Sleep Medicine 16 (2015) 364–371

Contents lists available at ScienceDirect

Sleep Medicine

journal homepage: www.elsevier.com/locate/sleep

Original Article

Longitudinal changes in insomnia status and incidence of physical, emotional, or mixed impairment in postmenopausal women participating in the Women's Health Initiative (WHI) study

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ARTICLE INFO

Article history:
Received 29 August 2014
Received in revised form 10 November 2014
Accepted 12 November 2014
Available online 15 December 2014

Keywords:
Insomnia
Older adults
Women's health
Functioning
Longitudinal

ABSTRACT

Objectives/Background: We assessed prevalence and correlates of insomnia; associations between changes in insomnia with incidence of physical, emotional, and mixed impairments (PI, EI, and MI, respectively); and age as a moderator in these relationships.
Participants/Methods: The Women's Health Initiative (WHI) clinical trial (CT) and observational study (OS) cohorts with 1- and 3-year follow-ups, respectively, were studied. Participants included 39,864 CT and 53,668 OS postmenopausal women free of PI or EI at baseline. Insomnia Rating Scale (IRS), with a cutoff score of ≥9 indicated insomnia. Normal–Normal, Abnormal–Abnormal, Normal–Abnormal, and Abnormal–Normal categories indicated change in insomnia over time. PI, EI, and MI were constructed using Short Form-36 (SF-36) Physical and Emotional subscales (cutoff ≤60) and the modified Center for Epidemiological Studies Depression scale (cutoff ≤0.06).
Results: Among 93,532 women, 24.5% had insomnia at baseline. The highest odds ratios (ORs) for impairments were found in the Normal–Abnormal and Abnormal–Abnormal categories. In the CT cohort, Normal–Abnormal category, ORs were 1.86 (95% CI = 1.57–2.20) for PI, 4.11 (95% CI = 3.59–4.72) for EI, and 6.37 (95% CI = 4.65–8.74) for MI. Respective ORs for the OS cohort were 1.70 (95% CI = 1.51–1.89), 3.80 (95% CI = 3.39–4.25), and 4.41 (95% CI = 3.56–5.46). Interactions between changes in insomnia and age showed distinct albeit nonsignificant patterns.
Conclusions: The results suggest that exposure to insomnia increases vulnerability to impairment. Future studies are needed to understand the directionality of these relationships.

1. Introduction

Gender differences in sleep disturbances have repeatedly demonstrated a greater frequency of sleep complaints in women than in men [1–3], which has often been attributed to hormonal changes, particularly during the midlife years [4–7]. Increasing age has also been associated with increased frequency of sleep disturbance; however, this relationship is considerably modified when screening for comorbidity [2,8] and depends on the specific definition provided for the assessment of sleep disturbance [1,9]. In a recent cross-sectional investigation of sleep disturbances across the lifespan (n = > 155,000 participants of the Behavioral Risk Factor Surveillance System – BRFSS), a nonlinear, bimodal distribution emerged, with the highest rates of self-reported sleep disturbance found for young (ages 18–24) and midlife (ages 50–59) men and women [2]. Rates of sleep disturbance were lowest in the oldest age group, were significantly higher in women, and were associated with poor general health and depression. In a systematic review of the literature, symptoms of insomnia were shown to increase with age, whereas self-reported sleep dissatisfaction was unrelated to age [1].

Numerous cross-sectional and longitudinal population studies have investigated disturbed sleep, in both quality and quantity, in

Abbreviations: BMI, body mass index; CESD, Center for Epidemiological Studies Depression; CT, clinical trial; EI, emotionally impaired; EW, Emotional Well-Being; IRS, Insomnia Rating Scale; KoGES, Korean Genome and Epidemiology study; MI, mixed impairment; OS, observational study; PF, Physical Functioning; PI, physically impaired; QOL, quality of life; UI, unimpaired; WHI, Women's Health Initiative.

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http://dx.doi.org/10.1016/j.sleep.2014.11.008
1389-9457/

association with a wide array of medical [10–14] and mental disturbances [14–16], but few have investigated the associations between sleep disturbance and physical and mental quality of life (QOL) and functioning in community-dwelling men and women [17]. As health-related QOL has been found to be an important predictor of healthy aging and cardiovascular morbidity [18,19], understanding the long-term dynamics between poor sleep, health, and QOL may be of interest for epidemiological and clinical purposes. Findings from a cross-sectional study of >4000 adults (ages 18–65) demonstrate that comorbid sleep disturbance with physical illness increases the likelihood of poor health-related QOL, compared to the presence of physical illness alone, even after adjusting for sociodemographic factors and mental and medical comorbidities [17]. In a cross-sectional analysis of women aged 32–58 in Finland, more severe physical and mental QOL conditions incurred higher risks for self-reported sleep problems [20]. Similar findings were reported in a sample of postmenopausal women in Australia [21].

Taken together, a growing body of evidence suggests that sleep disturbance may have adverse long-term effects on health and functioning. Sleep disturbance is more prevalent in women, and findings indicate that such effects may also be more pronounced in women. Yet studies using longitudinal data and powered by large population-based samples aimed to address the dynamics of sleep disturbance and physical and mental aspects of QOL in older women are currently lacking. Thus, the present investigation aims to enhance the empirical evidence regarding the longitudinal impact of insomnia on physical and mental health and functioning among postmenopausal women (aged 50+) participating in the Women's Health Initiative (WHI) clinical trial (CT) and observational studies (OS). The presence of insomnia symptoms (hereafter insomnia) in the WHI study was based on the frequency of insomnia-related symptoms during the past 4 weeks using previously validated Insomnia Rating Scale (IRS) instrument [22].

The study aims were to describe baseline prevalence and correlates of insomnia in otherwise physically and emotionally unimpaired women; to evaluate the association of 1- and 3-year changes in insomnia status with physical, emotional, or mixed impairment (PI, EI, and MI, respectively) incidence; and to assess age categories as the moderator in the relationship between changes in insomnia status and rates of impairment.

We expected to observe a relationship between changes in insomnia status and development of PI and EI. Specifically, we anticipated an increased risk of PI and/or EI among those who developed insomnia as compared to the healthy group. Moreover, we hypothesized that the risk of impairment in the persistent insomnia group would be similar to that in the incident insomnia group. Likewise, we expected that the risk of impairment in the healthy (i.e., non-insomnia) group would be comparable to that in the remissive insomnia group. Finally, we expected to observe an interaction between age categories and changes in insomnia status, so that an increased risk of impairment would be found in older incident and persistent insomnia participants compared to their younger counterparts.

2. Methods

2.1. Study population

The WHI is a study of postmenopausal women's health and risk factors for cancer, heart disease, and osteoporotic fractures. It was designed as a set of randomized controlled CTs and an OS. Details of the design, recruitment strategies, data collection methods, and baseline data are available elsewhere [23]. Briefly, women aged 50–79 were recruited for the WHI from 1993 to 1998 at 40 clinical centers in the USA, which yielded a diverse population of postmenopausal women, of whom 18% were from underrepresented racial and ethnic groups. Women were excluded for medical conditions with a predicted survival of three years or less, for conditions limiting adherence or retention (eg, alcohol or drug dependency and dementia), or for active participation in any other intervention study. The CTs ($N = 68,132$) included three overlapping components: the hormone therapy, the dietary modification, and the calcium and vitamin D trials. Women who were ineligible or unwilling to join the CTs were invited to join the OS, in addition to those who were specifically recruited for the OS ($N = 93,676$). The CT and OS women attended baseline and protocol-defined clinical visits. All WHI participants provided written informed consent, and institutional review board approval was obtained at each of the 40 WHI clinical centers and at the Clinical Coordinating Center at the Fred Hutchinson Cancer Research Center, Seattle, WA, USA. Analyses for this study were limited to the subset of CT and OS participants who were free of PI or EI at baseline and who had available IRS, RAND 36-Item (SF-36) [24] Health Survey Physical Functioning (PF) and Emotional Well-Being (EW) subscales, and the depression index based on six items for the Center for Epidemiological Studies Depression (CESD) scale and two items from the diagnostic interview schedule at the following measurement occasions: baseline (CT cohort; $N = 46,022$; OS cohort; $N = 62,579$), year 1 (CT cohort; $N = 39,864$), and year 3 (OS cohort; $N = 53,668$; see Fig. 1). Impairment was defined as scores ≤60 on each of the SF-36 subscales and, similarly, scores ≥0.06 on the modified CESD scale.

2.2. Measures

2.2.1. Impairment

The outcomes of interest are four mutually exclusive groups representing normal impairment, PI, EI, or MI. The groups were constructed using SF-36 PF and EW subscales with a cut point of 60, indicating impairment. The cut point was selected as indicating low functioning in comparable-age cohorts [25]. In addition, the modified CESD scale scores were used to define EI with a cut point of 0.06 and higher, in accordance with Burnam's algorithm suggestive of depression [26]. Further details about these classifications are described below:

Unimpaired (UI) group: This group consisted of women who scored >60 on both the PF and EW subscales and <0.06 on the modified CESD scale.

Physically impaired (PI) group: This group comprised women who scored ≤60 on the PF, but >60 or <0.06 on the EW and the modified CESD, respectively.

Emotionally impaired (EI) group: This group included women who scored ≤60 or ≥0.06 on the EW and the modified CESD scales, respectively, and >60 on the PF scale.

Mixed impairment (MI) group: This group consisted of women who scored either ≤60 or ≥0.06 on the EW and the modified CESD scales, respectively, and also ≤60 on the PF scale.

The UI group was assigned as the reference category.

2.2.2. Insomnia rating scale

The IRS scores were the primary exposure variables. The IRS consists of five items pertaining to quality of sleep, trouble falling asleep, waking up several times, waking up earlier than planned, and trouble getting back to sleep in the past four weeks [22]. The items are measured on a scale of 0–4, with higher scores representing more frequent or more severe symptoms. A final score, ranging from 0 to 20, is calculated by summing the scores for the five items. IRS measures were collected at baseline for all WHI participants and in year 1 for CT participants, and in year 3 in the OS cohort. Insomnia was defined using the IRS cut point of 9 [22]. This threshold has been widely used in previous studies investigating insomnia and health-related outcomes among WHI cohorts [27–29]. Categories