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Initial Validation of the Symptom Cluster of Fatigue, Weight Gain, Psychologic Distress and Altered Sexuality

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ABSTRACT

This descriptive pilot study was designed to provide initial validation of a proposed symptom cluster of fatigue, weight gain, psychologic distress and altered sexuality in breast cancer survivors. A convenience sample of 183 women 6-18 months post breast cancer received letters inviting them to participate this study; 21 of 50 respondents (30% response rate) met inclusion criteria and 15 returned completed questionnaires. Potential subjects were identified from a local hospital tumor registry and were mailed an introductory letter and invited to call the researchers. Those who agreed to participate after this phone call received a set of questionnaires in the mail, including the Piper

Fatigue Scale, the Profile of Mood States, the Wilmoth Sexual Behaviors Questionnaire, and demographic data form. Clustering was defined as concurrent elevation of three or more of the symptoms examined: fatigue, weight gain, altered sexuality, and psychological distress. Clustering of all the symptoms was observed in 7 of the subjects. Clustering of three of the symptoms occurred in 7 subjects. One survivor reported experiencing only one of the four symptoms. Further study with a larger sample is needed before these symptoms can be called a symptom cluster. Future work should use more clearly defined inclusion criteria and more effective subject recruitment techniques.

Initial Validation of the Symptom Cluster of Fatigue, Weight Gain, Psychologic Distress and Altered Sexuality

The majority of women who are diagnosed with breast cancer have a life expectancy of 20 years or longer and will experience unique side effects as a result of their treatment that will affect their quality of life for many years.[1] The side effects of cancer treatments are commonly referred to as symptoms and the subsequent medical, nursing, and self-care they require is called symptom management.[2] Symptom management has been characterized as a dynamic and multidimensional process that is undertaken to relieve or decrease the distress of a symptom.[2] Breast cancer treatment and its effects often cause debilitating side effects in those diagnosed with this disease; many of these side effects last long after treatment has been completed. Some of these symptoms occur together and may be viewed as a 'symptom cluster'. A symptom cluster has been defined as a grouping of three or more interrelated symptoms (at elevated levels) that occur as a result of cancer treatment.[3] Identification of symptom clusters can facilitate development of interventions that can be used to reduce clusters of symptoms concurrently and lead to more efficient treatments and improved quality of life.

Review of the literature suggests that fatigue, weight gain, psychological distress, and altered sexuality often occur concurrently, so it has been proposed to call them a symptom cluster among breast cancer survivors.[4] This proposition requires empirical confirmation. The purpose of this pilot study was to provide initial data regarding this proposed symptom cluster and to pilot the selected measures for their use in this population.

Literature Review

Theoretical Framework

The Theory of Unpleasant Symptoms (TUS)[5] was used as the framework for this pilot study. The TUS describes the characteristics of symptoms and their holistic effect on the individual and hypothesizes that multiple symptoms can be experienced simultaneously. This middle-range theory postulates that there are four dimensions to each symptom: intensity, timing, level of distress, and quality.

Intensity refers to strength or severity of the symptom reported by a subject and is commonly measured by the scores on a self-report measure. Timing includes duration and frequency of occurrence over time, while level of distress is the perception of degree of discomfort.[5] Quality of the symptom experience is a descriptive labeling of the symptom, for example, throbbing vs. sharp when describing a pain symptom.[5]

Fatigue

Fatigue is the most common complaint reported by women during adjuvant breast cancer chemotherapy, with approximately 70%-100% of all cancer patients reporting fatigue as a result of cancer treatment.[6,7] At least 99% of cancer patients report some level of fatigue during treatment and more than 60% rate their level of fatigue as moderate to severe.[7] Fatigue is also a complex symptom that is subjective to the person experiencing it and has therefore been difficult to assess and conceptualize.

There does not appear to be a difference in levels of fatigue between breast cancer patients receiving breast-conserving surgery and those who have had a mastectomy.[8] However, the pattern of fatigue appears to vary between cancer patients receiving radiation therapy and those receiving chemotherapy. Those receiving radiation therapy experience fatigue as a steadily increasing phenomenon as treatment continues while patients receiving chemotherapy report a fluctuating, cyclic patter of fatigue.[6,7] Bower et al.[7] suggest that fatigue is a persistent problem for breast cancer patients with 34% of subjects (n = 763) in their study reporting significant fatigue at 5 to 10 years post diagnosis.

Weight Gain

Weight gain appears to be a unique symptom in breast cancer survivors who receive adjuvant chemotherapy.[7,11] This gain in weight ranges from 2.5-6.2 kg but gains of up to 10 kg are not unusual and are more common in premenopausal women and may last well beyond completion of treatment.[10,11] This increase in weight may contribute to the breast cancer survivor developing a negative body image, fatigue, depression, and a decreased desire for sexual activity.[12]

Psychological Distress

Estimates of psychological distress in women with breast cancer vary from 4.5 to 58%.[13] Other literature suggests that the prevalence of distress in breast cancer patients is 32.8%.[14,15] The wide range in estimates of the prevalence of distress in breast cancer survivors may reflect the age of the women in a sample, the length of time since they were diagnosed or individual responses to the varying types of surgical procedures and adjuvant therapies. It is important to note that the symptoms of anxiety and depressive symptoms do appear to diminish

between the time of initial treatment and diagnosis and post treatment. However, even though rates of psychological distress diminish over time,[13] it appears that approximately 15% of women continue to have some degree of psychological distress 5 years after initial diagnosis of breast cancer and treatment. Treatment for distress often includes the prescribing of SSRI's which have as one side effect, a blunting or diminishment of sexuality.[16]

Altered Sexuality

The prevalence of altered sexuality in female cancer survivors is estimated to be between 25% and 80%.[17] This range in prevalence reflects the varying degree to which different cancers affect female sexuality, the impact varying treatments have on sexuality as well as the varying ages of women when cancer diagnosed. Surgery for breast cancer does have major implications for body image and for self-concept but the literature indicates it has little impact on physiological sexual functioning.[18,19] However, chemotherapy has a major impact on physiological sexual functioning as well as on body image.[20] These changes in sexual functioning may be temporary as a result of treatment or they may become permanent. Sexual side effects reported by half of breast cancer survivors include decreased desire, decreased arousal, changes in responsiveness to physical sensations, difficulty reaching orgasm, painful intercourse, and loss of pleasure from sex.[21] The weight gain secondary to chemotherapy affects women's sense of their own sexual desirability and may impact their partner's attraction to them as well.[21,22]

While the literature suggests these symptoms may occur concurrently, there is little empirical literature that definitively links these four symptoms as a symptom cluster. This pilot study will provide initial documentation on this hypothesized symptom cluster. Validation of these symptoms as a cluster will facilitate development of interventions that can efficiently and effectively lead to improved outcomes and quality of life. This study will use the TUS[5] and examine the intensity, level of distress, and quality of each of the four symptoms comprising this postulated symptom cluster. Intensity of each symptom will be determined from scale scores; higher degrees of each symptom will be assumed as having greater intensity of the symptom. It has been postulated that the symptom experience in general has an effect on the individual[5] and for this study the effect or outcome of the symptom experience will be measured by quality of life.

Research Questions

- What levels of fatigue, weight gain, psychological distress, and altered sexuality are reported by breast cancer survivors?

- What is the relationship among the symptoms of fatigue, weight gain, psychological distress and altered sexuality on quality of life (QOL)?

Methods

Design

Descriptive methods were used to provide initial insight into the proposed symptom cluster of fatigue, weight gain, psychological distress and altered sexuality and the effect of these symptoms on quality of life in breast cancer survivors.

Sample and setting

A convenience sample was recruited from a group of 183 breast cancer survivors who had received treatment for breast cancer within the past 6-18 months at a regional cancer center in the southeastern United States. Inclusion criteria included being less than 50 years of age and premenopausal at the time of their breast cancer diagnosis.

Instruments

Demographic data collected included date of diagnosis, type of treatment, weight prior to diagnosis and weight at the current time, education level, and presence of other health problems. Measures used for data collection included the Piper Fatigue Scale (PFS),[23] the Profile of Mood States (POMS), the Wilmoth Sexual Behaviors Questionnaire (WSBQ),[25] and the Functional Assessment of Cancer Therapy- Breast Cancer (FACT-B).[26] The PFS is a 22-item scale with 4 subscales measuring items on an 11 item numeric rating scale (0-10).[23] Scoring includes total and subscale scores with values ranging from 0-10, with higher scores indicating greater fatigue. Construct validity was verified through use of factor analysis and reliability has been reported as 0.97 for the total scale and between .92 and .96 for the subscales.[23] The POMS is a 65-item self-report rating scale that measures six mood states on a 5-point response scale from 0 (not at all) to 4 (extremely). The internal consistency for the entire scale has been reported as .93 and the test-retest reliability coefficient for the Tension-Anxiety subscale is .70.[24] The WSBQ is a 54 item tool that assesses female sexual behaviors on a Likert scale.[25] Higher scores indicate greater consistency in use of a specific behavior and thus fewer alterations in their sexuality. Factor analysis identified seven subscales: Communication, Techniques, Sexual Response, Self-Touch, Body Scar, Masturbation, and Relationship Quality. The WSBQ is sensitive to group differences. Internal consistency for the total scale has been reported as 0.94. Test-retest reliability has been reported to range between 0.7-0.87 on the subscales. The FACT-B is a 44 item self-report instrument that measures the multidimensionality of quality of life in women treated for breast cancer. Internal consistency reliability is reported as 0.90 with subscale alphas reported between 0.63-0.86. Construct validity has been estimated for the FACT-B and the FACT-General.[26] The approximate time to complete all instruments was 50 minutes.

Procedure

The study was approved by the Institutional Review Board of both institutions. To initiate the subject accrual process, an introductory letter describing the study and introducing the PI was sent from the Medical Consultant and Director of the Cancer Center to all women meeting eligibility criteria. Women were invited to call the PI to learn more about the study. If they contacted the PI, they were provided with a verbal description of study. Upon expression a desire to participate, a study packet was mailed to an address they provided. In this study packet were[2] copies of the written informed consent (one to keep; one to sign and return to PI) and the booklet of study questions. A Self-addressed stamped envelope was provided for return to the PI at their convenience. No financial incentive was offered to participate in the study and there were no conflicts of interest by the researchers.

Statistical Methods

Descriptive statistics were used to summarize study variables. Simple linear regression was used to study the association of symptoms with quality of life using SAS.[28]

Results

Of the 183 introductory letters to women who met the time since diagnosis criteria for the study that mailed to potential subjects, 18 letters were returned because of incorrect addresses. Fifty women (30% response rate) contacted the researcher expressing an interest in participating in the study with 15 of the 21 women who met inclusion criteria returning completed questionnaires for analysis. There are no data available regarding those who chose not to contact the PI. The majority (n = 29; 58%) of women who contacted the PI seeking more information about the study were post-menopausal and had been prior to their diagnosis, making them ineligible for the study.

Sample Description

All fifteen subjects were Caucasian, 13 were married, one divorced, and one unmarried. Mean age of the sample was 45.3 years; range was 34-47 years. All 15 subjects had received chemotherapy with 10 subjects also having radiation therapy. Time since diagnosis ranged from 6-36 months with a mean of 21.8 months.

Variables

The presence of the symptom cluster of fatigue, weight gain, psychological distress and altered sexuality was defined a priori as having concurrent elevation of three or more of the surveyed symptoms. To determine the presence of an

elevated level of each symptom, the average total possible response on each scale was determined by averaging the number of items across the range of possible scaled responses. Elevated levels were then defined as being greater than the average score for each measure. The average scaled score for each measure is: fatigue > 2 on (22 items, 1-10), psychological distress > 1 (65 items, range 0-4), altered sexual behavior < 5 (53 items, 0-6) and weight gain ≥ 2kg since diagnosis. (Table 1)

After determining a cut-off score for each measure that determined presence of that symptom, each subject's score was then determined to either be greater than or less than this point. A score that was equal to or greater than the cut-off score indicated presence of the symptom. A subject was determined to exhibit the symptom cluster if three or more symptoms were determined to be present. Additionally, the relationship between symptom levels and impact on quality of life was determined. A verage scores on the Functional Assessment of Cancer Therapy – Breast Cancer (FACT-B) ranged 0.42 – 2.31 (1.40 ± 0.58), with lower scores indicating a negative perception of quality of life.

Findings

The mean and standard deviation of averaged fatigue scores was 4.8 ± 2.4 with range 1.55-9.45; a score greater than 2 indicated the presence of the fatigue symptom. Weight gain ranged from a loss of 32 lb (14.5 kg) to a gain of 22 lb (10 kg) (x = 6.2 ± 13.8lb). Profile of Mood State scores (POMS) averages ranged 0.33 – 1.91 (1.10 ± 0.83), with scores greater than 1 indicating presence of the symptom. The average scores on the WBSQ ranged from 0.88 to 4.14 (3.13 ± 0.82) indicating a moderate change in usual pattern of sexual behaviors.

Every subject (n = 15) had a score greater than the cutoff for the symptoms of fatigue and sexual behaviors, indicating these two symptoms occurred together in this sample. Thirteen subjects had scores greater than the cut-off point for the symptom of psychological distress, indicating that ~87% experience the cluster of fatigue, psychological distress and altered sexuality.

Forty percent of subjects (n = 6) had elevated scores on all 4 of the symptoms and seven subjects (47%) had elevated scores on three of the symptom measures with only two subjects reporting elevation in two symptoms or less. Increased fatigue was associated with poorer quality of life (p=0.03). There was indication of positive association of altered sexual behaviors with QOL (p=0.14), and negative association of weight gain with QOL (p=0.18). (Tables 2, 3)

Discussion

All women in this sample were premenopausal at the time of diagnosis and all had received chemotherapy with two-thirds of them also having adjuvant radiation therapy. All were beyond the stage of active treatment, with the mean

time since diagnosis being 22 months. The demographic data form had omitted an item asking the women about what type of surgical procedure they had undergone. However, there are data to support the assertion that the type of surgical procedure has little impact on the symptoms under study.[18,29,30] The a priori decision to limit the sample to premenopausal women was done with the intent to obtain data on the effects of chemotherapy on sexuality in women who might be experiencing the sudden menopause that commonly occurs following its administration to add to the understanding of this experience.

These preliminary data lend tentative support to the proposed symptom cluster of fatigue, weight gain, psychologic distress and altered sexuality. Scores on the PFS ranged from 22-220 with high scores indicating more fatigue. Scores in this sample ranged from 34-208 with a mean of 105, with averaged scores ranging from 1.55-9.45, all indicating a moderate to high level of fatigue in women who were on average nearly 2 years since diagnosis. Not all subjects gained weight; one woman lost 32 pounds between the time of diagnosis and the time of the study. However, on average subjects experienced a 6.2 pound weight gain during this time period, which is consistent with reports in the literature.[8] The possible range of scores on the POMS is between 0 and 260 and in this sample total scores ranged from 27-91 and averaged scores ranged 0.33 – 1.91 (1.10 ± 0.83). Since higher scores indicate greater psychological distress, it appears that this symptom was reported as low by members of this sample. The literature suggests that anxiety and depression only occurs in about 25% of women in the second year post-diagnosis,[13] so one could assume that the women who chose to participate in this study were not experiencing a great deal of anxiety or depression.

Scores on the WSBQ can range between 0-318 with higher scores indicated greater consistency in use of a set of behaviors and fewer alterations in sexuality. The scores in this sample ranged from 143-202 and averaged scores were between 0.88-4.14, indicating moderate to low levels of alterations in sexual behaviors. These findings support data suggesting that younger, premenopausal women experience do sexual difficulty subsequent to chemotherapy, particularly vaginal dryness.[31] The impact of these symptoms on the outcome of quality of life was within expected findings for younger women diagnosed within the past 2 years with breast cancer.[29] Quality of life in this sample appeared to be negative as scores ranged between 15-83 and averaged scores were 0.42-2.31. This suggests that this group of symptoms is still present two years following diagnosis with a negative impact on quality of life in this group of women.

In keeping with the tenets of the TUS, the study was able to validate the timing of these symptoms as well as level of distress of these symptoms in women with breast cancer. The duration of individual symptoms was shown to linger as much as two years following diagnosis and treatment with a continued impact on quality of life. The timing of when each symptom began to be experienced was not able to be determined in this study design nor was quality of each symptom

accurately determined. The intensity of symptoms was verified through the use of cut-off scores for each symptom that then provided a limited degree of empirical evidence for the proposed symptom cluster. Future work will incorporate more precise measures of the quality, intensity, timing and level of distress of each of these symptoms.

Limitations

Study findings are limited by very small number of subjects (n=15) and by its lack of cultural diversity (all subjects Caucasian) in its ability to generalize findings. However, it should be noted that the response to the initial letter describing and inviting women to contact the PI was 30% and within the norm of response rates to mailed questionnaires without any follow-up or other enhancements.[32] HIPAA regulations prevented the PI from initiating contact with the 183 women who comprised the initial pool of subjects.[33] The requirement of the potential subject to initiate contact with the PI following receipt of the introductory letter may have impacted final study sample size. Future research will utilize a different recruitment approach. Finally, while information on type of breast surgery the woman experienced was not collected, it was deemed a minor issue since the literature suggests that breast cancer surgery has little direct effect on sexuality.[18,34]

Conclusion

This pilot study provides preliminary support to the hypothesis suggesting that there is an interrelationship among the four commonly occurring symptoms of fatigue, weight gain, psychological distress and altered sexuality. More rigorous work with a larger, more diverse sample should be convened to empirically validate these symptoms as a cluster in order to develop an effective intervention for this group of symptoms. Refining the methods of determining the existence of a symptom cluster is also needed.[35] Examination of the impact of this symptom cluster on quality of life and identification of an effective intervention is indicated to assist women in living productive lives after receiving a diagnosis of breast cancer.

Table 1

Cut Off Scores for Each Symptom

Presence of Symptom	Cut-Off Score
Fatigue	Avg Score > 2
Weight Gain	Avg gain > 2.45lb

Psychological Distress	Avg Score > 1
Altered Sexuality	Avg Score < 5

Table 2

Scale	Sum Range / Mean ± sd	Average Scale Score / Mean ± sd	Frequency	Percent with Symptom
Fatigue (PFS)	34 – 208 105±53	1.55 - 9.45 4.8 ± 2.4	13	87
Weight Gain (lbs)	- 32 - + 22	6.2 ± 13.8	8	53
Psychological Distress (POMS)	27 – 91 56±24	0.33 - 1.91 1.10 ± .83	13	87
Altered Sexuality (WSBQ)	143 – 202 174±22	0.88 - 4.14 3.13 ± 0.82	14	94
Quality of Life (FACT-B)	15 – 83 52±22	0.42 - 2.31 1.40 ± 0.58		

Table 3

Individual Subject Averaged Scores

Subject	PFS Avg Score	Weight	POMS Avg	WSBQ AVG	FACT-B AVG
1	6.86	-32	1.13	0.88	1.28
2	7.41	+5	1.52	2.74	2.00
3	3.82	0	0.85	3.25	1.03
4	2.23	+18	0.42	3.81	0.89
5	2.91	+3	0.78	3.68	0.89
6	3.86	-0.4	1.23	2.96	1.50
7	1.55	+20	0.46	3.26	0.80
8	5.23	+14	1.40	3.53	1.56
9	7.86	+22	1.91	2.70	2.31

10	4.73	+12	0.92	2.04	2.28
11	5.36	0	1.88	3.13	1.39
12	1.55	0	0.33	3.60	0.42
13	5.95	+6	1.45	3.77	1.08
14	3.09	missing	missing	4.14	1.46
15	9.45	+13	missing	3.47	2.19

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