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Sleep Aid Use During and Following Breast Cancer Adjuvant Chemotherapy

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Abstract

Background—Knowledge of sleep aid use is limited despite the high prevalence of insomnia among women before, during, and following breast cancer adjuvant chemotherapy treatments (CTX). This study's purpose was to 1) determine the frequency and characteristics of participants taking sleep aid(s); 2) identify the frequency and percent of sleep aid use by category (prescription sedative/hypnotics, prescription anti-depressants, prescription analgesics, prescription anti-emetics, over-the-counter (OTC) analgesics, OTC cold/flu/sinus, OTC sleep, alcohol, and herbal supplements); and 3) compare sleep aid use by category in the experimental and control groups within a randomized-controlled clinical trial RCT).

Methods—Longitudinal, descriptive, secondary RCT data analysis of women (n=219) receiving out-patient CTX, and at 30, 60, and 90 days following the last CTX and 1 year following CTX1. Participants recorded daily sleep aid use on a Sleep Diary. Analyses included descriptives, chi-square, and RM-ANOVA.

Results—Approximately 20% of participants took at least one sleep aid before CTX1; usage decreased over time (12-18%); a 2nd sleep aid was used infrequently. Prescription sedative/hypnotics (46%) and OTC analgesics (24%) were used most frequently. OTC sleep aids were most commonly used as a 2nd aid. Prescription sedative/hypnotics [F(7,211)=4.26, p=0.00] and OTC analgesics [F(7,211)=2.38, p=0.023] use decreased significantly over time.

Conclusions—Results reflect the natural course of CTX, recovery, and healing. Comprehensive screening for sleep-wake disturbances and sleep aid use may lead to a better understanding of the risks and benefits of pharmacologic and non-pharmacologic interventions, and ultimately lead to selection of the safest and most effective treatment.

Keywords

sleep; insomnia; breast cancer; drug therapy; self-medications; oncology

Introduction

Insomnia symptoms are prevalent and approximately three times higher in patients with cancer than in the general population [1]. Unresolved insomnia symptoms are burdensome to patients during and following breast cancer treatment [2]. Problems sleeping persisted in > 50% of breast cancer survivors (median = 4 years after cancer treatment ended) [3]. Sleep-

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wake disturbance is the term used to describe the symptom of undiagnosed insomnia characterized by difficulty falling asleep, staying asleep, early morning awakenings, nonrestorative sleep, and daytime sleepiness for 3 or more nights per week for at least 1 month [3,4]. Women with sleep-wake disturbances often experience disruptions in their psychological health [5].

Sleep aids to treat sleep-wake disturbances have been documented among women in the general population. The 2007 National Sleep Foundation (NSF) survey focused on women (n=1000) and reported 29% used a form of sleep aid at least a few nights a week [6]. Specifically, 15% used prescription sleep aids, 12% took over-the-counter (OTC) sleep aids, 5% consumed alcohol as a sleep aid, and 2% used herbal supplements at least a few nights a week.

Limited knowledge exists regarding sleep aid use in cancer patients. In a study authored by Derogatis [7], 51% cancer patients (n=1579) received a prescription for a psychotropic medication; 44% were written to improve sleep and 25% to reduce nausea/vomiting. Another classic study by Jaeger and colleagues [8]found over 80% of the medications prescribed to advanced cancer patients (n=1000) to reduce psychological distress, sleep disorders, and nausea/vomiting were psychotropic medications, specifically antipsychotic agents and hypnotics. A recent retrospective study [9] documented medications prescribed for symptom relief of cancer patients (n=93) being discharged from an acute rehabilitation center. Seventy percent of patients were discharged with a prescription for an analgesic, 24% for a hypnotic, 31% for an antidepressant, and 16% for an anti-emetic. Sleep aid use also has been reported incidentally in studies involving cancer patients. Savard et al. [10] reported approximately 40% of breast cancer survivors with insomnia used hypnotics at study baseline. The intervention group significantly reduced sleep aid use compared to the control group. Descriptive studies assessing sleep disturbances in cancer patients have reported 37% (n=100)[11], 35% (n=150) [12], and 28% (n=74) [13]took sleep medications. These reports document the accepted use of prescription medications to treat sleep-wake disturbances despite the lack of a diagnosed insomnia disorder or randomized-controlled clinical trials (RCT) demonstrating their effectiveness in cancer patients.

This report presents data from the first RCT designed to test a behavioral sleep intervention before, during, and following adjuvant breast cancer chemotherapy treatment (CTX) [14,15]. Although the intervention was behavioral, use of prescriptions, OTC medications, alcohol, and herbal supplements, collectively referred to as sleep aids, was not restricted, but documented. The purpose of this secondary analysis was to: 1) determine the frequency and characteristics of participants taking sleep aid(s) at each measurement time; 2) identify the frequency and percent of sleep aid use by category; and 3) compare participants' sleep aid use by category in the total sample and in the experimental and control groups at each measurement time and over time.

Methods

Design

This longitudinal, descriptive secondary analysis used data from a RCT. Further details regarding all aspects of the methods used in the parent study are available [14,15].

Sample

The sample was recruited before their first out-patient breast cancer adjuvant CTX in the Midwestern United States. Inclusion criteria were: 1) women aged ≥ 19, 2) first diagnosis of stages I to IIIA breast cancer, 3) post-modified radical mastectomy or lumpectomy, 4) prescribed to begin four anthracycline-based intravenous CTX; with or without taxanes (four

additional CTX) , and 5) Karnofsky Performance Scale score > 60. Sleep disturbance was not an inclusion criterion. Exclusion criteria were self-reported history of diagnosis of comorbidities associated with poor sleep and fatigue: chronic insomnia, chronic fatigue syndrome, unstable heart, lung or neuromuscular disease, insulin-dependent diabetes, sleep apnea, chronic oral steroid therapy, and night-shift employment.

Procedure

The study obtained approval from the Institutional Review Board at all participating sites. After signing the consent, a stratified randomized sampling procedure was used to control for past sleep quality (good/poor) using the Pittsburgh Sleep Quality Index (PSQI) [16] and the type of CTX prescribed [14]. Participants were assigned to the experimental [Behavioral Therapy (BT)] or control [Healthy Eating (HEC)] group. The research nurse instructed participants to complete the sleep diary for 9 nights; 2 nights before and 7 nights during each CTX . Sleep diaries were then completed for 7 nights at 30, 60, and 90 days following the last CTX and 1 year following CTX1.

Instrument

The Sleep Diary, adapted from the Morin Sleep Diary, [17] was used to collect data on sleep. The revised diary included 14 items related to sleep/wake patterns and took approximately 5 minutes to complete each morning. The sleep diary asked, “I took __ mg of medication and/or __oz ___alcohol as a sleep aid;” the participants were instructed to report any form of sleep aid used (up to two entries per night). The participants were not asked about their past habitual use of sleep aids. This data was entered as four items: Yes/No use of sleep aid; name of sleep aid; Yes/No use of 2nd sleep aid; name of 2nd sleep aid.

Data Analysis

Prior to analysis, all reported sleep aids were combined into 10 categories: prescription sedative/hypnotics, prescription anti-depressants, prescription analgesics, prescription anti-emetics, over-the-counter (OTC) marketed as analgesics, OTC marketed as cold/flu/sinus medications, OTC marketed as sleep medications, alcoholic beverages, herbal supplements, and “other”. The number of “other” medications was less than 1% of the total; therefore, this category was eliminated. Using SPSS 16.0 (Chicago, IL), descriptive statistics determined the frequency and percentage of participants taking one or two sleep aid(s) each night at each measurement time and sleep aid use by category. The Wilks’ Lambda Test for RM-ANOVA was used to examine changes over time in each category for the total sample. The test of within subject effects was used to examine changes over time in each category between the BT and HEC groups.

Next, participant distribution and characteristics of sleep aid use was analyzed. Participants were separated at each measurement time based on sleep aid use: none (no sleep aids), sporadic (1-2 sleep aids), and regular (>2 sleep aids). Chi-square and ANOVA were used to compare differences in sleep aid use based on intervention group (BT/HEC), age (years), past sleep quality [PSQI > 5.0 (poor sleep) and ≤ 5.0 (good sleep)], education (years), and type of CTX prescribed (with or without taxanes). For the past sleep quality analysis, sporadic and regular sleep aid use were combined.

Results

The sample of 219 participants included 113 in the BT and 106 in the HEC groups. All key variables were similar between groups at baseline [14,15]. Total baseline PSQI scores indicated poor sleep quality in the past month by 124/206 (60.0%) and good sleep by 82/206 (40%) participants. Mean age of the entire sample was 52.1 (30-83); the majority was white,

partnered, post-menopausal, and employed outside the home. The majority of the sample (86%) had stage I or II breast cancer. One-half received standard (every 3 weeks) and one-half received dose-dense (every 2 weeks) CTX of doxorubicin hydrochloride and cyclophosphamide. Based on the type of CTX prescribed (with or without taxanes), participants had data at eight measurement times (CTX1-4 and the four times following) or 12 measurement times (CTX1-8 and the four times following); approximately half received taxanes (CTX5-8) [18].

First, descriptive frequencies and percentages of participants taking one or two sleep aids from the categories at least one night at each measurement time were determined. A sum of 3018 sleep aids was recorded by participants in the daily diary. On the two nights before CTX1, only 35 (17%) and 40 (20%) participants took one sleep aid, respectively. Usage decreased from 46 (23%) participants on the first night of CTX1 to 29 (14%) on the seventh night. No more than six participants took a 2nd sleep aid on any night. Sleep aid use on the nights before and during CTX2 to CTX4 remained consistent with CTX1.

Of the 118 participants who received taxanes, 14-20 (12-17%) participants took a sleep aid on the two nights before CTX5 to CTX8. Only 12 (10%) to 27 (23%) took sleep aids during the first 7 nights during CTX5 to CTX8. Sleep aid use gradually decreased over the 7 nights and at subsequent CTXs. Five or fewer participants took a 2nd sleep aid on any night. Sleep aid use ranged from 21 (12%) to 32 (18%) participants on any night at 30, 60, and 90 days following the last CTX and 1 year following CTX1, with only 1 to 3 participants taking a 2nd sleep aid on any night.

Table 1 displays the number and percent of total and 2nd self-reported sleep aid use by category. The sleep aid category most frequently used was prescription sedative/hypnotics (46%). OTC analgesics accounted for 24% of the total sleep aids. Of all the sleep aids used, 25% were taken following CTX completion. When a 2nd medication was taken, 39% were OTC sleep medications. The categories of prescription analgesics, prescription anti-emetics, alcohol, and herbal supplements were used infrequently as sleep aids.

No significant differences were found in sleep aid use (none, sporadic, regular) between BT and HEC groups except at 60 days [X^2 (df=2,n=181)=7.78,p=0.02]. Sleep aid use was significantly different by age at CTX6 [F(2, 107) =3.18, p=0.046] and 90 days [F(2,175)=4.46, p=0.013]. Post-hoc analysis with the Bonferroni correction showed a higher mean age in the “none” vs. sporadic use. Participants with poorer past sleep quality took more sleep aids at all times; results were significantly different (p=0.000-0.037) except at CTX7, CTX8, and 1 year. Sleep aid use was not different by education or type of CTX.

Changes over time were compared between the BT and HEC groups and within each sleep aid category at the eight times when all participants provided data (CTX1-CTX4) and the four times following CTX. CTX5 to CTX8 times were not used since only 1/2 the sample had eight CTXs. Table 2 displays the frequency, percent and changes over time of sleep aids taken. Usage in the categories prescription sedative/hypnotics [F(7,211)=4.257, p=0.00] and OTC analgesics [F(7,211)=2.383, p=0.023] decreased significantly over time. The category prescription analgesics trended toward decreased use over time [F(7,211)=2.018, p=0.054]. No significant differences were found between the BT and HEC groups over time.

Discussion

This analysis determined that 15-20% of participants took at least one sleep aid on at least one night before, during, and following adjuvant CTX. The usage of a 2nd sleep aid was low at all times and comprised only 7.6% of all sleep aids used. Those with poor sleep quality at baseline were more likely at all times to take a sleep aid. The most frequently used sleep aid

categories were prescription sedative/hypnotics and OTC analgesics; use decreased significantly over time. These results reflect the natural course of CTX, recovery, and healing. A minority of participants, including those that reported poorer sleep quality before CTX, took sleep aids during CTX and most decreased use following adjuvant CTX. This finding suggests situational stressors precipitating sleep disturbances diminish as time passes for most participants.

Comparing our results with previous studies is difficult. We included all categories of sleep aids, including OTC and alcohol, whereas other studies were specific to sedative/hypnotic medications or did not specify if other sleep aids (i.e. OTC, alcohol) were included [10,12]. Dramatic changes have occurred in available medications since the investigations lead by Derogatis [7] and Jaeger [8]. Our findings cannot be compared with Guo's [9] because of differences in medication categories and the clinical setting. Furthermore, in Guo's study, the source of information, including indications for writing the prescription, was the physician. Our study's source was the participant's entries on the daily dairy. This study found lower sleep aid use (~15-20%) compared to women in the general population (29%)[6], in cancer patients (28-37%) [11-13] and in breast cancer survivors with insomnia (40%) [10]. Our findings may be due to participation in this non-pharmacologic RCT study stratified for past sleep quality, reluctance to take additional medications during and following CTX, shorter duration of sleep disturbances, or advice from health care providers. These factors may explain why no significant differences in sleep aid use were found over time between the RCT groups. The lower use may have created a floor effect, restricting the range necessary to obtain significant differences between groups.

Insomnia is prevalent, yet undermanaged, in cancer patients receiving chemotherapy [1,3]. The benefits of sleep aids may outweigh the risks when acute sleep disturbances occur during and following CTX. However, potential risks of using sleep aids in this population must be considered. According to the safety information for a prescription sleep aid[19], side effects of sleep aids include sleepwalking, and eating or driving while not fully awake, with memory loss for the event, next-day drowsiness, dizziness and headache. Medications that may decrease clotting factors are contraindicated in patients receiving CTX. Drug-herb interactions also may occur between chemotherapy and herbal sleep aids [20].

Strengths of the study are the longitudinal design and the daily sleep diary data. Weaknesses include possible missing or inaccurate data not confirmed by monitoring prescriptions. Future research needs to consider the inclusion/exclusion criteria and/or guidelines for use of sleep aids in behavioral sleep interventions and the risk/benefit ratio and costs. Implications for practice include comprehensive screening for sleep-wake disturbances and sleep aid use in cancer patients during and following CTX. Increased awareness may lead to a better understanding of the risks and benefits of pharmacologic and non-pharmacologic interventions, and ultimately lead to the identification and selection of the safest and most effective treatments.

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Table 1

Number and Percent of Self-Reported[a] Sleep Aid Use by Category During and Following Chemotherapy

Sleep Aid Category (3 most commonly reported sleep aid used)	Total Sleep Aids[c]	2nd Sleep Aid[d]
Prescription Sedative/Hypnotics (zolpidem, lorazepam, eszopiclone)	1395 (46%)	23 (10%)
Prescription Anti-depressants (escitalopram oxalate, mirtazapine, venlafaxine)	38 (1%)	0 (0%)
Prescription Analgesics (tramadol HCL, metaxalone, hydrocodone bitartrate)	203 (7%)	17 (7%)
Prescription Anti-emetics (prochlorperazine, dolasetron, ondansetron)	26 (1%)	9 (4%)
Over-the-counter (OTC) marketed as Analgesic (acetaminophen, ibuprofen, aspirin)	716 (24%)	63 (28%)
OTC marketed as Cold/Flu/Sinus (diphendydramine, NyQuil® (Procter & Gamble, Cincinnati, OH), loratadine)	334 (11%)	17 (8%)
OTC marketed as Sleep (diphenhydramine HCl/doxylamine succinate, diphenhydramine, "sleep aid")	153 (5%)	90 (39%)
Alcoholic Beverages (beer, wine, "alcohol")	125 (4%)	2 (1%)
Herbal Supplements (melatonin, valerian, tea)	28 (1%)	7 (3%)
TOTAL Sleep Aids	3018 (100%)	228 (7.6%)

b= participants provided data at several times over 1 year

[a] 219 participants

[c] the % out of total sleep aids used (n=3018)

[d] the % out of total sleep aids used as 2nd sleep aid (n=228)

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Table 2

Number and Percent of Self-Reported Sleep Aid Use by Category at Each Measurement Time[a] During and Following Chemotherapy[a,b]

Time	Rx Sedative/ Hypnotic	Rx Anti-Depressant	Rx Analgesic	Rx Anti-Emetic	OTC Analgesic	OTC cold/flu/ sinus	OTC sleep	Alcoholic Beverages	Herbals	Total Sleep Aids taken (% of 3018)
CTX1 (n=203)	140 (42%)	3 (0.8%)	30 (9%)	22 (6%)	88 (26%)	19 (6%)	21 (6%)	12 (4%)	1 (0.2%)	336 (11%)
CTX2 (n=188)	198 (56%)	1 (0.2%)	28 (8%)	3 (0.8%)	73 (21%)	35 (10%)	8 (2%)	9 (2%)	0 (0%)	355 (12%)
CTX3 (n=189)	191 (51%)	0 (0%)	30 (8%)	0 (0%)	96 (26%)	29 (8%)	16 (4%)	8 (2%)	2 (1%)	372 (12%)
CTX4 (n= 180)	189 (49%)	0 (0%)	27 (7%)	1 (0.2%)	97 (25%)	31 (8%)	24 (6%)	13 (4%)	3 (0.8%)	385 (13%)
CTX5[b] (n=112)	101 (46%)	9 (4%)	4 (2%)	0 (0%)	59 (27%)	29 (13%)	10 (5%)	6 (2%)	1 (1%)	219 (7%)
CTX6[b] (n=110)	95 (46%)	9 (4%)	7 (3%)	0 (0%)	50 (24%)	25 (12%)	11 (5%)	10 (5%)	1 (1%)	208 (7%)
CTX7[b] (n=93)	96 (49%)	9 (5%)	12 (6%)	0 (0%)	40 (20%)	19 (9%)	11 (6%)	9 (5%)	0 (0%)	196 (7%)
CTX8[b] (n=88)	74 (40%)	0 (0%)	6 (3%)	0 (0%)	47 (26%)	30 (16%)	13 (7%)	10 (5%)	6 (3%)	186 (6%)
30 days (n= 182)	96 (46%)	0 (0%)	24 (12%)	0 (0%)	52 (25%)	15 (7%)	12 (6%)	8 (3%)	1 (1%)	208 (7%)
60 days (n= 181)	81 (39%)	0 (0%)	14 (7%)	0 (0%)	52 (25%)	26 (12%)	12 (6%)	16 (7%)	9 (4%)	210 (7%)
90 days (n= 178)	74 (39%)	7 (4%)	13 (7%)	0 (0%)	37 (20%)	39 (21%)	8 (4%)	10 (5%)	0 (0%)	188 (6%)
1 Year (n=173)	60 (39%)	0 (0%)	8 (5%)	0 (0%)	25 (16%)	37 (24%)	7 (4%)	14 (9%)	4 (3%)	155 (5%)
Total	1395** (46%)[c]	38 (1%)[c]	203 (7%)[c]	26 (1%)[c]	716* (24%)[c]	334 (11%)[c]	153 (5%)[c]	125 (4%)[c]	28 (1%)[c]	3018

[a] 9 nights total for each CTX (2 nights before & 7 nights during CTX); 7 nights total at 30, 60, & 90 days following the last CTX; 7 nights total 1 year following CTX1

[b] shaded area denotes participants with taxanes.

[c] % out of total sleep aids used (3018)

* Wilks' Lambda Test for RM-ANOVA (CTX1-CTX4,30,60,90,1year) significant at $p<0.05$

** Wilks' Lambda Test for RM-ANOVA (CTX1-CTX4,30,60,90,1year) significant at $p<0.01$