green, & Garcia, 1998), creates a structure that divides patient QOL into four categories, physical, psychological, social, and spiritual well-being, and associated symptoms that may affect these four aspects. Based on these two models, the authors chose the FACT-ES questionnaire to check all

Table 2. Distribution of Participants' Cancer Treatment

Variable	n	%
Current hormonal treatment		
Tamoxifen	72	54
Letrozole	34	26
Anastrozole	21	16
Exemestane	3	2
Raloxifene	2	2
Additional hormonal treatment		
Leuprolide acetate	5	4
Goserelin	1	1
Type of breast surgery		
Partial mastectomy	78	59
Total mastectomy	51	39
No surgery	3	2
Previous chemotherapy		
Yes	74	56
No	58	44
Previous radiation treatment		
Yes	103	78
No	29	22
Previous hormonal treatment		
Tamoxifen	38	29
Goserelin	4	3
Letrozole	2	2
Other treatment		
Biologic treatment (trastuzumab)	2	2
Homeopathy	1	1
Immunotherapy	1	1
Oophorectomy	1	1

N = 132

aspects of QOL relevant to women receiving hormonal therapy. Little information was collected on spiritual well-being because the FACT-ES questionnaire does not focus on this category.

Methods

Research Design

This was a descriptive, correlational study whose target population included a convenience sample of patients with primary breast cancer, aged 18 years and older, literate in Hebrew, with no comorbidities that could affect their QOL according to their individual perception, and who came for follow-up at the oncology clinic of the tertiary medical center where the study was conducted. All participants had been prescribed adjuvant hormonal treatment for at least three months. The study was approved by the institutional ethics committee.

Instruments

Data collection was conducted with two questionnaires. One was a **self-administered sociodemographic and medical history questionnaire** that was developed for this study. Sociodemographic factors included age, ethnicity, marital status, religion, and level of religiosity. Medical information included adjuvant therapy that the patient received, type and duration of the hormonal therapy received during the study, information about menopausal status upon diagnosis, whether the patient exercised on a regular basis, and additional treatment (alternative and conventional) for the side effects of menopause. Cancer type and stage were not queried.

The second questionnaire was the **FACT-ES**. The FACT-ES is part of the Functional Assessment of Chronic Illness Therapy (FACIT) (www.facit.org). The FACT-ES is a self-administered questionnaire that measures the QOL of patients with breast cancer receiving hormonal treatment. It includes the FACT general questionnaire (Cella et al., 1993) that addresses physical well-being (seven questions), social and family well-being (seven questions), emotional well-being (seven questions), functional well-being (seven questions), and an endocrine scale (ES) addressing symptoms related to hormonal treatment (19 questions). All questions were designed on a Likert scale ranging from 0 (not at all) to 4 (very much). The questionnaire was verified for validity and reliability among 265 women with breast cancer that were receiving hormonal therapy and 41 women without breast cancer receiving hormone replacement therapy. The Cronbach α for the ES was 0.79, and 0.92 for the entire questionnaire (Fallowfield, Leaity, Howell, Benson, & Cella, 1999). The test-retest reliability also was conducted on the questionnaire, and high and significant correlation was found ($r = 0.93$ for the ES only, and $r = 0.86$ for the entire questionnaire).

The questionnaire was translated into Hebrew by the investigator with the assistance of the FACIT organization, according to the instructions of the organization. A pilot study of 15 patients was conducted with the Hebrew translation. Results of the pilot study showed high reliability (Cronbach $\alpha = 0.92$) for the Hebrew version. Therefore, no changes were made to the Hebrew version of the FACT-ES questionnaire.

Data Analysis

The demographic data, QOL scores, and symptoms were summarized with descriptive statistics. Continuous variables were analyzed with the mean and minimum and maximum; categorical variables were analyzed with frequency and percentages. The data were compared with the t test and analysis of variance. Categorical variables were displayed with numbers and percentages and compared with chi-square and the Fisher exact test.

The correlation between the level of QOL scores and symptoms was measured with the Pearson correlation coefficient between each symptom in the ES and the overall QOL and the subcategories of QOL that included

physical, social and family, emotional, and functional well-being.

Results

Study Population

Data collection was conducted between August and November of 2007. Participant compliance was high; 132 of 155 possible women participants (85%) completed the questionnaires. The average age of the patients was 58.3 years (SD = 10.9), and the age range was from 31–93 years. Sixty-one percent of the patients were postmenopausal when they were diagnosed with breast cancer (n = 81). The rest of the women were perimenopausal (n = 43, 33%) or premenopausal (n = 8, 6%).

Table 1 displays the sociodemographic characteristics of the participants. Most were born in Israel, Jewish, of Ashkenazi background, and married. Fifty percent defined themselves as secular.

Current and previous therapies received by the participants are displayed in Table 2. Fifty-four percent of the participants were currently taking the hormonal treatment tamoxifen. Of those who had previously received another hormonal treatment, the majority had taken tamoxifen. Almost all of the participants had undergone breast surgery; of them, 78 had lumpectomies and 51 had total mastectomies. The majority of the women also had received radiation treatment and chemotherapy. Most (n = 125, 95%) were not taking anything to reduce the side effects of hormonal therapy. Fifty-two percent (n = 68) exercised on a regular basis.

Description of Symptoms and Participants' Quality of Life

Of the 19 symptoms that were examined, 10 were experienced severely (consisting of those who indicated very much or quite a bit) by more than 20% of the participants (see Table 3). These symptoms included

Table 3. Severity of Characteristic Hormonal Treatment Symptoms

	Very Much		Quite a Bit		Somewhat		A Little Bit		Not at All	
Variable	n	%	n	%	n	%	n	%	n	%
Breast sensitivity	1	1	11	8	24	18	39	30	57	43
Cold sweats	16	12	18	14	9	7	30	22	59	45
Diarrhea	–	–	1	1	6	5	7	5	118	89
Dizziness	2	2	4	3	20	15	37	28	69	52
Feeling bloated	3	2	14	11	24	18	25	19	66	50
Headaches	2	2	11	8	20	15	38	29	61	46
Hot flashes	27	21	25	19	28	21	19	14	33	25
Irritability	9	7	22	17	30	23	37	28	34	25
Joint pain	21	16	25	19	23	17	20	15	43	33
Lost interest in sex (N = 104)	16	15	10	10	34	33	14	13	30	29
Mood swings	8	6	20	15	34	26	31	23	39	30
Night sweats	20	15	23	17	19	14	25	20	45	34
Pain with intercourse (N = 86)	9	10	10	12	16	19	23	27	28	33
Vaginal bleeding or spotting	–	–	1	1	2	1	8	5	121	91
Vaginal discharge	2	1	4	3	14	11	34	26	78	59
Vaginal dryness (N = 130)	18	14	16	12	22	17	29	22	45	35
Vaginal irritation	3	2	9	7	11	8	26	20	83	63
Vomiting	27	21	1	1	–	–	5	4	126	95
Weight gain	10	8	20	15	38	28	19	15	45	34

N = 132 unless noted otherwise

Table 4. Comparison of QOL Scores Among Study Participants, the General Population, and Patients With Cancer From the FACT-G Study

Variable	Total Possible QOL Score	Average in Current Study (N = 132)	FACT-G Study: Average Healthy Women (N = 544)	FACT-G Study: Average Women Patients With Cancer (N = 1,271)
Emotional well-being	24	18.3	19.4	18.7
Functional well-being	28	20.5	18.3	19.5
Physical well-being	28	22.7	22.1	21.6
Social and family well-being	28	20.9	19.8	22.3
Total	108	82.4	79.6	82.1

FACT-G—Functional Assessment of Cancer Therapy–General; QOL—quality of life

Note. Based on information from Brucker et al., 2005.

hot flashes (n = 52, 39%), joint pain (n = 46, 35%), night sweats (n = 43, 33%), cold sweats (n = 34, 26%), vaginal dryness (n = 34, 26%), irritability (n = 31, 23%), weight gain (n = 30, 23%), mood swings (n = 28, 21%), loss of interest in sex (n = 26 of 104 respondents, 21%), and pain with intercourse (n = 19 of 86 respondents, 22%). Hot flashes was the most common symptom among the participants on all levels of severity (n = 99, 75%).

In the area of physical well-being, the participants selected lack of energy (n = 92, 70%) and pain (n = 69, 52%) as the most frequent symptoms; 10 of those women reported experiencing pain "very much." Sixty-two percent of the participants (n = 82, 62%) were bothered by side effects of the hormonal treatment they were taking.

Under social and family well-being, the responses of the participants showed that they were receiving quite a bit to very much support from their families (n = 109, 83%), their partners (n = 93, 70%), and their friends (n = 81, 61%). Thirty participants preferred not to answer the question referring to satisfaction with their sex lives. Of the 81 participants who did answer, 27% were not satisfied at all with their sex lives. Some women responded that they did not have a current partner (n = 22, 17%).

In regard to their emotional well-being, 80 participants (60%) mentioned feeling nervous; of them, 14 (10%) felt it strongly or very strongly. Eighty-four participants (71%) were worried that their condition would get worse. Despite the symptoms and worry, loss of hope was low (84% reported no loss of hope) and the majority of the women expressed satisfaction with how they were coping with the illness (75% said "quite a bit" and "very much").

The average score for functional well-being was 20.5 out of 28. Not sleeping well was one of the most significant distressors among 32% of the women (n = 42). The average score for overall QOL for the participants was 82.4 out of a possible 108. Table 4 displays the overall QOL of the participants in various areas compared to healthy women and women with cancer in the United States. Similar QOL evaluations were found among women patients in the United States and were higher than in healthy women in the U.S. study population (Brucker, Yost, Cashy, Webster, & Cella, 2005).

Relationship Between Symptoms and Quality of Life

The Pearson Correlation Analysis examined correlation between the 19 symptoms and QOL. Table 5 presents 7 of the 10 most frequent symptoms where a statistically significant correlation was identified between the symptom and QOL. Mood swings and irritability were moderately to strongly associated with a decline in QOL ($r = 0.65–0.68$, $p < 0.001$). This correlation was particularly evident in functional well-being ($r = 0.65$, $p < 0.001$) in the areas of ability to work ($r = 0.47–0.51$, $p < 0.001$) and to enjoy hobbies and life ($r = 0.48–0.55$, $p < 0.0001$).

Hot flashes and night sweats, despite their frequency and strong presence, had a weak correlation with reduction in QOL scores. Loss of interest in sex had a moderate correlation ($r = 0.43$, $p < 0.001$) with QOL in the area of social and family well-being.

When comparing the average score of the 19 hormonal treatment symptoms included in the FACT-ES with the QOL scores in the four areas (physical, social and

Table 5. Pearson Correlation Between Symptoms and Quality of Life (QOL)

Symptom	Physical Well-Being	Social and Family Well-Being	Emotional Well-Being	Functional Well-Being	General QOL
Hot flashes	0.25**	0.009	0.23**	0.23**	0.2*
Irritability	0.6***	0.4***	0.57***	0.6***	0.65***
Joint pain	0.47***	0.27***	0.24**	0.31***	0.39***
Lost interest in sex	0.21*	0.43***	0.096	0.28**	0.33***
Mood swings	0.62***	0.42***	0.61***	0.65***	0.68***
Night sweats	0.25**	0.07	0.24**	0.21*	0.22**
Pain with intercourse	0.23*	0.158	0.099	0.187	0.205

* $p < 0.05$; ** $p < 0.01$; *** $p \leq 0.001$

Note. The responses concerning symptoms are scored by reversing the scores; therefore, all correlations are positive.

family, emotional, and functional well-being) and general QOL scores, a weak-to-moderate statistically significant correlation was found ($r = 0.25–0.52$, $p < 0.001–0.004$). The correlation between physical side effects and QOL was greater and statistically significant ($p < 0.001$).

Type of Hormonal Treatment and Level of Symptoms

Of the 132 participants, 74 (56%) were treated with SERMs (tamoxifen: n = 72, 54%; raloxifene: n = 2, 2%) and 58 (44%) were treated with AIs (letrozole: n = 34, 26%; anastrozole: n = 21, 16%; exemestane: n = 3, 2%). No statistically significant differences in QOL scores were observed for the four domains of well-being or overall QOL between the group that received SERMs and the one that received AIs.

When comparing symptoms between the SERM and AI groups, participants felt more vaginal dryness ($p = 0.045$, 17% and 87%, respectively), loss of interest in sex ($p = 0.009$, 60% and 87%, respectively), and more severe joint pain ($p < 0.001$, 22% and 52%, respectively).

Additional Variables and Areas of Quality of Life

Women born in the United States and Western Europe had a statistically significant higher average QOL. Secular women also reported a higher QOL. Women who were postmenopausal at the time of diagnosis reported fewer symptoms as compared to perimenopausal women. Married women also reported a higher QOL as compared to others, but this was not statistically significant.

The type of surgery and treatment (e.g., radiation, chemotherapy) received did not have a correlation with the overall QOL scores or with the four areas of well-being. Consistent exercise was one of the independent variables that had a positive statistically significant correlation with QOL in all areas. Table 6 shows the differences in the average QOL scores of women who engaged in regular exercise compared to women who did not.

Discussion

This study analyzed 132 patients with breast cancer receiving hormonal therapy to identify menopausal symptoms, participants' overall QOL, the correlation between symptoms and QOL, the influence of various types of hormonal therapy on the severity of symptoms, and the influence of physical exercise on participants' overall QOL. Just as in other studies, hot flashes was the most common symptom (at all levels of severity) (Alfano et al., 2006; Glaus et al., 2006). Other QOL studies on patients with breast cancer receiving adjuvant hormonal therapy reported an overall high QOL (Day et al., 1999; Fallowfield et al., 2004, 2006; Land et al., 2006; Whelan & Pritchard, 2006). The level of QOL of this study's participants was very similar to those reported by women patients in the United States and even higher than those reported by healthy U.S. women (Brucker et al., 2005). This may be because patients with cancer receive more support from family and friends (Schultz et al., 2005).

Similar to other studies (ATAC Trialists' Group, 2004; Fallowfield et al., 2004; Garreau et al., 2006), mood swings and irritability were experienced by a significant percentage of participants. However, when examining the correlation between frequent symptoms and QOL, mood swings and irritability were strongly connected to a diminished QOL. This finding is not evident in the literature and could be an important indication of a cultural difference or caused by the fact that the participants felt comfortable expressing their feelings on this topic.

Similar to other researchers' findings (ATAC Trialists' Group, 2004, 2006), a significant correlation was found between three symptoms and the type of hormonal treatment being used. Joint pain, loss of interest in sex, and vaginal dryness were found to be more strongly associated with women taking AI hormonal therapy. Regular exercise was an independent variable with a strong significant association to a higher QOL.

Limitations

This study did not have a control group of patients with breast cancer who were not receiving adjuvant hormonal therapy. A control group would have allowed for the validation that the symptoms stemmed only from the hormonal therapy. An additional control group may have been needed to distinguish between the effects of menopausal symptoms on women without breast cancer as compared to symptoms experienced by women with breast cancer receiving hormonal therapy.

Table 6. Differences in Average Quality-of-Life Scores by Exercise Level

	Exercise Regularly (N = 68)		Do Not Exercise Regularly (N = 64)	
Variable	$\bar{X}$	SD	$\bar{X}$	SD
Emotional well-being	19.5**	3.7	17.1**	4.4
Functional well-being	22.4**	4.1	18.5**	5.5
Physical well-being	24.3**	4.2	20.9**	5.4
Social and family well-being	22.7*	4.7	18.9*	6.8
General quality of life	88.9**	13.1	75.4**	18.2

* $p < 0.01$; ** $p \leq 0.001$

As in larger studies, symptoms caused by menopause as compared to symptoms of hormonal therapy also were not differentiated (ATAC Trialists' Group, 2004; Big 1–98 Collaborative Group, 2005). In addition, this study was conducted on a convenience sample in one hospital and may not represent the population at large.

The study instrument was another limitation. The FACT-ES does not include questions that refer to urinary incontinence, cognitive decline, or frequency or existence of regular sexual activity. Because no questions asked whether the participants had regular intercourse, it was unclear whether the lower response to the sexually related question was because of a lack of personal relevance or refusal to answer the question.

Future studies should include a control group to confirm the existence of the influence of this unique group of symptoms caused by hormonal treatment on patients' QOL. The study population also should be expanded, and additional areas that were not addressed by the research instrument of this study should be examined.

Implications for Nursing

Nurses have an important function in counseling women receiving adjuvant therapy and preventing noncompliance with treatment. This function includes offering emotional support as well as informative and practical advice according to patient needs (Miaskowski, Shockney, & Chlebowski, 2008). According to the results of this study, a need exists to offer various nursing interventions to increase coping and symptom management connected with adjuvant hormonal therapies to improve patient QOL over this period of time. Nurses may

- Suggest various ways in which patients can cope with symptoms, particularly when they influence the patient's QOL (mood swings and irritability). In addition, when taking tamoxifen, patients should avoid taking antidepressive drugs from the selective serotonin reuptake inhibitor group that are known to reduce the side effects of hot flashes and mood swings (Graf & Geller, 2003; Hartman & Helft, 2007; Kimmick, Lovato, McQuellon, Robinson, & Muss, 2006; Loprinzi et al., 2000) but also reduce the efficacy of tamoxifen (Hartman & Helft, 2007).
- Emphasize to patients the importance of regular exercise and the connection between improvement in QOL and regular exercise.
- Create a long-term follow-up plan for patients receiving adjuvant hormonal therapy. Patients should have access to various healthcare professionals and support groups to expand the level of provided counseling and support.
- Develop easy and efficient instruments with which to measure symptoms of hormonal treatment in light of the variability among measurement tools as described in the literature.
- Establish nursing guidelines so uniformity exists in symptom measurement (Leining et al., 2006; McGurk et al., 2006; Miaskowski et al., 2008; Pennery, 2008).

Conclusion

The results of this study demonstrate that nurses and other healthcare professionals need to further establish follow-up and intervention methods for women receiving hormonal therapy and experiencing treatment-related symptoms.

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