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Sleep and Daily Functioning during Androgen Deprivation Therapy for Prostate Cancer

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Abstract

A limited body of evidence suggests that sleep problems are common in prostate cancer patients undergoing androgen deprivation therapy, yet little is known about sleep characteristics and the effects of poor sleep on daily functioning in this population. This study assessed sleep in 60 prostate cancer patients taking androgen deprivation therapy with wrist actigraphy and daily diaries for 7 days. The Epworth Sleepiness Scale and the general version of the Functional Assessment of Cancer Therapy scale were also administered. On average, total sleep time was 5.9 ($SD = 1.4$) hours, and sleep efficiency was 75.0 percent ($SD = 12.0$) as assessed by actigraphy. There was generally poor concordance between actigraphy and daily diary for most sleep metrics. Subjects reported awakening, on average, 2.7 times per night, most commonly for nocturia and hot flashes. Assessment of daily functioning showed that participants had mild daytime sleepiness, which was predicted by total sleep time ($F(1,47) = 4.5, p = .04$). General quality of life was not impaired. This study supports more research on the predictors of poor sleep in order to identify effective interventions.

Keywords

Prostate cancer; hormonal therapy; sleep; actigraphy; nocturia

Introduction

Sleep problems are prevalent among prostate cancer patients. The aetiology of these problems may stem from a range of factors including aging, emotional distress, and side effects of cancer treatment (Savard & Morin 2001). Among prostate cancer patients, limited research suggests those undergoing androgen deprivation therapy may be particularly vulnerable to developing sleep problems.

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In a cross-sectional study, 32% of 327 prostate cancer patients treated with radical prostatectomy in the past 10 years reported current sleep difficulties while 18% met criteria for an insomnia syndrome (Savard *et al.* 2005). Patients with hormone deprivation symptoms, such as hot flashes, were at increased risk for insomnia. In a prospective study of neoadjuvant androgen deprivation therapy prior to radiotherapy, prostate cancer patients reported sleeping less well following androgen deprivation therapy (Stephens *et al.* 2007). Similarly, another prospective study found that sleep problems were most severe before radiotherapy and gradually declined over 6 months (Thomas *et al.* 2010). Half of the men in this study were taking androgen deprivation therapy. These survey studies support additional research on sleep problems among patients taking androgen deprivation therapy.

The aims of this study were to conduct a more detailed analysis of sleep patterns and to assess the effects of poor sleep on daily functioning among prostate cancer patients undergoing androgen deprivation therapy. Identification of specific sleep problems and related consequences might help determine what treatment strategies would improve the lives of these men. Sleep patterns were determined subjectively with daily diaries and objectively with actigraphy, a measure of gross motor movements. In addition, the relationship between sleep and both daytime sleepiness and quality of life was assessed. We hypothesised that sleep would be disrupted and that poor sleep would be related to negative outcomes as demonstrated in other populations (Katz & McHorney 2002; Roth & Roehrs 2003).

Methods

Participants

From June 2004 until February 2006, 60 prostate cancer survivors were enrolled for a quality-of-life study approved by University of Pennsylvania's Institutional Review Board. Eligibility criteria included ongoing androgen deprivation therapy, Eastern Cooperative Oncology Group criteria of 0-3, and no current surgery, radiation, chemotherapy, or myelosuppressive medications. Participants were primarily recruited from the medical oncology clinic of the Abramson Cancer Center. Other participants were recruited from prostate cancer support groups, advertisements, and referrals from local urologists.

Measures

Actigraphy—Actigraphs are watch-like devices (Actiwatch-64®, Mini Mitter Co., Inc., Bent, OR, U.S.A.) that can be used to objectively monitor activity levels for assessment of wake and sleep episodes. The Actiwatch-64® device uses a miniaturized omnidirectional accelerometer that integrates the degree and speed of motion at a maximum sampling rate of 32 Hz to continuously determine activity levels. Actigraphy is reasonably well correlated with polysomnography results in elderly subjects (Colling *et al.* 2007), and has been used among cancer patients (Berger 1998).

The Actiwatch-64® has 64 KB of on-board memory and was programmed to record data in 15 s epochs. Actiwatch-64® data were retrieved via a personal computer-interface and analyzed using Actiware®-Sleep software (Mini Mitter, Bent, OR). The software uses algorithms to determine an activity count for each epoch. Sleep and wake periods were respectively identified as epochs with a total activity count below and above the default threshold value and were used to compute a variety of night-time and daytime sleep metrics. Night-time and daytime variables were determined by the times that men went to bed for the night and got out of bed for the day recorded on their daily diary.

Daily Diary—In the morning and evening of each assessment day, participants completed paper diaries. In addition to bedtimes, the morning diary queried sleep start/end as well as the number, duration, and reasons for night-time awakenings. The diary completed in the evening assessed daytime naps.

Questionnaires—Sociodemographic information was collected along with validated questionnaires of daytime sleepiness and quality of life. The Epworth Sleepiness Scale is an 8-item questionnaire. Scores range from 0 - 24, and values above 10 indicate clinically significant sleepiness. The test-retest reliability and internal consistency are good (Johns 1992). The Functional Assessment of Cancer Therapy - General (Cella *et al.* 1993) is a 27-item questionnaire designed for patients with cancer. Total scores range from 0 – 108 with higher scores indicate better quality of life. Normative data collected from the general U.S.A. population had a mean total score of 80.1 ($SD = 18.1$; Webster *et al.* 2003).

Medical Variables—Chart abstractions were used to collect information on cancer status, cancer treatment, current medication, and medical co-morbidities. Additionally, current medications were collected from participants in-person to ensure completeness of the medical chart data.

Procedures

Potential participants were screened either by telephone or in-person at the medical oncology clinic. After a full explanation of the study, a home visit was scheduled with eligible participants. At the start of the home visit, research assistants obtained participants' written informed consent if it had not been collected previously. Afterward, consenting participants were instructed to complete the questionnaire packet and diaries and were fitted with the Actiwatch-64® on their nondominant arm. Research assistants also compiled a list of all medications participants were receiving. Participants wore the Actiwatch-64® and completed the daily diary for 1 week at home after which the research assistant returned to collect the measures.

Data Analysis

Descriptive statistics of sociodemographic and medical information, actigraphy and diary sleep variables, and questionnaire scores were computed to characterize the sample. Sleep variables included sleep latency (i.e., number of minutes it took to fall asleep), sleep efficiency (i.e., the percentage of the time in bed spent asleep), wake after sleep onset (i.e., minutes spent awake during the night), total sleep time, and daytime naps. Actiware®-Sleep software was programmed to detect a nap as ≥ 5 consecutive minutes of sleep, and the end of a nap was determined as the last minute of sleep prior to ≥ 30 consecutive minutes of wake. The duration of each nap was calculated as the number of minutes from nap onset to nap end. The strength of the relationship between actigraphy and diary sleep variables was determined with Pearson correlations.

In addition to determining sleep patterns, activity data were subjected to cosinor analysis (Nelson *et al.* 1979). Cosinor analysis is used to determine if there is a rhythmic pattern in a set of data. A common application is to examine 24-h cycles (i.e., circadian rhythm) in various behavioural processes. Circadian rhythms are thought to enhance functional ability. A cosine curve was fit to the seven-day raw activity data using least squares methods. This allows the estimation of circadian rhythm parameters, such as the acrophase (i.e., timing of the peak of the rhythm) and amplitude (i.e., the mid-distance between the peak and the trough).

Total sleep time was chosen as the main sleep parameter in assessing the effect of sleep on daily functioning because of the extensive literature demonstrating associations between sleep time and well-being (Grandner *et al.* 2010) and in order to avoid conducting too many statistical tests with multiple sleep variables. Age, marital status, educational status, ethnicity, and income were considered as potential covariates. Selection of dependent variables was based on the conceptualisation of the Epworth Sleepiness Scale as a subjective measure and actigraphy-assessed nap total time as an objective measure of daytime sleepiness, and the Functional Assessment of Cancer Therapy - General providing a global indication of well-being.

For General Linear Model analyses, actigraphy-assessed total sleep time was used as the independent variable, and only dependent variables that were significantly related to sleep time in Pearson correlations were assessed. Potential covariates were assessed in a General Linear Model by removing one at a time using a backward selection strategy until the only variables that remained were at an alpha level of $p \leq .10$. These covariates were then entered in a new General Linear Model with the independent variable. An alpha level of $\leq .05$ (two-sided) was considered statistically significant for all analyses.

Results

Sociodemographic Background

A total of 60 patients were recruited. Characteristics of the study sample are reported in Table 1. The mean age of participants was 71.4 ($SD = 9.6$) and ranged from 54 to 88 years. Most participants were Caucasian, married, and retired and had completed college or graduate school. Participants lived in the Philadelphia metropolitan region in either urban or the surrounding suburban areas.

Medical history

Seven medical charts could not be obtained for abstraction. Of 53 participants, the average number of years since diagnosis of prostate cancer was 6.77 ($SD = 5.12$). Nearly 50% of participants received external beam radiation while less than 10% received brachytherapy. Only 7% were treated with chemotherapy. A prostatectomy was performed on 26%, and only one participant had a bilateral orchiectomy. At the time of their enrolment into the study, the cancer had metastaticized in 49%, biochemically progressed in 30%, and remained local in 21%.

Of all 60 participants, the most common medication was a luteinizing hormone-releasing hormone agonist with 88% receiving leuprolide acetate injections. An anti-androgen, normally bicalutamide, was taken by 25%, and 12% were receiving ketoconazole. Duration of androgen deprivation therapy could not be calculated accurately for most men, primarily due to intermittent treatment, but extended use was suspected. There were no clear patterns for other medication use except that 78% of participants were taking antihypertensive and/or cholesterol-lowering medications.

Night-time Sleep

Sleep data from 7 days of actigraphy and sleep diaries are presented in Table 2. On average, subjects took longer than 30 minutes to fall asleep and slept 6 hours per night. For the night-time sleep variables, most correlations between objective and patient-reported assessments were low and non-significant with the exception being total sleep time.

Subjects reported awakening, on average, 2.7 times per night. The most frequent reason cited for awakening was nocturia, with an average of 1.75 times per night. The remaining

reasons were hot flashes (0.54 times), pain (0.03 times), sweating (0.03 times), and *Other* (0.36 times). For the *Other* category, subjects reported reasons such as leg cramps and bed partner was awake. Diary entries also queried nocturia while awake at night. When including these episodes, nocturia occurred 3.1 ($SD = 3.2$) times per night on average.

Daily Functioning

According to actigraphy, each participant had evidence of circadian rhythmicity. The mean amplitude was estimated at 0.73, and the mean acrophase was 14:22 (i.e., 2:22 P.M.). The Epworth Sleepiness Scale score had an average of 7.2 ($SD = 4.5$), which is suggestive of mild levels of sleepiness. Fourteen men (23%) had elevated scores of 10 or above. Actigraphy-measured napping was frequent, and naps lasted on average 14.42 ($SD = 4.34$) minutes. Moderate correlations between objective and subjective napping variables, shown in Table 2, were statistically significant. However, diary entries markedly underestimated nap frequency and the minutes spent napping compared to actigraphy. The Functional Assessment of Cancer Therapy - General mean score was 85.6 ($SD = 12.2$), which is indicative of normal well-being.

Of the daily functioning measures, only the Epworth Sleepiness Scale score was significantly correlated with total sleep time ($r = -.36, p = .007$) indicating that greater hours of sleep was associated with less sleepiness as expected. Of the possible covariates, level of education ($F(4,48) = 3.7, p = .01$) and marital status ($F(2,48) = 4.1, p = .02$) were significantly related to Epworth Sleepiness Scale scores. In the final model, total sleep time was significantly associated with Epworth Sleepiness Scale scores ($F(1,47) = 4.5, p = .04$) over and above the effects of the covariates.

Discussion

Sleep problems have been shown to have broad deleterious effects. Difficulty sleeping was found to be predictive of psychiatric disorders (Ohayon & Roth 2003; Taylor *et al.* 2003) and was associated with medical conditions, such as heart disease and hypertension (Taylor *et al.* 2007). Other consequences of difficulty sleeping include decreased cognitive functioning, daily accomplishments, enjoyment of relationships, emotional well-being, and quality of life (Chevalier *et al.* 1999; Léger *et al.* 2008; Roth & Ancoli-Israel 1999; Vandekerckhove & Cluydts 2010). Similarly, among patients with chronic illness, difficulty sleeping was associated with worse health-related quality of life after accounting for the effects of depression, anxiety, and medical comorbidities (Katz & McHorney, 2002).

Previous survey studies suggest that prostate cancer patients on androgen deprivation therapy are vulnerable to sleep problems. Using more time-sensitive instruments, this study similarly found evidence of sleep problems in this population. Specifically, patients had trouble sleeping at the beginning and during the night, and daytime naps were common. Even though hot flashes are common in this population (Hanisch *et al.* 2009), nocturia was reported by participants as the primary cause of awakenings. Most striking, the average sleep duration noted by both objective and subjective measures was approximately 6 hours per night.

In spite of low total sleep time, normal functioning was indicated by findings of circadian rhythmicity in activity levels and patient-reported general quality of life. Current reports of general quality of life appear consistent with previous androgen deprivation therapy studies (Arai *et al.* 2008; Joly *et al.* 2006; Sakai *et al.* 2009). Conversely, clinically significant daytime sleepiness was reported by 23% of participants, and actigraphy results suggest that participants were napping during the day. To our knowledge, sleepiness has not been assessed previously among prostate cancer patients on androgen deprivation therapy, but

similar mean scores were found prior to and after radiotherapy for prostate cancer (Monga *et al.* 2005).

Only patient-reported daytime sleepiness was related to objective total sleep time. This was contrary to our hypothesis that poor sleep would be related to multiple negative outcomes and suggests that daytime nap time and quality of life are not related to night-time sleep time. Likewise, another study found that older age was associated with fewer daytime symptoms despite increases in night-time sleep problems (Unruh *et al.* 2008). It is possible that older adults adapt to age-related (Unruh *et al.* 2008; Vitiello *et al.* 2004; Zilli *et al.* 2009) as well as treatment-related changes in sleep.

Low to moderate relationships were found between objectively measured and patient reports of sleep. Actigraphy detected worse sleeping patterns, consistent with other studies showing older men report better sleep on diaries compared to actigraphy (van den Berg *et al.* 2009). This is expected as persons are not likely to recall accurately when in a state of reduced consciousness, resulting in reporting biases, such as an overestimation of night-time sleep. On the other hand, although actigraphy is a validated measure of sleep, it is not accurate at differentiating between sleep versus restful wake periods, and wake versus periodic limb movements during sleep (Tryon 2004). These different sources of error may account for the weak relationships between actigraphy and diary-based estimates and support use of both measures for a comprehensive assessment of sleep.

This study had limitations. Data was obtained from a convenience sample, so results may not generalize. Future studies including a more representative sample may find that poor sleep has broader negative effects. Similar results may have been found if a control group of men not on androgen deprivation therapy or diagnosed with prostate cancer was included. However, such findings would not alter the implications for therapeutic targets or effects on daily life. Another primary limitation of the current study was the use of retrospective patient report for identifying the causes of awakenings at night. Participants may have recalled awakening mostly due to nocturia and hot flashes because both are salient events.

In conclusion, this study provides further evidence of poor sleep among prostate cancer patients on androgen deprivation therapy. It specifically showed that patients had problems with sleeping at the beginning and throughout the night and highlights the need to provide distressed patients with effective interventions targeting sleep latency and disruption. Results suggests that nocturia and hot flashes are common causes of sleep disruption in this population, but there may be other contributing factors, such as sleep apnoea and emotional distress, that are not as readily detected or associated with sleep problems by patients. More research is needed to identify the effect of each factor on sleep in order to provide more tailored interventions for patients.

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Table 1
Sociodemographics of Study Participants

Variable	N	%
Age		
54-64 years	18	30.0
65-75 years	14	23.3
76-88 years	28	46.7
Race		
Caucasian	44	73.3
African-American	15	25.0
Other	1	1.7
Education		
High School or less	11	18.7
Trade School or College	21	35.6
Graduate/Professional training	27	45.7
Partner status		
Never married	4	6.7
Married/Partnered	47	78.3
Other	9	15.0
Living situation		
Alone	7	12.1
With adults only	42	72.4
With children	9	15.5
Employment		
Retired	40	66.7
Full-time	15	25.0
Other	5	8.3
Annual Income		
≤ \$39,999	21	35.6
\$40,000-\$69,000	15	25.4
≥ \$70,000	20	33.9
Refused	3	5.1
Health insurance		
None	1	1.7
Private	13	21.7
Medicare/Medicaid	38	63.3
Other	8	13.3

Note: N may be less than 60 for some variables due to missing data

Table 2
Night-time and daytime sleep by actigraphy and patient report

Sleep Variable	Actigraphy <i>M</i> (<i>SD</i>)	Sleep Diary <i>M</i> (<i>SD</i>)	<i>r</i>
Sleep latency (minutes)	43.0 (38.8)	32.5 (23.6)	.18
Total sleep time (hours)	5.9 (1.4)	6.1 (1.3)	.43**
Sleep efficiency (percent)	75.0 (12.0)	76.5 (14.7)	-.06
Wake after sleep onset (minutes)	49.4 (33.4)	20.0 (15.0)	.11
Number of naps per day	3.7 (1.5)	0.3 (0.3)	.32*
Total nap time per day (minutes)	58.8 (31.7)	17.4 (28.9)	.56**

* $p < 0.05$,

** $p < 0.01$