Title
Differences in sleep parameters between oncology patients and their family caregivers

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Differences in sleep parameters between oncology patients and their family caregivers

by

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THESIS

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I dedicate this Master's Thesis to my husband, Samuel.

ABSTRACT

PURPOSE: This study compared the occurrence rates for and severity of sleep disturbance in cancer patient-family caregiver (FC) dyads.

PATIENTS AND METHODS: One hundred and two dyads were recruited from two radiation therapy (RT) departments. Patients and their FCs completed the Pittsburgh Sleep Quality Index (PSQI) and the General Sleep Disturbance Scale (GSDS) and wore wrist actigraphs to obtain subjective and objective measures of the occurrence and severity of sleep disturbance at the initiation of RT.

RESULTS: While the occurrence rates of clinically significant levels of sleep disturbance were high for both patients and their FCs, no differences were found between the dyads in these occurrence rates. Very few between group differences were found in the severity of any of the sleep-wake parameters using both the subjective and objective measures of sleep disturbance.

CONCLUSIONS: The findings from this study suggest that cancer patients and their FCs experience similar levels of sleep disturbance and that both groups could benefit from interventions that aim to promote restful sleep. In addition to routine and systematic assessment of sleep disturbance by oncology clinicians, interventions are needed that take into account the specific needs of the patient and the FC as well as the potential for partners' sleep patterns to influence one another.

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INTRODUCTION

Poor sleep has been linked to negative health outcomes including impaired cognitive, psychological, and physical functioning and a lower quality of life (Ancoli-Israel, et al., 2006; Berger & Mitchell, 2008; Byar, Berger, Bakken, & Cetak, 2006; Carter & Chang, 2000; Wielgus, Berger, & Hertzog, 2009). Prevalence of sleep disturbances amongst cancer patients ranges from 30% to 55%, about twice the rate found in the general population (Berger, 2009). Cancer patients are at high risk for developing sleep disturbance due to the physiological and/or psychological factors related to the disease process, cancer therapies, and the day-to-day burden of living with cancer. Also at risk are cancer patients' family caregivers (FCs), who are assuming more and more responsibility for the care of their loved one as health care delivery grows increasingly more complex and outpatient focused. While cancer patients report significant distress as a result of poor sleep, the magnitude and severity of sleep disturbance is not routinely assessed and managed by oncology clinicians. The prevalence and severity of sleep disturbances in FCs of oncology patients has received even less attention despite serious health and safety implications for both the patient and their FC (Berger, et al., 2005; Carter, 2002; Swore Fletcher, Dodd, Schumacher, & Miaskowski, 2008).

While it is clear that both oncology patients and their FCs experience sleep disturbance, it is unclear how or to what degree the sleep patterns of patients and FCs within dyads differ and how partners' sleep patterns may

influence one another. Only one study simultaneously measured the sleep habits of advanced cancer patients and their FCs and found a similar prevalence of poor sleep in both groups (Gibbins, et al., 2009) and the sample size was relatively small (n=60 dyads). Given the paucity of research on sleep disturbance in oncology patient/FC dyads, the purposes of this study were to evaluate for differences in the occurrence of sleep disturbance as well as in the severity of self-reported sleep disturbance and objective measures of nocturnal sleep/rest, daytime wake/activity, and circadian activity rhythm parameters in oncology patients and their FCs at the initiation of radiation therapy (RT).

METHODS

Participants and Settings

This descriptive, correlational study is part of a larger, longitudinal study that evaluated multiple symptoms in patients who underwent primary or adjuvant RT and their FCs (Aouizerat, et al., 2009; B. A. Fletcher, et al., 2009; B. S. Fletcher, et al., 2008; Miaskowski, et al., 2008). Participants were recruited from two RT departments located in a Comprehensive Cancer Center and a community-based oncology program at the time of the patient's simulation visit.

Patients were eligible to participate if they: were ≥18 years of age; were scheduled to receive primary or adjuvant RT for one of four cancer diagnoses (i.e., breast, prostate, lung, brain); were able to read, write, and understand English; gave written informed consent; and had a Karnofsky Performance Status (KPS) score of ≥ 60. Patients were excluded if they had metastatic disease, more than one cancer diagnosis, or a diagnosed sleep disorder.

FCs were eligible to participate if they were an adult (≥18years of age); were able to read, write, and understand English; gave written informed consent; had a KPS score of ≥ 60; were living with the patient; and did not have a diagnosed sleep disorder.

Instruments

The study instruments included a demographic questionnaire, the KPS scale (Karnofsky, Abelmann, Craver, & Burchenal, 1948), the Pittsburgh Sleep Quality Index (PSQI) (Buysse, Reynolds, Monk, Berman, & Kupfer, 1989), and the General Sleep Disturbance Scale (GSDS) (Lee, 1992). Objective data on

sleep-wake circadian activity rhythms were obtained by continuous noninvasive monitoring of activity over 48 hours using a wrist motion sensor (Mini Motionlogger Actigraph, Ambulatory Monitoring, Inc., Ardsley, NY) (Ancoli-Israel, et al., 2003; Berger, et al., 2008; Morgenthaler, et al., 2007). A minimum of 36 hours of continuous data are necessary to have sufficient data to calculate circadian rhythm parameters for a 24-hour period (Berger, et al., 2008).

The demographic questionnaire obtained information on age, gender, marital status, education, ethnicity, employment status, and the presence of a number of co-morbid conditions.

The PSQI consists of 19 items designed to assess the quality of sleep in the past month. The global PSQI score is the sum of the seven component scores (i.e., subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medication, daytime dysfunction). Each component score ranges from 0 to 3 and the global PSQI score ranges from 0 to 21. Higher global and component scores indicate more severe complaints and a higher level of sleep disturbance. A global PSQI score of >5 indicates a significant level of sleep disturbance (Buysse, et al., 1989). A cutoff score of 8 was found to discriminate poor sleep quality in oncology patients (Carpenter & Andrykowski, 1998). The PSQI has established internal consistency, test-retest reliability, and construct validity (Beck, Schwartz, Towsley, Dudley, & Barsevick, 2004; Buysse, et al., 1989; Carpenter & Andrykowski, 1998). In this study, the Cronbach's alpha for the global PSQI score was 0.72 for patients and 0.68 for FCs.

The GSDS consists of 21-items designed to assess the quality of sleep in the past week. Each item was rated on a 0 (*never*) to 7 (*everyday*) numeric rating scale (NRS). The GSDS total score is the sum of the seven subscale scores (i.e., quality of sleep, quantity of sleep, sleep onset latency, mid-sleep awakenings, early awakenings, medications for sleep, excessive daytime sleepiness) that can range from 0 (*no disturbance*) to 147 (*extreme sleep disturbance*). Each mean subscale score can range from 0 to 7. Higher total and subscale scores indicated higher levels of sleep disturbance. Subscales scores of $\geq$ 3 and a GSDS total score of $\geq$ 43 indicates a significant level of sleep disturbance (B. S. Fletcher, et al., 2008). The GSDS has well-established validity and reliability in shift workers, pregnant women, and patients with cancer and HIV (Lee, 1992; Lee & DeJoseph, 1992; Miaskowski & Lee, 1999). In the current study, the Cronbach's alpha for the GSDS total score was 0.84 for patients and 0.79 for FCs.

Objective data on sleep-wake circadian activity rhythms were obtained by continuous noninvasive monitoring of activity over 48 hours using wrist actigraphy. Seven nocturnal sleep/rest, four daytime wake/activity, and six circadian activity rhythm variables were selected that were identified by a National Cancer Institute sponsored conference (Berger, et al., 2005), an expert panel that recommended a standard set or research assessments in insomnia (Buysse, Ancoli-Israel, Edinger, Lichstein, & Morin, 2006), and recently published studies (Berger, Farr, Kuhn, Fischer, & Agrawal, 2007; Berger, Wielgus, Hertzog, Fischer, & Farr, 2009). Wrist actigraphy has been validated with EEG measures of sleep and awakenings on men and women with both healthy and disturbed

sleep patterns (Ancoli-Israel, et al., 2003; Buysse, et al., 2006; Morgenthaler, et al., 2007). It provides continuous motion data using a battery-operated wristwatch-size microprocessor that senses motion with a piezo-electric beam and detects movement in all three axes. The accompanying Action 4® software (Ambulatory Monitoring Inc., Ardsley, NY) allows analysis of activity and nonactivity as well as automatic scoring of sleep and wake episodes in minutes.

Patients and FCs were asked to use the event marker on the wrist actigraph to indicate “lights out” and “lights on” time. Participants reported no difficulty wearing the wrist actigraph. Since the actual time is important in the calculation of the amount of sleep obtained in the amount of time designated for sleep, having an additional source of information about nap times, bed times, and wake times is important. This information was recorded by patients and FCs in a two-day diary. Upon awakening, the patients and FCs used the diary to indicate the number of awakenings during the night.

Study Procedures

The study was approved by the Committee on Human Research at the University of California, San Francisco and at the second site. At the time of the simulation visit (i.e., approximately one week prior to the initiation of RT), patients and their FCs were approached by a research nurse to discuss participation in the study. After obtaining written informed consent, patients and FCs completed the demographic questionnaire, KPS scale (Karnofsky, et al., 1948), PSQI (Buysse, et al., 1989), and GSDS (Lee, 1992). Medical records were reviewed for disease and treatment information.

Actigraphy data were collected for two consecutive days prior to the start of RT. Participants wore the wrist actigraph to monitor sleep and activity continuously for two consecutive days. They completed the two day diary that included sleep and wake times, naps, meal times, and level of physical activity during the day. Patients and FCs returned the questionnaires and actigraphs to the research nurse in the RT department at the completion of the two days of data collection.

Data Analysis

Data were analyzed using SPSS version 15. Descriptive statistics and frequency distributions were generated for the sample characteristics and symptom data. Actigraphy files in zero-crossing mode were analyzed using the Cole-Kripke algorithm in the Action 4® software by two of the researchers (KL and CW). First, the file was first scanned for missing data. If more than four hours of day data or two hours of night data were missing, that day's or night's data were not used in the analyses. Time limits were set for the 48 hour period. The file was reviewed and intervals were individually set for each day and night period using, in order of priority as decision guides, the event marker, dairy data, channel data, and cascading movement data. Cosinor analysis fit a cosine and sine wave to the wrist actigraphy data using a least-squares cosinor regression model (Lentz, 1990). The mesor (24-hour adjusted mean value or y-intercept), amplitude, and acrophase (time of day for peak activity) were the circadian rhythm parameters obtained from the regression model. The autocorrelation

coefficient for a 24-hour rhythm was obtained from the Action 4® software program.

In order to evaluate for differences in occurrence rates for the subjective and objective measures, the PSQI global score (>5), GSDS total score (≥ 43), and total sleep time (TST; <420 minutes) were dichotomized using clinically meaningful cutpoints**.** Match-paired t-tests were used to evaluate for differences in demographic characteristics, symptom occurrence rates, and symptom severity scores between patients and their FCs. All calculations used actual values. Adjustments were not made for missing data. Therefore, the cohort for each analysis was dependent on the largest set of available data across groups. A p-value of <0.05 was considered statistically significant.

RESULTS

Patient and Family Caregiver Characteristics

Table 1 presents a summary of the demographic characteristics of the 102 patient-FC dyads. No differences in demographic characteristics were found between the dyads except for age and gender. Patients were significantly older ($p<0.0001$) and more likely to be male ($p<0.0001$). Patients were diagnosed with prostate (59.2%), breast (26.2%), lung (7.8%), or brain (6.8%) cancers. The majority of the FCs (91.2%) were the patient's spouse or partner.

Differences between patients and FCs in the occurrence of sleep disturbance

As shown in Figure 1, while occurrence rates were between 40% to 50%, no differences were found between patients and their FCs in the occurrence rates for clinically significant levels of sleep disturbance based on cutoff scores for the PSQI global score ($p=0.40$), the GSDS global score ($p=0.89$), or TST ($p=1.00$).

Differences between patients and FCs in the severity of sleep disturbance

Subjective data

As shown in Figure 2, no differences were found between patients' and their FCs' in any of the PSQI global or subscale scores, except for the use of sleep medications. Patients reported significantly higher use of sleep medication scores than their FCs ($p=0.01$). As shown in Table 2, the majority of the correlations between patients' and FCs' PSQI subscale and global scores were not significant.

In contrast to the PSQI, which assesses participants' sleep experiences over the past month, the GSDS assesses the quality of sleep over the past week. As shown in Figure 3, patients scored significantly higher than their FCs on the GSDS subscales of midsleep wakes ($p=0.01$) and use of sleep medications ($p=0.04$). As shown in Table 2, most of the correlations between patients' and their FCs' GSDS subscale and total scores were not significant.

Objective data

As shown in Table 3, actigraphy data revealed that patients and their FCs had similar nocturnal sleep/rest, daytime wake/activity, and circadian activity rhythm parameters. Of all of the objective measures, the only significant difference between patients and their FCs was for sleep efficiency (SE). Patients mean SE was significantly less than their FCs ($p=0.03$). As shown in Table 3, strong and statistically significant correlations were found between patients and FCs on most of the sleep/rest, wake/activity, and circadian activity rhythm parameters.

DISCUSSION

This study is the first to evaluate for differences in the occurrence and severity of sleep disturbance within oncology patient/FC dyads using both subjective and objective measures. Across both types of measures, rates of sleep disturbance in both patients and their FCs ranged from 40% to 50%. These results are consistent with a previous report of patients with advanced cancer and their FCs that reported sleep disturbance in 47% of the patients and 42% of the FCs (Gibbins, et al., 2009).

Across both the subjective and objective measures, few differences were found in patients' and FCs' sleep/wake and circadian activity rhythm parameters. Based on these data, both patients and FCs had significant problems with sleep initiation and sleep maintenance and both groups slept only 6.75 hours per night. Use of medication for sleep was the only PSQI ($p=0.01$) and GSDS subscale ($p=0.04$) scores in which patients reported higher scores than FCs. This finding is consistent with a previous study in which FCs reported reluctance to use sleeping medications because it might interfere with their ability to perform caregiving duties at night (Carter & Chang, 2000). In terms of the GSDS data, patients' reported a higher number of midsleep wakes ($p=0.01$) compared to their FCs. This finding may be partially explained by the large number of patients with prostate cancer who may have been awakened with urinary symptoms or hot flashes (Savard, et al., 2005). In terms of objective data and consistent with the increased number of awakenings in patients, sleep efficiency was the only parameter in which patients had lower scores than their FCs ($p=0.03$).

Not only did patients and their FCs have similar sleep/rest, wake/activity, and circadian activity rhythm parameters, their objective measures suggest that the severity of sleep disturbance was worse than that appreciated through self-report measures. This finding is consistent with a previous study in which FCs of oncology patients underreported sleep disturbance compared to actigraphy data (Carter, 2003). Strong positive correlations were found with almost all of the objective measures, which suggests that if a patient slept poorly, so did his or her FC. Strong correlations between patients and their FCs were not observed with the self-report data. This finding may be attributed to the fact that subjective measures reflect individuals' perceptions, are not always consistent with objective measures of the same phenomenon, and are more prone to external influences and variability. This finding warrants replication in future studies.

Several study limitations need to be acknowledged. Because participants were asked to reflect back and report on their sleep habits over the past month and week using the two self-report measures, responses were subject to recall bias. However, this limitation was partially mitigated by the collection of 48 hours of objective measurements using wrist actigraphy. In addition, the homogeneity of the participants in terms of ethnicity and education limits the generalizability of the study findings.

Despite these limitations, findings from this study suggest that occurrence of clinically significant sleep disturbance was high for both oncology patients and their FCs. In addition, given the similarities in the severity of sleep disturbance across both subjective and objective sleep parameters, oncology patients and

their FCs appear to be at similar risk for the development of other symptoms and negative outcomes as a result of sleep disturbance including depression, anxiety, fatigue, impaired functional status, and reduced quality of life. Associations between sleep disturbance and these symptoms and outcomes have been documented in studies of both oncology patients and FCs (Carter, 2002; Cho, Dodd, Lee, Padilla, & Slaughter, 2006; Flaskerud, Carter, & Lee, 2000; McKibbin, et al., 2005; Pal, et al., 2004; Sato, Kanda, Anan, & Watanuki, 2002).

In addition, the findings from this study suggest potential implications for patient and FC well-being and safety. In light of current trends toward more outpatient focused health care delivery that places increasing burden on informal caregivers, more research is needed around understanding sleep disturbance in FCs and its impact on their health and functioning. The effect of sleep disturbance on the ability of FCs to carry out caregiving duties has not been adequately addressed and is an important area for investigation.

In addition to routine and systematic assessment of sleep disturbance by oncology clinicians, interventions are needed that take into account the specific needs of individual patients and FCs as well as the potential for partners' sleep patterns to influence one another. Unfortunately, studies that evaluated the effectiveness of interventions for sleep disturbance in oncology patients are limited and only one intervention study was done with FCs of oncology patients (Carter, 2006). Additional research is warranted to increase our understanding of the causes and characteristics of sleep disturbance in oncology patients and FCs and to develop interventions that promote restful sleep.

Table 1. Demographic and clinical characteristics-patients and family caregivers

	Mean (SD)	Mean (SD)	
Age (years)	64.41 (10.22)	61.69 (10.37)	3.65; 0.00
Education (years)	16.29 (3.10)	15.73 (3.02)	1.66; 0.10
KPS score	91.83 (11.51)	93.87 (10.64)	-1.38; 0.17
Number of comorbidities	4.57 (2.57)	4.18 (2.92)	1.13; 0.26
	n (%)	n (%)	
Gender Male Female	 70 (68.6) 32 (31.4)	 29 (28.4) 73 (71.6)	 <0.0001
Marital Status Married/partnered Not married	 97 (95.1) 5 (4.9)	 97 (95.1) 5 (4.9)	 1.00
Ethnicity White Nonwhite	 81 (80.2) 20 (19.8)	 79 (78.2) 22 (21.8)	 0.727
Work for pay Yes	 42 (42.4)	 46 (46.5)	 0.618
Children living at home Yes	 14 (18.9)	 14 (18.9)	 1.00
Parent living at home Yes	 1 (1.3)	 1 (1.3)	 1.00
Relationship to patient: Spouse\partner Significant other Child Friend		 93 (91.2) 5 (4.9) 2 (2.0) 2 (2.0)	
Bed partner or roommate: Partner in same bed Partner in same room but different bed Partner in different room	 79 (79.0) 5 (5.0) 6 (6.0)	 80 (80.8) 5 (5.1) 7 (7.1)	

Table 2. Correlations between Pittsburgh Sleep Quality Index (PSQI) and General Sleep Disturbance Scale Scores (GSDS) between patients and their family caregivers

Instrument	r-value	p-value
Pittsburgh Sleep Quality Index (PSQI)		
Sleep quality	-0.03	0.76
Sleep latency	0.13	0.20
Sleep duration	**0.22**	**0.04**
Sleep efficiency	0.13	0.21
Sleep disturbance	-0.09	0.41
Use of sleep medication	**0.26**	**0.009**
Daytime dysfunction	**0.24**	**0.02**
PSQI Global score	0.04	0.71
General Sleep Disturbance Scale (GSDS)		
Sleep quality	**0.21**	**0.03**
Sleep latency	-0.05	0.65
Sleep quantity	0.14	0.16
Mid sleep wakes	0.09	0.37
Early awakenings	**0.22**	**0.03**
Use of sleep medication	0.19	0.06
Excessive daytime sleepiness	0.06	0.54
GSDS total score	0.14	0.18

Table 3. Differences in and Correlations Between Objective Sleep/Rest, Wake/Activity and Circadian Activity Rhythm Parameters Between Patients and Their Family Caregivers. Values are listed in minutes unless otherwise specified.

Characteristic	Patient	Family Caregiver	r-value (p-value)	t-value (p-value)
	Mean (SD)	Mean (SD)		
Nocturnal Sleep/Rest				
Sleep onset latency	17.33 (26.06)	13.06 (10.68)	**0.60 (<0.001)**	1.90 (0.06)
Wake after sleep onset as % of total sleep time	14.64 (13.46)	12.49 (10.03)	**0.56 (<0.001)**	1.81 (0.07)
Number of wakes	17.97 (9.32)	17.60 (9.50)	**0.49 (<0.001)**	0.38 (0.71)
Wake duration	4.26 (6.85)	3.37 (2.15)	**0.45 (<0.001)**	1.37 (0.18)
Total sleep time	405.50 (85.83)	408.50 (78.74)	**0.41 (<0.001)**	-0.32 (0.75)
Time in bed	496.51 (67.37)	485.91 (78.48)	**0.42 (<0.001)**	1.28 (0.21)
Sleep efficiency index as % of time in bed asleep	81.36 (14.79)	84.17 (10.90)	**0.57 (<0.001)**	**-2.16 (0.03)**
Daytime Wake/Activity				
Total day sleep time	57.60 (92.13)	44.49 (69.50)	0.19 (0.11)	1.07 (0.29)
Total wake time per day	662.41 (92.13)	675.51 (69.50)	0.19 (0.11)	-1.07 (0.29)
Day sleep as % of day asleep from 0900 to 2059	8.00 (12.80)	6.18 (9.65)	0.19 (0.11)	1.07 (0.29)
Wake day as % of day awake from 0900 to 2059	92.00 (12.80)	93.82 (9.65)	0.19 (0.11)	-1.07 (0.29)
Circadian Rhythm Activity				
Mesor as movements/minute	65.51 (9.58)	67.75 (8.26)	0.11 (0.48)	-1.23 (0.23)

Amplitude as movements/minute	51.07 (10.48)	52.97 (9.57)	**0.52 (<0.001)**	-1.26 (0.21)
Peak activity as movements/minute	116.58 (16.50)	120.72 (13.42)	0.30 (0.06)	-1.51 (0.14)
Circadian quotient as a ratio	0.79 (0.16)	0.79 (0.16)	**0.43 (0.004)**	-0.10 (0.92)
Autocorrelation as a ratio	0.44 (0.17)	0.44 (0.14)	**0.31(0.04)**	-0.24 (0.81)

Figure 1. Differences between patients and family caregivers in the occurrence of sleep disturbance using the Pittsburg Sleep Quality Index (PSQI) and General Sleep Disturbance Scale GSDS)

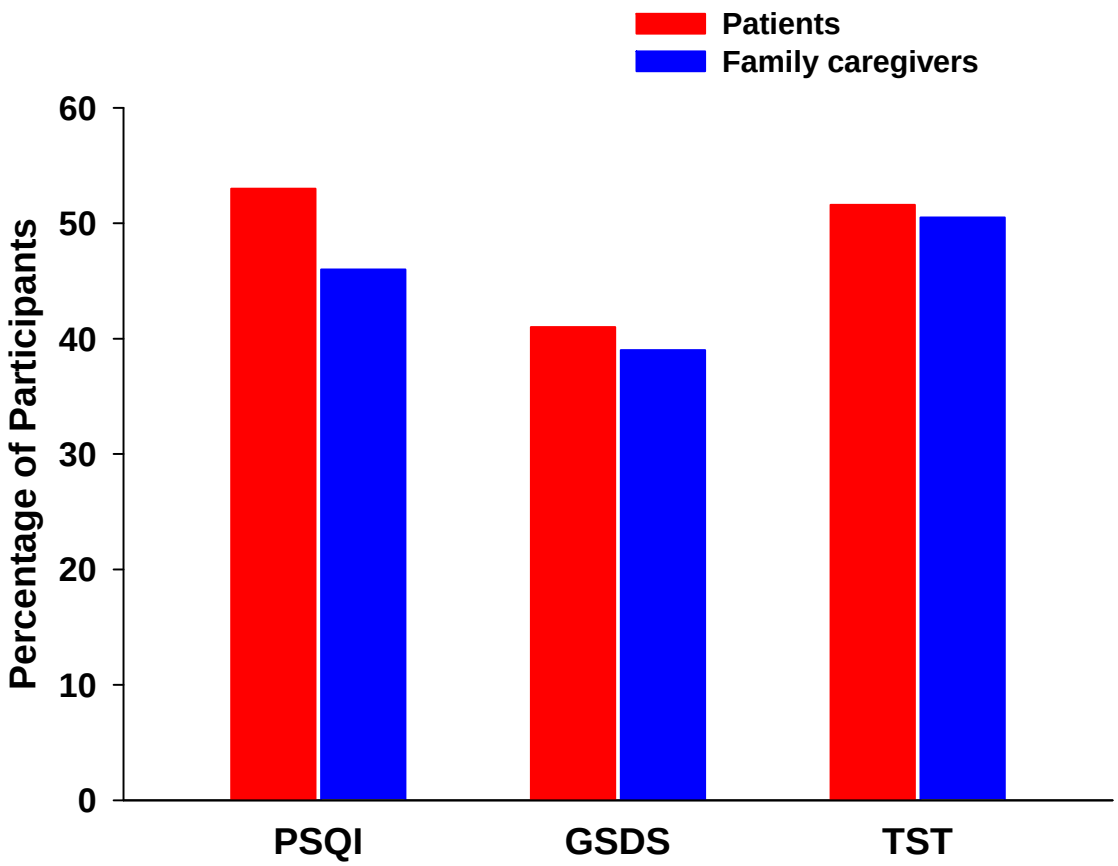


Figure 2. Differences between patients and family caregivers in sleep disturbance severity using the Pittsburgh Sleep Quality Index (PSQI) global and subscale scores. * Significant differences between the groups at p≤0.05.

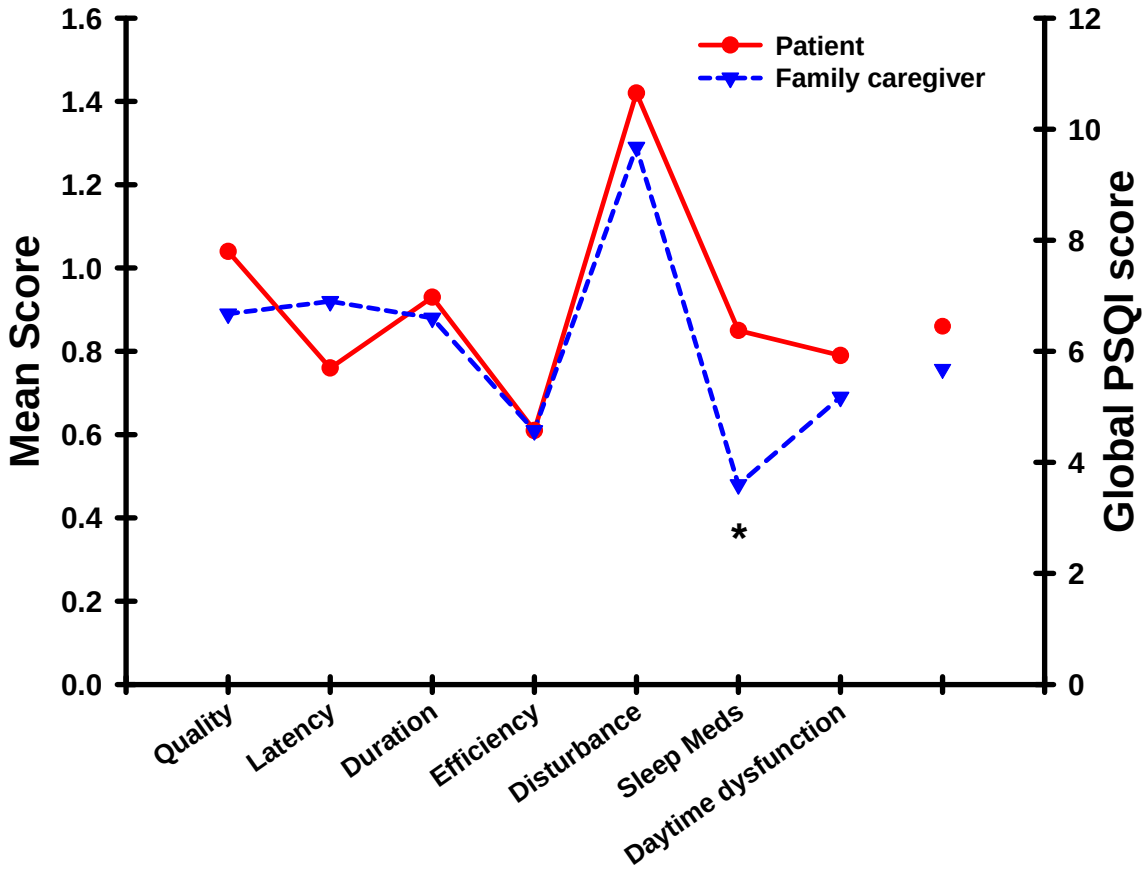
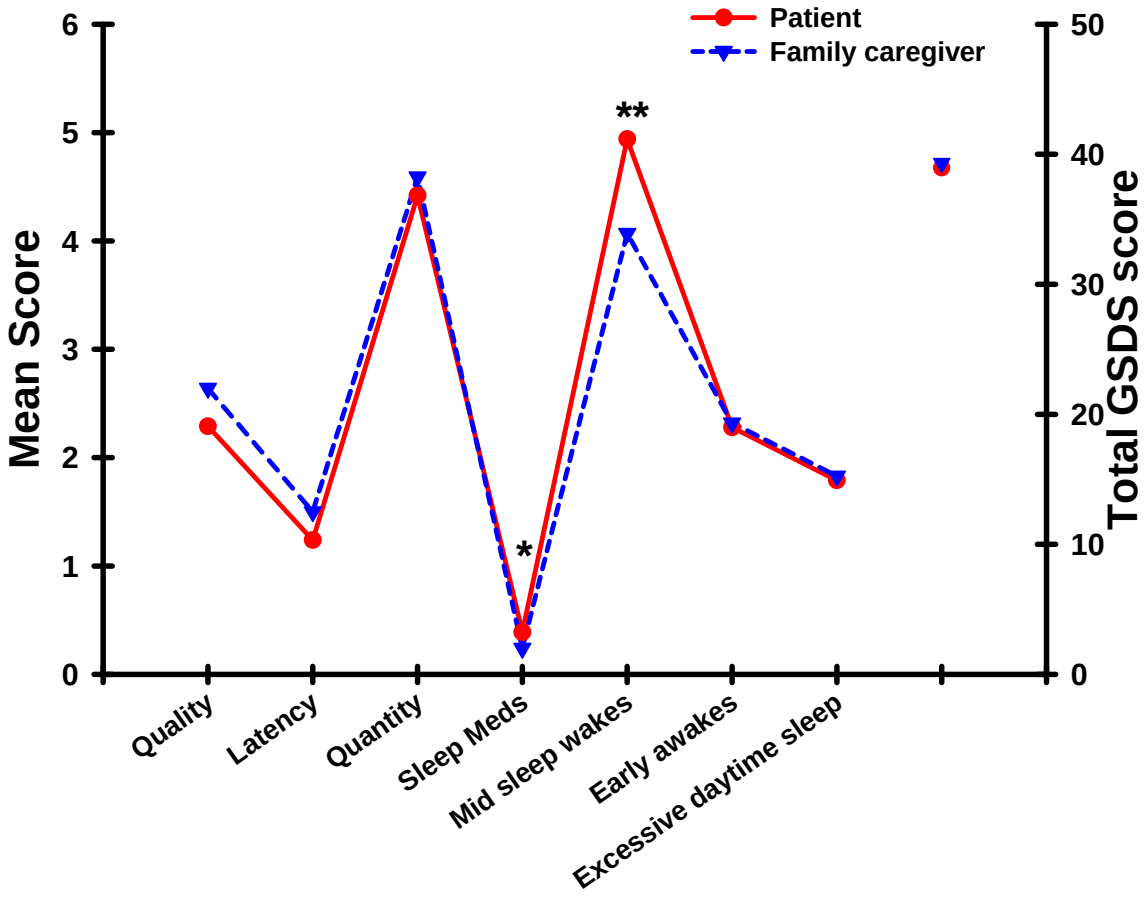


Figure 3. Differences between patients and FCs mean subscale and total General Sleep Disturbance Scale (GSDS) scores. * Significant differences between the groups at $p \leq 0.05$.



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