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The Relationship between Hot Flashes and Sleep Quality in Women Being Treated for Breast Cancer

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The Relationship between Hot Flashes and Sleep Quality in Women Being Treated for
Breast Cancer

by

Carly Pabon, RN, BSN

A thesis submitted in partial fulfillment
of the requirements for the degree of
Master of Science
College of Nursing
University of South Florida

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modulator

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Dedication

This is dedicated to my wonderful husband Eddie, my sister Beth, my mother and father, my grandmothers and my friends. Eddie, this is for our family and our peanut. You never let me lose sight of what I really think is important. You understood the sacrifices that needed to be made for this and made me feel that it was worth it. You are more than anyone could ever hope for. You make me the luckiest girl in the world. To Bethy- thank you for stepping in as the big sister and taking care of me. The Starbucks, the dinners and even a place to nap never went unnoticed. You are one of the most selfless people I know, I hope to earn a place in your dedication one day! For my mom who started my hot flash interest and pretended to understand and be interested when I needed you to. I appreciate the “gentle pushing” that gave me the foundation that I needed to eventually become a good student. I hope I make you proud. To Nana for all of your “Mazel Tov’s” even if you really didn’t know why I was so excited. I know you are always on my side. To Dad and Nanny for checking up on me and supporting all of my decisions. Lastly, to my classmates and friends Cindy and Natalie- we did it!! You understood when no one else could and made the journey worth it, our friendship is the best thing to come out of this.

The words on this page cannot fully express the gratitude I have for each of you for helping me to achieve this goal. You are so special to me. I love you all.

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The Relationship between Hot Flashes and Sleep Quality in Women Being Treated for Breast
Cancer

Carly Pabon

ABSTRACT

Hot flashes are one of the most bothersome symptoms experienced by women who have undergone breast cancer treatment-induced menopause. This vasomotor symptom has been hypothesized to be responsible for decreased sleep quality. This study further investigated the relationship between hot flashes and sleep quality in this population.

The convenience sample consisted of 30 women being seen at an outpatient clinic in a comprehensive cancer center in southwest Florida. All participants were between the ages of 36-65, had a diagnosis of breast cancer and were currently taking a selective estrogen receptor modulator for at least six weeks. The participants completed the Hot Flash Diary, Hot Flash Questionnaire, Hot Flash Related Daily Interference Scale, Pittsburgh Sleep Quality Index and a demographic form.

The mean sleep score of the sample was 9.33 (SD= 4.4). Global sleep scores above five are indicative of poor sleep quality, and global sleep scores of eight or more have been linked to cancer-related fatigue. Sleep was strongly correlated with hot flash distress ($r = .754, p = .000$) and hot flash severity ($r = .718, p = .000$) and moderately correlated with hot flash interference ($r = .507, p = .004$) and hot flash frequency while asleep ($r = .680, p = .000$).

The small sample size was a study limitation. However, study results do support findings from previous studies. This study addresses a symptom management problem that may give nurses better understanding of the experiences of their patients. These findings also may assist

patients in helping their providers to understand the frustration they are experiencing with regard to their decreased sleep quality.

Chapter One

Introduction

Hot flashes are among the most common symptoms in women experiencing menopause. After breast cancer treatment-induced menopause, about 65% of women will have sudden episodes of intense warmth, which may begin in the chest and progress to the neck and face. Hot flashes may be accompanied by other bothersome symptoms such as anxiety, palpitations, profuse sweating, and red blotching of the skin (Finck, Barton, Loprinzi, Quella &, Sloan, 1998; Shanafelt, Barton, Adjei &, Loprinzi, 2002).

The concept of a decrease in sleep quality (waking episodes) in postmenopausal women with hot flashes has been accepted since 1981 (Erluk et al., 1981). However, it is only in the past 10 years that this topic has been investigated further to benefit the women experiencing this symptom distress. Women who are severely bothered by hot flashes may be placed on estrogen therapy, which has been shown to be the most effective choice to eliminate hot flashes in postmenopausal women (Carpenter et al., 1998; Jacobson et al., 2001). However, women with breast cancer are not given this option; because estrogen has been contraindicated for this population (Carpenter et al., 1998). Other pharmaceuticals and alternative therapies used to treat hot flashes, such as black cohosh, venlafaxine, clonidine, and gabapentin are currently under investigation (Carpenter et al., 1998; Jacobson et al., 2001; Loprinzi et al., 2000; Shanafelt, Barton, Adjei &, Loprinzi, 2002).

Decreased sleep quality can be related to many different physiological responses, and is often perceived by health care professionals as a symptom caused by anxiety or depression, which are both common in the cancer population (Carpenter, Elam, Ridner, Carney, Cherry & Cucullu, 2004). A review of the literature by Savard and Morin (2001) concluded that between 30% and 50% of recently treated cancer patients reported sleep problems. This problem has not been adequately addressed in breast cancer survivors experiencing hot flashes.

Problem Statement

Women who go through menopause naturally are expected to have hot flashes and sleep disturbances. It has been hypothesized that women who undergo breast cancer treatment with tamoxifen (a selective estrogen receptor modulator or SERM) experience decreased sleep quality and increased hot flash experience (including hot flash frequency, severity, and distress) compared to their healthy counterparts (Carpenter & Andrykowski, 1999). In a study examining the circadian rhythm of postmenopausal breast cancer survivors, hot flashes were experienced up to seven times a night. Twenty-one percent of all hot flashes experienced by these women occurred between 11 p.m. and 6 a.m. (Carpenter, Gautam, Freedman &, Andrykowski, 2001). This increase in hot flashes during sleeping hours commonly disrupts the woman's sleep. However, it is not presently clear what characteristics of the hot flash experience are related to decreased sleep quality.

Research Purpose

The purpose of this study is to evaluate the relationships between the hot flash experience and sleep quality in breast cancer patients who are taking a selective estrogen receptor modulator.

Research Questions

The following research questions were addressed in this study.

For breast cancer survivors taking a selective estrogen receptor modulator, including tamoxifen, toremifene and raloxifene:

1. Is there a relationship between hot flash frequency and sleep quality?
2. Is there a relationship between hot flash severity and sleep quality?
3. Is there a relationship between hot flash distress and sleep quality?
4. Is there a relationship between hot flash interference and sleep quality?

Definitions of Terms

The following terms are defined for the purposes of this study:

Hot Flash Experience: The full spectrum of a hot flash experience, including the distress, frequency, interference, and severity perceived by the patient (Carpenter, Johnson, Wagner, & Andrykowski 2002).

Hot Flash Frequency: Number of hot flashes in 24-hour period (Carpenter, Johnson, Wagner, & Andrykowski, 2002).

Hot Flash Distress: The extent to which hot flashes are bothersome (Carpenter, Johnson, Wagner, & Andrykowski, 2002).

Hot Flash Interference: The degree hot flashes interfere with daily living (Carpenter, 2001).

Hot Flash Severity: The intensity of the hot flash physiological experience (Finck, Barton, Loprinzi, Quella &, Sloan, 1998).

Sleep Quality: “Includes quantitative aspects of sleep, such as sleep duration, sleep latency, or number of arousals, as well as more purely subjective aspects”(Buysse, Reynolds, Monk, Berman &, Kupfer, 1989, p. 194).

Significance of the Problem

Women who experience SERM induced menopause endure a different hot flash and sleep quality disturbance than those in natural menopause. The sleep pattern disturbances of breast cancer survivors are currently clustered with anxiety and depression without investigation into the impact of the woman’s hot flashes. This inadequacy presents as missed assessments of the true etiology of the breast cancer survivors’ poor sleep quality. Understanding the relationship between sleep quality and hot flash severity, frequency, distress and sleep interference is necessary to provide evidence based nursing care. However, current knowledge does not provide adequate information for nurses to fully explore sleep quality in the breast cancer survivor in a meaningful way. This research may add to the body of nursing knowledge from which nursing assessments, teaching, interventions and research are derived.

Chapter Two

Review of Literature

It was first hypothesized in a study by Erlik et al. (1981) that hot flashes affected sleep. Since that time there have been countless research studies on both hot flashes and sleep. First, the conceptual framework will be discussed. This will be followed by a review of literature that focuses on menopausal symptoms and hot flashes in breast cancer patients. Then, literature is presented examining sleep in these patients and the impact that it has on the quality of life of those being studied. Finally a synthesis of the two topics, hot flashes and sleep in the breast cancer survivor is reviewed.

Model of Symptom Management

The framework for this study is the Model of Symptom Management created by the University of California, San Francisco School of Nursing (Larson et al., 1994). This framework focuses on the subjective view of the patient for gathering data and symptom management. This model focuses on three interrelated components: Symptom experience, symptom management strategies, and symptom outcomes.

This model exemplifies a comprehensive approach to symptom management, focusing on the three components and the integration to form the best possible strategy for care. The first dimension of the model of symptom management is the symptom experience, which contains the patient's perception of his or her symptoms, the evaluation of those symptoms, and the patient's response to those symptoms. In this case

the symptom experience would be that of the hot flash experience and of sleep disturbance (Larson et al., 1994). This is the dimension of this framework that was the focus of this study.

The second dimension is symptom management strategies. This is the symptom's treatment that has been found acceptable for the patient, the family and the healthcare provider. These strategies may be aimed at one or more components of the symptom experience. This is what can be perceived as the goal in most of the research discussed here. The research is designed with the thought that better understanding of the first dimension may help us to improve this second dimension.

The third and last dimension of the Symptom Management Model is symptom outcomes. These have been conceptualized as 10 multidimensional indicators including: symptom status, financial status, self care ability, quality of life, morbidity and co-morbidity, mortality, health service utilization, functional status, and emotional status. Symptom status is central and influences the other indicators, and hot flashes and sleep heavily influence this dimension. That can be determined by examining this dimension.

Review of Empirical Literature

Hot Flashes and Breast Cancer

The purpose of the cross sectional descriptive study by McPhail and Smith (2000) was to evaluate the menopausal symptom experience in both women who were receiving adjuvant chemotherapy for treatment of breast cancer and women who were without breast cancer. Four hundred questionnaires were sent out to participants in the two groups, obtained from either a cancer center in Scotland where the women were receiving adjuvant chemotherapy or a breast screening service where the women had no cancer

diagnosis. One hundred and thirty-nine breast cancer patients returned the questionnaires, while 99 of the healthy women returned questionnaires. The instrument in the questionnaire was newly developed for this study and consisted of three sections: general health and menstrual history; questions about patient's breast cancer diagnosis, cancer treatment and symptoms (not included for the healthy women); and questions to assess menopausal history and symptoms. Excluded from this study were those who had recurrent or metastatic disease, those over 65 years of age, those with a history of a co-morbid disease process, and those who were unable to complete the packet independently.

The study (McPhail & Smith, 2000) revealed four symptoms significant to breast cancer patients compared with their healthy counterparts: increased tiredness (higher in those receiving chemotherapy $p = 0.016$); increased hot flashes (more frequent in those taking tamoxifen $p = 0.002$); and an increase in night sweats ($p = 0.04$). Healthy counterparts reported an increased frequency of headaches compared to the breast cancer patients ($p = 0.025$). These investigators concluded that hot flashes were the second most common symptom of breast cancer survivors and that this symptom was significantly worse for breast cancer patients than for healthy women.

Carpenter and Andrykowski (1999) conducted telephone interviews of post-menopausal breast cancer survivors who were at least three months post-treatment ($n = 114$) to identify the most commonly reported menopausal symptoms. Menopausal status and symptoms were assessed using questions adapted from the Massachusetts Women's Health Study and an adapted version of the Blatt Menopausal Index and Severity Index, respectively. Quality of life was assessed using the SF-12 Health Survey. Seventy-five

percent or more of the sample reported joint pain, feeling tired, trouble sleeping, and hot flashes/night sweats. Fifty-nine percent of those reporting hot flashes ranked them as being quite a bit or extremely severe. Sleep disturbance was reported in 77% of the study population, with 43% of these calling the severity quite a bit or extreme. A higher prevalence and severity of these symptoms was correlated with lower physical ($r = -0.36$) and emotional ($r = -0.44$) quality of life.

Carpenter et al. (1998) conducted a study of the prevalence and severity of hot flashes and associated variables. The study also examined the knowledge of the breast cancer survivors on hot flash treatment and the relationship between the hot flashes and quality of life. The women were no longer receiving treatment for breast cancer, with the exception of tamoxifen. Participants were sent a questionnaire packet to complete while on the phone with study personnel. The packet included demographic questions, and questions that were adapted from the Massachusetts Women's Health Study regarding menopausal status. Also included were instruments assessing current and past hot flash management and a quality of life survey.

Hot flashes were reported in 65% of postmenopausal women with breast cancer and 72% of women taking tamoxifen. These analyses showed that women more likely to have severe hot flashes were typically greater in body mass index ($p < 0.05$), younger at diagnosis ($p < 0.01$), had received chemotherapy ($p < 0.05$) and were users of tamoxifen ($p < 0.01$). Women with hot flashes reported a lower quality of life ($p < 0.10$). Study limitations included a small sample and one geographic area. Also, hot flash information was limited to prevalence, severity and symptom bother. The data would be more

informative if compared to a group of menopausal women without breast cancer, as well as inclusion of daily frequency, daily pattern, and intensity (Carpenter et al., 1998).

A study conducted by Carpenter, Johnson, Wagner, and Andrykowski (2002) compared the severity of hot flashes in breast cancer survivors with healthy women going through menopause. Breast cancer survivors ($n = 67$) were age-matched (within 2 years) to healthy menopausal subjects. The breast cancer group had a first time diagnosis of breast cancer, no other cancer diagnosis, was disease free at the time of enrollment, three months past any treatment (including chemotherapy, radiation therapy or surgery) with the exception of tamoxifen (which they needed to be on for six weeks prior to the start of the study), and less than or equal to six years after diagnosis. The healthy women had no history of cancer, and an intact uterus and ovaries. A packet was sent to each woman describing the study and containing several instruments: a demographic, disease and treatment form, and gynecologic and reproductive history form for menopausal status; questions from the Massachusetts Women's Health Study to determine menopausal status; Profile of Mood States Short Form; Positive and Negative Affect Scale; Hot Flash-Related Daily Interference Scale; and a hot flash questionnaire. The hot flash questionnaire items included severity, bother, quality, aggravating factors, alleviating factors, and temporal pattern. A 48-hour detailed hot flash diary also was included for completion. The 48-hour hot flash diary is considered the gold standard of subjective hot flash frequency and severity measurement (Barton et al., 1998; Carpenter et al., 1998). Results were that breast cancer survivors have more frequent ($p = 0.006$), more severe ($p = 0.001$), more bothersome ($p = 0.001$) and longer ($p = 0.002$) hot flashes than their healthy counterparts. Findings also suggest that if women continue to have hot flashes,

they are more prone to negative psychosocial effects ($p < 0.005$). Therefore, alleviating hot flashes may improve overall quality of life, including mood, affect, sleep, concentration, and sexuality.

Quality of life is a focus of cancer patient care. Stein, Jacobsen, Hann, Greenberg and, Lyman, in 2000, focused on the impact of hot flashes on quality of life. This study examined 70 postmenopausal women with breast cancer who were over 18, receiving adjuvant chemotherapy or radiotherapy, without unstable medical problems or neurologic disorders, and without history of other cancers. Using nine different measurements, the impact of hot flashes on their quality of life was determined. All of the data was collected 4-6 weeks after the start of therapy. Of the 70 women in the study, 42 were receiving radiation therapy, and 28 chemotherapy, 6 were also taking tamoxifen. The measures used in the study included, a demographic data form, the SF-36 health survey, Memorial Symptom Assessment Scale, State-Trait Anxiety Inventory, Center for Epidemiological Studies Depression Scale, Profile of Mood States Fatigue Scale, Fatigue Symptom Inventory, Multidimensional Fatigue Symptom Inventory, and the Pittsburgh Sleep Quality Index.

Forty percent of the 70 women in the study by Stein et al. (2000) were having hot flashes. Sixty-seven percent stated that they were moderate to severe, and 58% stated that they were somewhat to very much distressed by the symptom. Compared to the women in the study who did not report having hot flashes, the women with hot flashes were 66% more fatigued, 63% had poorer sleep quality, and 20% had poorer health.

Sleep and Cancer

Engstrom, Strohl, Rose, Lewandowski and, Stefanek (1999) conducted a study on sleep disturbances in patients with cancer. A convenience sample of lung cancer (n=57) and breast cancer (n=93) patients was studied. Inclusion criteria included that the patient had to have received (67%) or be currently (33%) receiving either chemotherapy, hormone therapy, radiation therapy, surgery, or was considered to be receiving supportive care only. An 82-item detailed questionnaire was administered over the phone.

The results of the study found no relationship between sleep disturbances and day naps, pain or nausea, diagnosis, stage of disease, or treatment. Forty-four percent reported sleep disturbances occurring within one month of the assessment. Only 16.6% of those patients reported sleep problems to a nurse or doctor. When asked why they did not report sleep symptoms one patient stated, "I thought it was not as important as having the cancer itself" (Engstrom et al., 1999, p. 149).

Fortner, Stepanski, Wang, Kasprovicz and Durrence (2002) conducted a cross sectional survey of breast cancer and medical patients to investigate the characteristics of their sleep. Seventy-two breast cancer patients and 50 healthy women were given the Pittsburgh Sleep Quality Index and Rand 36 item Health Survey. Of the 72 breast cancer patients, 19 were pre-cancer treatment, 29 were receiving treatment and 23 had received treatment in the past. Sixty-one percent of the breast cancer patients had a significant decrease in sleep quality. This was attributed to several things. The most frequent reason for sleep disturbance was reported to be the need to use the bathroom, followed by feeling too hot, middle of the night or early awakening, and coughing or sneezing loudly. The only reported difference between the healthy group and breast cancer group was the

use of medication to facilitate sleep, with breast cancer patients more likely to use medications than their healthy counterparts. There was also a decreased amount of total sleep time of the breast cancer group compared to the healthy group.

Kravitz et al. (2003) created a large study depicting the differences in sleep in midlife women when considering ethnicity and the different stages of menopause. There were 12,603 participants in this study, all of whom were between 40 and 55 years of age. Ethnicity was defined as either African American, Caucasian, Chinese, Japanese or Hispanic. Menopausal status was defined as premenopausal, early perimenopausal, late perimenopausal, naturally postmenopausal, surgically postmenopausal, or postmenopausal on hormone replacement therapy. Subjects were all requested to take a 12-item symptom questionnaire regarding sleep and a demographic form, which helped to determine stage of menopause. The women who were the least likely to have sleep difficulties were premenopausal and Japanese. The women most likely to have sleep difficulties were Caucasian, had higher education, vasomotor symptoms (hot flashes), psychologic symptoms, increased perceived stress, poorer self perceived health, decreased quality of life, decreased physical activity, current smokers and a diagnosis of arthritis. Forty percent of Caucasian women, 38% of Hispanic women, 35% of African American women, 31% of Chinese women, and 28% of Japanese women reported sleep difficulty. Late perimenopausal women were the most common menopausal status group to have sleep difficulty.

Hot flashes and Sleep in the Breast Cancer Survivor

It is important to understand the potential for sleep disruptions in women who are breast cancer survivors because this is what will fuel the treatments of the future.

Carpenter, Gautam, Freedman and Andrykowski (2001) took on the investigation of the circadian rhythm of objectively recorded hot flashes in this population. Twenty-one women were connected to a sternal skin conductance monitor for 24 hours to record hot flash activity. These women all had a first time diagnosis of breast cancer, were postmenopausal, 3 months post diagnosis, were currently disease free, and currently having hot flashes but not taking medication to treat them. The women, in addition to being connected to a monitor for 24 hours, were asked to keep an activity diary keeping track of activities, including exercise, work, driving, bed time and sleep time and perceived hot flashes. The findings from this study suggest that the circadian rhythm is disrupted among breast cancer survivors. Twenty-one percent of hot flashes were between 11 p.m. and 6 a.m. and half the sample had at least three and up to seven hot flashes during sleep. This significant number of hot flashes during sleep hours leads to fatigue, poor sleep quality and sleep disturbances (Carpenter et al., 2004). The limitations of this study were suggested to be a small sample size, only a 24 hour recording period and lack of a control group.

Carpenter et al., (2004) compared hot flashes, sleep quality and disturbance, fatigue and depressive symptoms between breast cancer survivors (n = 46) and healthy women. Criteria for breast cancer was older than 21, English speaking, peri or postmenopausal, experiencing daily hot flashes, in good general health, not depressed, not taking hot flash treatment, first diagnosis of cancer, disease free at time of study enrollment, at least 4 weeks post cancer treatment and, if applicable, on tamoxifen for at least 6 weeks. These women were matched to healthy women. The subjects were given a demographic form, the Pittsburgh Sleep Quality Index, the Profile of Mood States Short

Form, and Center for Epidemiological Studies-Depression Scale, and were monitored with a sternal skin conductance monitor to assess hot flashes. The monitor was placed on the subject for two 24-hour periods spaced one week apart. The women were also asked to complete a hot flash diary to assist in interpreting the data from the monitor. The results of the study were that both groups reported similar sleep quality, though breast cancer survivors experienced more nighttime hot flashes than the healthy women did. Both samples were found to have had a symptom cluster of poor sleep, fatigue and depression, possibly related to menopausal status (Carpenter et al., 2004).

The last study in this review seems to connect the rest of the studies that were reviewed. This study by Savard et al. (2004) assessed the relationship between objectively measured nighttime hot flashes and objectively measured sleep quality. Participants were breast cancer survivors (n = 24) with a diagnosis of insomnia as dictated by the International Classification of Sleep Disorders and Diagnostic and Statistical Manual of Mental Disorders IV (American Psychiatric Association, 1994). The measures used in this study included an Insomnia Interview Schedule, a medication record, and the Hot Flash item of the European Organization for Research and Treatment of Cancer and the Breast Cancer Specific Quality of Life Questionnaire. A skin conductance monitor objectively measured the hot flashes. Sleep was objectively measured by polysomnography, including electroencephalograph (EEG), electromyography (EMG), and electrooculograph (EOG) recordings. Several variables were measured with these instruments, including: time in bed, total wake time, total sleep time, percentage of time in each stage of sleep, percentage of time awake, number and duration of brief arousals, number of awakenings, sleep efficiency, latency time in each

stage of sleep, and number of changes from a higher level of sleep to a lesser level of sleep. Each woman was studied three nights in the sleep lab, with data from only the last two nights included in the data analysis to avoid a threat to external validity.

The data collected revealed that hot flashes could be associated with sleep disruption in breast cancer survivors. There was an increase in the frequency of the hot flashes between 3 a.m. to 5 a.m. and 11 p.m. to 12 a.m. with an increase in wake time and higher number of stage changes to lighter sleep 10 minutes before or after the hot flash was experienced. A limitation to the study was that when a hot flash was detected there was a 20-minute window where a new hot flash could not be identified (Savard et al., 2004). The subject is more likely to be awake making them unlikely to wake up again. This may account for the lack of difference between the number of awakenings between hot flash time and non hot flash time. This should be considered a limitation of this study.

Summary

The studies reviewed have suggested that there is a relationship between hot flashes and sleep quality. It is clear that there is a difference between women who are survivors of breast cancer who take tamoxifen and those who have never had the disease in their menopausal experience. No studies were found that have subjectively evaluated the relationship between each aspect of the hot flash symptom experience and sleep quality.

Chapter Three

Methods

This chapter presents the study design and methods. The purpose of this study is to evaluate the relationships between the hot flash experience and sleep quality in breast cancer patients who are taking a selective estrogen receptor modulator. The relationship between hot flashes and sleep quality was evaluated using quantitative research with a non-experimental correlational design. It was anticipated that breast cancer survivors who have increased hot flash severity, distress, frequency, and interference would have decreased sleep quality.

Sample

The setting for this study was an outpatient breast clinic in a comprehensive cancer center in Southwest Florida. Women eligible to participate in the study had to meet the following criteria: 1) a diagnosis of breast cancer, 2) currently taking a SERM, either tamoxifen, toremifene, or raloxifene for at least six weeks, 3) be over age 18, 4) able to read, write, and understand English, and 5) able to provide informed consent. Exclusion criteria included a diagnosis of any other type of cancer, and treatment of any cancer including radiation therapy, chemotherapy or surgery in the past six months to avoid their confounding effects. A convenience sample of 88 women who had been diagnosed with breast cancer and were currently taking a SERM was sought. Using variables at an interval level of data, a Pearson's r was planned to describe the

relationship between two variables. With alpha at .05, two-tailed, a population correlation coefficient of .30 for a moderate effect size, and a power of .80, the sample size needed for this study was 88.

Instruments

The researcher reviewed four self-report measures with the participants. One measure was gathered from the medical record by the researcher.

Hot Flash Diary

The Hot Flash Diary (Appendix A) is a brief questionnaire that was used to assess patient perceptions regarding hot flash frequency, hot flash distress and hot flash severity. This included definitions (Appendix B) that assisted the woman to place each of her hot flashes in one of the four severity categories ranging from mild to very severe (Sloan et al., 2001). The number of hot flashes the woman has experienced in the past 24 hours and during her sleep was assessed with this instrument as well. Women were also asked to provide an overall rating of how bothered they are by their hot flashes using a 10-point numeric scale 0 (not at all) to 10 (extremely). This type of diary has been used previously and is considered the gold standard for assessing hot flash frequency and severity subjectively (Barton et al., 1998; Sloan et al., 2001). This Diary has been used to assess hot flashes at present as well as hot flashes over an extended period of time. In this study the Hot Flash Diary was used as a four-question twenty-four hour recall. Validity and reliability has been reported by Sloan et al., (2001) who states that the Hot Flash Diary has concurrent and discriminant validity and reliability from the study of a placebo controlled trial.

Hot Flash Related Daily Interference Scale

The Hot Flash Related Daily Interference Scale (HFRDIS) developed by Carpenter (2001) is a 10-item scale measuring the degree hot flashes interfere with nine daily activities; the tenth item measures the degree hot flashes interfere with overall quality of life (Appendix C). The HFRDIS was developed to include daily life activities specific to the impact of hot flashes. Participants rate the degree to which hot flashes have interfered with each item during the previous week using a 0 (do not interfere) to 10 (completely interfere) point scale. A total score is computed by summing these items. Higher scores indicate higher interference due to hot flashes and thus, greater impact on quality of life. Women without hot flashes are asked to simply mark 0 for each item. Internal consistency reliability was estimated with a Cronbach alpha coefficient and reported to be 0.96. Validity was supported through 1) correlations with other hot flash variables, 2) correlations with measures of affect and mood, 3) significant differences between women with hot flashes and those without, and 4) demonstrated sensitivity over time (Carpenter, 2001).

Pittsburgh Sleep Quality Index (PSQI)

Sleep quality was assessed using the PSQI, which is a standardized measure of sleep quality. The PSQI (Appendix D) consists of 19 items which are combined to produce a global sleep quality score and 7 component scores: sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbance, use of sleeping medications, and daytime dysfunction. Each of the component scores range from 0 (no difficulty) to 3 points (severe difficulty). These scores are summed to make the global score, which

ranges from 0-21 and reflects the number and severity of sleep problems. This score was used to determine sleep quality. Global scores of 5 or greater indicate poor sleep quality and high sleep disturbance. In addition to being indicative of poor sleep quality and high sleep disturbance, global scores of eight or more have been linked to cancer-related fatigue in survivors of breast cancer and other cancers (Carpenter & Andrykowski, 1998). In a psychometric evaluation of the PSQI in 1998 by Carpenter and Andrykowski, the Cronbach's alpha coefficient was calculated as 0.80 for the global sleep score.

Demographic and disease treatment information

A demographic form (Appendix E) was used to assess demographic information, including birth date, ethnicity, and education level. Information was also gathered (Appendix F) from the medical record including date and stage at diagnosis, how long since last cancer treatment, what kind of treatments have been received, and when current anti-estrogen therapy started.

Procedures

This study involved several procedural steps. The first step was approval from Moffitt Cancer Center Protocol Review and Monitoring Committee to conduct the study, followed by approval from the University of South Florida Institutional Review Board. Following approval, potential subjects were identified for inclusion criteria by clinic nurses in the Moffitt Cancer Center ambulatory clinic patients. Once identified, potential subjects were approached regarding study participation. An informed consent and HIPPA form was given to all participants (Appendix G and H). These forms included the title of the study, the principal investigator, general information about the study, the plan of study, the benefits and the risks of participation, and a statement about confidentiality.

The study was explained, and all questions will be answered. After agreeing to participate, the woman then signed the consent form and a copy was given to the woman for her records. Following signed consent to participate, the women completed the Hot Flash Diary, Hot Flash Questionnaire, Hot Flash Related Daily Interference Scale, Pittsburgh Sleep Quality Index and a demographic form. Completing these scales took about 15 minutes.

Data Analysis

The data analysis involved two steps. The first step was an analysis of demographic and treatment information using descriptive statistics. The forms were composed of interval data and nominal data.

Step two involved answering the research questions:

In breast cancer survivors on a selective estrogen receptor modulator:

1. Is there a relationship between hot flash frequency and sleep quality?
2. Is there a relationship between hot flash severity and sleep quality?
3. Is there a relationship between hot flash distress and sleep quality?
4. Is there a relationship between hot flash interference and sleep quality?

The data in each question was analyzed using Pearson's correlations with alpha set at .05.

Chapter Four

Results, Discussion and Conclusions

This chapter presents the findings of the study. Included in this chapter are the study results, discussion of the results, conclusions, and suggestions for future research.

Results

Demographic Data

The sample consisted of 30 patients, all women with ages ranging from 36 to 65 years with a mean age of 54 (SD=8.2). Years of education ranged from 12 to 18 years with a mean of 14.2 years. The majority of patients (n=28) were Caucasian. The stage of disease reported most frequently was stage I. Stage 0 represents carcinoma in situ (Table 1).

Table 1. Frequency and Percent of Women by Ethnicity and Stage of Disease

| Variable | Frequency | Percent |
|-----------|-----------|---------|
| Ethnicity | | |
| White | 28 | 93.9 |
| Hispanic | 2 | 6.7 |
| Stage | | |
| 0 | 3 | 10 |
| I | 15 | 50 |
| II | 6 | 20 |
| III | 2 | 6.7 |
| IV | 1 | 3.3 |
| Unknown | 3 | 10 |

All of the patients had a diagnosis of breast cancer, half of them with right sided occurrence (n=15). All of the women were taking tamoxifen. Twelve patients reported that they had chronic illnesses. Types of cancer treatment are reported in Table 2.

Table 2. Frequency and Percent of Women by Type of Cancer Treatment

| Medical Variable | Frequency | Percent |
|----------------------|-----------|---------|
| Chemotherapy | | |
| Yes | 15 | 50 |
| No | 15 | 50 |
| Type of SERM | | |
| Tamoxifen | 30 | 100 |
| Breast Surgery | | |
| Lumpectomy | 20 | 66.7 |
| MRM | 5 | 16.7 |
| RM | 3 | 10 |
| Unknown | 2 | 6.7 |
| Hysterectomy | | |
| With oophorectomy | 0 | 0 |
| Without oophorectomy | 3 | 10 |
| No | 27 | 90 |
| Radiation Therapy | | |
| Yes | 17 | 56.7 |
| No | 13 | 43.3 |

Sleep Quality

Sleep quality was determined by the PSQI. Using a formula, the global sleep quality was determined. A global sleep score above 5 is indicative of poor sleep quality and a score of 8 or more has been linked to cancer related fatigue in breast cancer patients. There are also some patients who are taking a sleep medication three or more times a week (16.7 %). The majority of women (n = 24) had global sleep scores greater

than 5, and 14 women (46.7 %) had global sleep scores greater than 8. Scores ranged from 2 to 18 on a scale of 0-21; the mean for all patients (n=30) was 9.33 (SD=4.4).

Hot Flash Frequency

The patients answered two different questions regarding frequency. The first was how many hot flashes they had experienced in the previous 24 hours and the second was how many of those were experienced while the patients were sleeping. There were ten patients who experienced no hot flashes. A mean of 3.7 (SD=4.8) hot flashes were experienced by the patients in the previous 24 hours, the maximum number of hot flashes reported was 24 in a 24 hour period. A mean of 1.3 (SD= 1.6) of those occurring while the patient was sleeping, the maximum reported while sleeping was 7. The number of hot flashes experienced in 24 hours was found to have a weak positive relationship with sleep quality, however the result was not statistically significant ($r=.306$, $p=.10$) (Table 3). The frequency of hot flashes experienced while sleeping had a moderate, positive, statistically significant relationship with global sleep score ($r=.507$, $p=.004$) (Table 3).

Table 3. Correlations Between Global Sleep Scores and Hot Flash Experiences

| Hot Flashes | Global Sleep Score | |
|-------------------|--------------------|------|
| | r | p |
| Severity | .718 | .000 |
| Distress | .754 | .000 |
| 24 hour Frequency | .306 | .100 |
| Sleep Frequency | .507 | .004 |
| Interference | .680 | .000 |

Hot Flash Severity

Severity of hot flashes was determined by multiplying the number of hot flashes experienced by the patient at each severity level and the severity level that they

experienced and dividing it by the number of total hot flashes experienced. The mean was 1.16 (SD 9.9). This was on a scale from zero to four; zero equating to no hot flashes and four meaning all very severe hot flashes. The patients were given definitions to use to classify their hot flash severity. No patients reported very severe hot flashes (Table 4). A strong, positive, statistically significant relationship was found between hot flash severity and global sleep score ($r=.718$, $p=.000$) (Table 3).

Table 4. Number and Frequency of Hot Flashes Experienced by the Severity Score

| <u>Severity</u> | <u>Frequency</u> | <u>Percent</u> |
|-----------------|------------------|----------------|
| None | 10 | 33.3 |
| Mild | 14 | 46.7 |
| Moderate | 12 | 40 |
| Severe | 9 | 30 |
| Very Severe | 0 | 0 |

Hot Flash Distress

Distress was measured by a zero to ten scale, zero meaning no distress and ten meaning extremely distressed. The mean score was 3.4 (SD=3.5). A strong, positive, statistically significant relationship was found between hot flash distress and global sleep score ($r=.754$, $p=.000$) (Table 3).

Hot Flash Interference

The hot flash interference score is a sum of ten questions. This number is on a scale of zero to one hundred, with zero implying hot flashes have no interference in the patient's life, and one-hundred meaning the most possible interference in the patient's life. Scores ranged from 0 to 75 with a mean interference score of 19.9 (SD=24.36). Hot

flash interference was found to have a strong, positive, statistically significant relationship with global sleep score ($r=.680$, $p=.000$) (Table 3).

Discussion

After approval from the Moffitt Cancer Center Protocol Review and Monitoring Committee and the University of South Florida Institutional Review Board, data was collected during the months of August through October of 2005. Few patients who were approached were unwilling to participate in this study.

Demographic Data

The sample consisted of a convenience sample of 30 breast cancer patients who were approached in an ambulatory care setting to participate in the study. The age range of patients participating in the study was 36 to 65 years of age with a mean of 54. This number is not representative of typical breast cancer patients due to the exclusion criteria. Women over the age of 65 were excluded from the study because previous studies have shown a decreased number of hot flashes on a SERM as women age. There were an equal numbers of women with right sided and left sided breast cancer. The sample was mostly Caucasian and few Hispanics with no African-American subjects. This is not representative of the United States breast cancer patient population; 24% of those with breast cancer are African American and 18% are Hispanic (Ries, 2004).

Another significant limitation of this study was the lack of patients found to be on a SERM. Rather, patients who are taking aromatase inhibitors (AI) as their anti-estrogen therapy seemed to be much more common. This is partly due to studies that have recently been published supporting AI therapy in both postmenopausal women and women with a breast cancer recurrence. Although hot flashes have been proven to be a bothersome side

effect for women who are taking a SERM, the AI had fewer incidences of hot flashes in preliminary studies. However, there is newer literature stating hot flashes are just as common in women who are taking an AI as those taking a SERM (Morales, 2004). Future research should compare the two classes of drugs according to women's sleep quality.

Sleep Quality

The mean global sleep quality score for these patients was 9.33, which indicates poor sleep quality. However, it is not only hot flashes that may influence sleep quality. Cancer patients typically have sleep problems related to their cancer diagnosis and disease process. Some patients in the sample were taking a sleep medication three or more times a week (16.7 %). This could have improved their sleep quality regardless of hot flashes. There are also many patients who are taking anti-depressant medications in the selective serotonin receptor modulator class in which a common side effect from these drugs is insomnia (Karch, 2006). Thus, there were confounding factors that might have influenced sleep quality.

Hot Flash Frequency

The time of the day that the hot flashes were experienced played a very important role when considering frequency. The frequency of hot flashes experienced during the day had no significant relationship to sleep quality. Only the frequency of hot flashes at night were influential on patients sleep quality. This finding supports earlier research by Carpenter, Gautam, Freedman and Andrykowski (2001) which both used objective hot flash data collection from skin conductance monitoring and a 24 hour diary. This data also supports research done by Savard et al. (2004) which also used objective measures

including hot flash skin conductance monitoring and objective sleep monitoring by polysomnography, EEG, EMG and EOG readings.

Hot Flash Severity

The severity of hot flashes had a very significant relationship with global sleep quality scores. There were no patients who reported having very severe hot flashes, yet it appears that the severity was strong enough to impact sleep quality. Women do not have to have severe hot flashes for them to be affecting their sleep. Limitations to this variable would include that some patients needed further prompting to quantify a number of hot flashes in each severity category.

Hot Flash Distress

Distress was quantified by one item. This one item had the strongest correlation with sleep quality scores. It is, therefore, the biggest predictor of poor sleep quality. Asking a woman how bothered she is by her hot flashes on a scale from 0 to 10 will predict how she is sleeping. This is a vital piece of information to be gathered when caring for her. A decreased sleep quality may then be addressed. Although the validity of this item has not been published, this strong, significant relationship would tend to support its validity.

Hot Flash Interference

The relationship between hot flash interference and global sleep score was strong and positive. The influence that hot flashes have on all aspects of the woman life correlates with the lack of sleep quality. Therefore, if women are having a difficult time sleeping because of their hot flashes they are most likely having trouble with hot flashes interfering with other life issues such as sexuality and enjoyment and quality of life. This

instrument was previously shown to have good reliability and validity, and results of this study further support its validity.

Conclusions

Hot flashes are a very common symptom for women who are taking a SERM. It seems that it is not the number of hot flashes alone that is decreasing the sleep quality of these women, but how distressing, severe and interfering the symptom is to them. Although results do not demonstrate a cause and effect, they do suggest that relieving hot flashes may have a positive effect on other aspects of quality of life including sleep.

Recommendations for future research

The prominence of aromatase inhibitors in the breast cancer population warrants similar studies with those medications, even comparing them with SERMs. A larger sample size, having a multi-site study in a broader geographical area and recruiting more African American women would all be recommendations for future research.

Oncology nursing education should include content about the likelihood of hot flashes and their impact not only on sleep quality, but on all aspects of everyday life. Assessment of hot flashes is one of the most important things nurses can do to assist their patients who are taking a SERM. Nurses should inquire about how bothersome the hot flashes are and ask if the hot flashes are interfering with sleep. Recommending techniques to improve sleep quality to women experiencing hot flashes is also appropriate.

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Appendices

Appendix A: Hot Flash Diary

1. How many hot flashes have you had in the past 24 HOURS? _____
2. How many of those were while you were sleeping? _____
3. Using the attached sheet as a guide, tell me how many of the hot flashes you have had in the past 24 HOURS were mild, moderate, severe, or very severe.

_____ mild

_____ moderate

_____ severe

_____ very severe

4. How bothered are you by your hot flashes on a scale from 0 to 10 (0 is not bothered at all, 10 is extremely bothered)? _____

Appendix B: Hot Flash Severity Definitions

PATIENT INFORMATION SHEET

HOT FLASH DEFINITIONS FOR THE FEMALE PATIENT

Please refer to these examples of hot flashes that have been given by cancer survivors in previous studies when describing their hot flash severity. One or more of these descriptions may help to categorize your hot flash as mild, moderate, severe, or very severe.

MILD

Duration: Lasting less than 5 minutes
Physical symptoms: Warmth, felt uncomfortable, red face
Emotional symptoms: Not expected
Action needed: Usually no action taken

MODERATE

Duration: Lasting up to 15 minutes
Physical symptoms: Head, neck, ears, or whole body felt warm; tense, tight muscles; clammy (wet skin; a change in heart rate or rhythm (heart speeds up or changes beat); some sweating; dry mouth
Emotional symptoms: Felt irritated, felt agitated (restless), felt as though energy was drained out, felt embarrassed when having a hot flash in front of others, felt tired, felt annoyed
Action needed: Needed to use a fan, awakened sometimes at night, needed to uncover, took off layers of clothing, drank water, opened the windows even when cold outside, wore lighter clothing

SEVERE

Duration: Lasting up to 20 minutes
Physical symptoms: Warmth, sometimes described as a raging furnace or burning up; a change in heart rate or rhythm (heart speeds up or changes beat); felt faint; headache; severe sweating; weakness, a pricking, stinging sensation over skin; chest heaviness
Emotional symptoms: Embarrassment, anxiety, feelings of having a panic attack
Action needed: Needed to stop what was being done at that time, usually awakened at night and removed covers, needed to remove clothes, opened windows, kept the house a cooler temperature, frequently used fans

VERY SEVERE

Duration: Lasting up to 45 minutes
Physical symptoms: Boiling heat, rolling sweat, difficulty breathing, felt faint, felt dizzy, feel and/or legs cramping, a change in the heart rate or rhythm (heart speeds up or changes beat), felt slightly sick to stomach
Emotional symptoms: Felt distressed, had the urge to escape, had difficulty functioning
Action needed: Awakened frequently at night, needed to change sheets and pajamas, needed to take a cold shower, needed to hold ice on skin

Appendix C: Hot Flash Related Daily Interference Scale

Please circle one number to the right of each phrase to describe how much **DURING THE PAST WEEK**, hot flashes has **INTERFERED** with each aspect of your life.

| | Does not Interfere | | | | | | | Completely interferes | | | | | |
|---|---------------------------|---|---|---|---|---|---|------------------------------|---|---|----|--|--|
| | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | | |
| 1. Work (work outside the home and housework) | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | | |
| 2. Social activities (time spent with family, friends, etc) | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | | |
| 3. Leisure activities (time spent relaxing, doing hobbies, etc.) | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | | |
| 4. Sleep | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | | |
| 5. Mood | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | | |
| 6. Concentration | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | | |
| 7. Relations with others | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | | |
| 8. Sexuality | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | | |
| 9. Enjoyment of life | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | | |
| 10. Overall quality of life | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | | |

Appendix D: Pittsburgh Sleep Quality Index

The following questions relate to your usual sleep habits **DURING THE PAST SIX WEEKS**. Your answers should reflect the **majority** of days and nights during the **past six weeks**.

1. During the PAST SIX WEEKS, when have you usually gone to bed at night?

_____ Usual bed time

2. During the PAST SIX WEEKS, how long has it usually taken you to fall asleep at night?

_____ Number of minutes

3. During the PAST SIX WEEKS, when have you usually gotten up in the morning?

_____ Usual getting up time

4. During the PAST SIX WEEKS, how many hours of actual sleep did you get at night?
(This may be different than the number of hours you spent in bed.)

_____ Hours of sleep per night

For each of the remaining questions, check the one best response. Please answer all questions. **During the PAST SIX WEEKS, how often have you had trouble sleeping because you...**

| | Not during the past month | Less than once a week | Once or twice a week | Three or more times a week |
|---|---------------------------|-----------------------|----------------------|----------------------------|
| 5. Cannot get to sleep within 30 minutes | 0 | 1 | 2 | 3 |
| 6. Wake up in the middle of the night or early morning | 0 | 1 | 2 | 3 |
| 7. Have to get up to use the bathroom | 0 | 1 | 2 | 3 |
| 8. Cannot breathe comfortably | 0 | 1 | 2 | 3 |
| 9. Cough or snore loudly | 0 | 1 | 2 | 3 |
| 10. Feel too cold | 0 | 1 | 2 | 3 |
| 11. Feel too hot | 0 | 1 | 2 | 3 |
| 12. Had bad dreams | 0 | 1 | 2 | 3 |
| 13. Have pain | 0 | 1 | 2 | 3 |
| 14. Other reasons | 0 | 1 | 2 | 3 |

Appendix D: Pittsburgh Sleep Quality Index

15. During the PAST SIX WEEKS how would you rate your sleep quality overall? (CHECK ONE)

- Very good
- Fairly good
- Fairly bad
- Very bad

16. During the PAST SIX WEEKS, how often have you taken medicine (prescribed or “over the counter”) to help you sleep? (CHECK ONE)

- Not during the past month
- Less than once a week
- Once or twice a week
- Three or more times a week

17. During the PAST SIX WEEKS, how often have you had trouble staying awake while driving, eating meals, or engaging in social activities? (CHECK ONE)

- Not during the past month
- Less than once a week
- Once or twice a week
- Three or more times a week

18. During the PAST SIX WEEKS, how much of a problem has it been for you to keep up enough enthusiasm to get things done? (CHECK ONE)

- No problem at all
- Only a very slight problem
- Somewhat of a problem
- A very big problem

19. Do you have a bed partner or roommate? (CHECK ONE)

- No bed partner or roommate
- Partner/roommate in other room
- Partner/roommate in same room, but not in same bed
- Partner in same bed

Appendix E: Demographic Questionnaire

DEMOGRAPHIC QUESTIONNAIRE

What is your age? _____ (on your last birthday)

What is your ethnicity?

- White _____ (1)
- African-American _____ (2)
- Hispanic _____ (3)
- American Indian _____ (4)
- Asian _____ (5)
- Pacific Islander _____ (6)

Please circle the highest grade of education you completed.

- 1 2 3 4 5 6 7
- 8 9 10 11 12 (high school)
- 13 14 15 16 (college)
- 17 18 (master's degree)
- 19 20 (doctorate)

What medications or supplements are you currently taking? (Please list all vitamins, herbs, supplements, and medications, including pills, inhalers, injections, and creams)

Do you have any chronic medical problems, such as arthritis or high blood pressure?

___ no (0)

___ yes (1), please list any medical problems:

Appendix F: Disease and Treatment Information

DISEASE & TREATMENT INFORMATION (To be filled out by researcher)

| | |
|--|--|
| <p>DIAGNOSIS Date: ____ - ____ - ____</p> <p>Location: ____ left (1) ____ right (2) ____ bilateral (3)</p> <p>Stage: T ____ N ____ M ____</p> <p>X ____ (0) (any Tx, any Nx, any Mx) 0 ____ (1) I ____ (2) IIA ____ (3) IIB ____ (4) IIIA ____ (5) IIIB ____ (6) IV ____ (7)</p> | <p>SURGERY Date: ____ - ____ - ____</p> <p>Type: ____ lumpectomy (1) ____ MRM (2) ____ RM (3) ____ other (4)</p> <p>Hysterectomy: ____ yes, with oophorectomy (1) ____ yes, without oophorectomy (2) ____ no (3)</p> |
| <p>CHEMOTHERAPY ____ none (0) ____ some (1), # cycles received? ____</p> <p>Begin date: ____ - ____ - ____ End date: ____ - ____ - ____</p> <p>ANTI-ESTROGEN THERAPY (current use) ____ no (0) ____ tamoxifen (Nolvadex)(1) ____ toremifene (Fareston) (2) ____ raloxifene (Evista) (3)</p> <p>Begin date: ____ - ____ - ____ End date: ____ - ____ - ____</p> | <p>RADIATION THERAPY ____ none (0) ____ some (1)</p> <p>Begin date: ____ - ____ - ____ End date: ____ - ____ - ____</p> <p>Complete Treatment Received: ____ surgery alone (1) ____ surgery + XRT (2) ____ surgery + chemo (3) ____ surgery + XRT + chemo (4)</p> <p>Date of last treatment: ____ - ____ - ____</p> |

| |
|------------------------------|
| IRB Approval FWA 000H1669 |
| IRB Number: 103878 |
| From 08/11/2005 |
| Thru 08/10/2006 |

Informed Consent

Social and Behavioral Sciences
University of South Florida

Information for People Who Take Part in Research Studies

The following information is being presented to help you decide whether or not you want to take part in a minimal risk research study. Please read this carefully. If you do not understand anything, ask the person in charge of the study.

Title of Study: The relationship between hot flashes and sleep quality in women being treated for breast cancer

Principal Investigator: Carly Pabon, RN, BSN

Study Location(s): H. Lee Moffitt Cancer Center & Research Institute Breast Clinic

Why are you being asked to take part?

We are asking you to take part in this study because you are a woman who is at least 18 years old who has been taking a medicine for breast cancer for at least six weeks.

General Information about the Research Study

The purpose of this research study is to find out if hot flashes caused by your breast cancer medication affects your sleep.

Plan of Study

You will be asked once to answer 38 questions regarding hot flashes and sleep. You will also be asked to fill out a form that tells us a little bit about you. This should take less than 30 minutes. We will also look at your medical records to find out a little more about your treatment.

Payment for Participation

It will not cost you anything to take part in the study.

Benefits of Being a Part of this Research Study

While you will not directly benefit from participating in this study, you may help women in the future by increasing knowledge about the issue.

Risks of Being a Part of this Research Study

There are no known risks to those who take part in this study.

Confidentiality of Your Records

Your privacy and research records will be kept confidential to the extent of the law. Authorized research personnel, employees of the Department of Health and Human Services, and the USF Institutional Review Board and its staff and any others acting on behalf of USF may inspect the records from this research project.

IRB Form: ICadult-LR-SBv17



The results of this study may be published. However, the data obtained from you will be combined with data from others in the publication. The published results will not include your name or any other information that would personally identify you in any way. Your name will not be on any forms used in this study.

Volunteering to Be Part of this Research Study

Your decision to participate in this research study is completely voluntary. You are free to participate in this research study or to withdraw at any time. There will be no penalty or loss of benefits you are entitled to receive, if you stop taking part in the study.

Questions and Contacts

- If you have any questions about this research study, contact Carly Pabon at (813) 786-1309.
- If you have questions about your rights as a person who is taking part in a research study, you may contact the Division of Research Compliance of the University of South Florida at (813) 974-5638.

Consent to Take Part in This Research Study

By signing this form I agree that:

- I have fully read or have had read and explained to me this informed consent form describing this research project.
- I have had the opportunity to question one of the persons in charge of this research and have received satisfactory answers.
- I understand that I am being asked to participate in research. I understand the risks and benefits, and I freely give my consent to participate in the research project outlined in this form, under the conditions indicated in it.
- I have been given a signed copy of this informed consent form, which is mine to keep.

Signature of Participant

Printed Name of Participant

Date



Investigator Statement

I have carefully explained to the subject the nature of the above research study. I hereby certify that to the best of my knowledge the subject signing this consent form understands the nature, demands, risks, and benefits involved in participating in this study.

Signature of Investigator
Or authorized research
investigator designated by
the Principal Investigator

Printed Name of Investigator

Date

Patient Name: _____
Study Subject Medical Record No.: _____
MCC No: 14189
IRB No: 103878

APPROVED
Approval #: 06-89005
Date: 8/17/2005
HLMCC – Privacy Office

Study Title: “The Relationship Between Hot Flashes and Sleep Quality in Women Being Treated for Breast Cancer”

**H. Lee Moffitt Cancer Center and Research Institute
at the University of South Florida**

RESEARCH AUTHORIZATION

We understand that information about you and your health is personal, and we are committed to protecting the privacy of that information. Because of this commitment, we must obtain your written authorization before we may use or disclose your protected health information for the research purposes described below. This form provides that authorization and helps us make sure that you are properly informed of how this information will be used or disclosed.

Research undertaken at the H. Lee Moffitt Cancer Center and Research Institute, Inc. or at any of its subsidiaries is undertaken jointly with the University of South Florida or other persons or entities under an organized health care arrangement. All persons or entities participating in such an organized healthcare arrangement are collectively referred to as the "Moffitt Cancer Center" in this form.

By signing this document you are permitting the Moffitt Cancer Center to use personal health information collected about you for research purposes internally within its organized health care arrangements. You are also allowing the Moffitt Cancer Center to disclose that personal health information to outside organizations or individuals that participate in this research study. Please read the information below carefully before signing this form.

USE AND DISCLOSURE COVERED BY THIS AUTHORIZATION

A representative of the Moffitt Cancer Center must answer these questions completely before providing this authorization form to you. DO NOT SIGN A BLANK FORM. You or your personal representative should read the descriptions below before signing this form.

Who will disclose, receive, and/or use the information? The workforce of the Moffitt Cancer Center is permitted by law to use and disclose your health information for treatment, payment and health care operations purposes. By signing below, you authorize the Moffitt Cancer Center to receive and obtain test results and your other personal health and related information arising from services or treatment provided to you by other health care providers in connection with this study. In addition to any uses or disclosures made for treatment, payment and health care operations purposes, the following person(s), class(es) of persons, and/or organization(s) will be allowed to disclose, use, and receive the information for the research purposes set forth in this form, but they may only use and disclose the information to the other parties on this list, to you or your personal representative, or as permitted by law.

Patient Name: _____
Study Subject Medical Record No.: _____
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1. Every research site for this study, including the Moffitt Cancer Center, and including each site's research staff and medical staff
2. Every health care provider and other member of the Moffitt Cancer Center workforce who provides services to you in connection with this study
3. Any laboratories and other individuals and organizations that use your health information in connection with this study in accordance with the study's protocol
4. Any sponsor of the study, including the following research sponsors: None
5. The United States Food and Drug Administration (FDA), Department of Health and Human Services (DHHS) and any other federal, state or local governmental agency that regulates the research study
6. The designated research Protocol Review and Monitoring Committees and related staff of the Moffitt Cancer Center
7. The National Cancer Institute (NCI) in evaluating the ongoing research of the Moffitt Cancer Center as a Comprehensive Cancer Center
8. The members and staff of any Institutional Review Board that has oversight responsibility for this study
9. The members and staff of the Moffitt Cancer Center's affiliated Privacy Board
10. Members of the study team, including the Principal Investigator, co-investigators, sub-investigators and others listed on your research study Informed Consent
11. Study Coordinators, Research Nurses and Data Managers involved in the research
12. Members of the Moffitt Cancer Center's Clinical Trials Office/Clinical Research Operations
13. Contract Research Organization (Name if known, None)
14. Data Safety Monitoring Board and Staff

Additionally, the following person(s), classes of person(s), and/or organization(s) (as described below):

None

The entities and persons listed above may employ or pay various consultants and companies to help them understand, analyze and conduct this study. All of these people may not be known now, but if you would like to have more specific information about this at any time during the study, you may ask the Principal Investigator and your questions will be answered.

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The Moffitt Cancer Center cannot guarantee the privacy of your information, or block further use or distribution, after the information has left the Moffitt Cancer Center. The sponsor of this study may further disclose your information. If disclosed by the sponsor or any other person or entity, the information may no longer be covered by the federal privacy regulations.

What information will be used or disclosed? By signing below, you authorize the use and disclosure of your entire research record and any medical or other records held by the Moffitt Cancer Center, including, but not limited to, disease treatment and stage, and medications prescribed, except for information that you expressly exclude below. The purpose for the uses and disclosures you are authorizing is to conduct the research project explained to you during the informed consent process and to ensure that the information relating to that research is available to all parties who may need it for research purposes.

Exclude the information expressly listed below (if blank, then no information excluded):

SPECIFIC UNDERSTANDINGS

By signing this research authorization form, you authorize the use and/or disclosure of your protected health information described above. Your information may also be used as necessary for your research-related treatment, to collect payment for your research-related treatment (when applicable), and to run the business operations of the Moffitt Cancer Center.

This information may be redisclosed if the recipient(s) described on this form is not required by law to protect the privacy of the information.

You have a right to refuse to sign this authorization. While your health care outside the study, the payment for your health care, and your health care benefits will not be affected if you do not sign this form, you will not be able to participate in the research described in this authorization and will not receive treatment as a study participant if you do not sign this form.

If you sign this authorization, you will have the right to revoke it at any time, except to the extent that the Moffitt Cancer Center has already taken action based upon your authorization or needs the information to complete analysis and reports of data for this research. Your revocation will apply prospectively only. All data collected prior to your decision to withdraw your authorization to use the data for research purposes - including documentation of your decision to withdraw - may still be used by the Principal Investigator and cannot be revoked. If medically necessary, the Principal Investigator or study staff may follow-up with you. If you have decided to withdraw your authorization to use the data for research purposes this follow-up information cannot be used or disclosed for research unless required by law.

Patient Name: _____
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This authorization will never expire unless and until you expressly revoke it; to revoke this authorization, please call (813) 745-4106 Clinical Research Operations Office or in writing to Moffitt Cancer Center, 12902 Magnolia Drive, Mail Stop: CB-CRO, Tampa, FL 33612.

By signing below, you acknowledge your receipt of a copy of this form.

SIGNATURE

I have read this form and all of my questions about this form have been answered. By signing below, I acknowledge that I have read and accept all of the above.

Signature of Subject or Personal Representative

Print Name of Subject or Personal Representative

Date

Description of Personal Representative's Authority

CONTACT INFORMATION

The contact information of the subject or personal representative who signed this form should be filled in below.

Address: _____

Telephone: _____ (daytime)
_____ (evening)

Email Address (optional): _____

Patient Name: _____
Study Subject Medical Record No.: _____
MCC No: 14189
IRB No: 103878

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*THE SUBJECT OR HIS OR HER PERSONAL REPRESENTATIVE MUST BE PROVIDED
WITH A COPY OF THIS FORM AFTER IT HAS BEEN SIGNED.*

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