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Effect of valerian on sleep quality in postmenopausal women: a randomized placebo-controlled clinical trial

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Abstract

Objective: Sleep disturbances reduce the quality of life. About 50% of postmenopausal women experience sleep disturbances such as insomnia. Complementary and alternative medical therapies may be useful for the management of sleep disturbances among postmenopausal women. The aim of the present study was to evaluate the effects of valerian extract taken nightly on the improvement of sleep quality in postmenopausal women experiencing insomnia.

Methods: A randomized, triple-blind, controlled trial design was used for this study. Participants consisted of 100 postmenopausal women aged 50 to 60 years who were experiencing insomnia. A demographic data form and the Pittsburgh Sleep Quality Index were used to collect data. The women were randomly divided into two groups. Each group received either 530 mg of concentrated valerian extract or a placebo twice a day for 4 weeks. Descriptive and inferential statistics were used to analyze the data.

Results: A statistically significant change was reported in the quality of sleep of the intervention group in comparison with the placebo group ($P < 0.001$). Also, 30% of the participants in the intervention group and 4% in the placebo group showed an improvement in the quality of sleep ($P < 0.001$).

Conclusions: Valerian improves the quality of sleep in women with menopause who are experiencing insomnia. Findings from this study add support to the reported effectiveness of valerian in the clinical management of insomnia.

Key Words: Menopause – Valerian – Insomnia – Pittsburgh Sleep Quality Index.

Menopause is defined as following the final menstrual period and usually confirmed when a woman has missed her periods for 12 consecutive months in the absence of other obvious causes.[1] Every year, millions of women enter menopause. By the year 2030, the World Health Organization estimates that 1.2 billion women will be 50 years or older.[2] Estrogen decline during menopause may result in various symptoms and complaints,[3-5] and sleep disturbance is an important complaint.[6]

Sleep disturbance is associated with negative health consequences, including impaired daytime function, fatigue, reduced quality of life, and increased healthcare utilization.[3,7] In addition, insomnia is a risk factor for major depression.[8]

Older adults commonly experience disturbed sleep, with nearly 50% reporting insomnia symptoms of prolonged sleep latency and frequent nocturnal or early-morning awakenings with an inability to return to sleep.[9] Approximately 61% of postmenopausal women have sleep problems, which can lead to other problems such as daytime drowsiness. Also, hot flushes, which affect 75% to 85% of postmenopausal women, and night sweats could affect sleep quality.[10]

There are a wide variety of pharmacologic and nonpharmacologic methods for addressing symptoms at this stage of life.[11,12] One of the pharmacologic methods is hormone therapy (HT).[5,13] Patient and physician attitudes regarding menopause and HT may affect decisions about their use.[5]

Complementary and alternative medical therapies may be useful for managing insomnia in older adults.[14] Gooneratn suggested five types of complementary and alternative medicines for treatment of sleep disturbance: acupuncture and homeopathy; meditation, yoga, and biofeedback; herbal products; massage therapy; and energy medicine.[15]

Older adults use prescribed and over-the-counter sleep aids more often than do young adults.[15] There is some evidence suggesting that community-dwelling older adults may use complementary and alternative therapies for sleep at a higher rate as well, although no systematic data have been collected.[16,17]

National surveys indicate that more than 50% of middle-aged to older adults use daily dietary supplements, particularly herbal products.[18-20] According to a recent survey, approximately 1.6 million Americans use complementary and alternative medical therapies to treat their sleep disturbances, and herbal therapies are commonly used for chronic symptoms of disturbed sleep.[21,22]

Valerian, which is the most commonly used herbal product for inducing sleep,[23] is among the eight most widely used

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herbal supplements.[24,25] Valerian is listed by the US Food and Drug Administration as a food supplement, and therefore, there are no contraindications for its use.[26]

The root of valerian, a perennial herb native to North America, Asia, and Europe, is believed to have sedative and hypnotic properties. Valerian has been suggested for several other uses, including alleviating anxiety, depression, stress, and menopausal symptoms, but there is limited research documenting its effects for these uses.[24] In a national survey conducted in 2002, 1.1% of the adult population in the United States, or approximately 2 million adults, reported using valerian in the past week.[27]

In a double-blind study by Leathwood and Chauffard,[28] eight participants with lengthy sleep latency wore a wrist meter to provide subjective sleep ratings in a study of the effects of valerian. In another randomized, placebo-controlled, double-blind, crossover study involving 16 women with insomnia, polysomnography (PSG) demonstrated no effects on sleep efficiency after a single 600-mg dose of valerian extract.[29]

During the last 20 years, a number of clinical trials have been conducted; however, few studies have examined the impact of valerian on sleep among older adults, and none have been conducted in a long-term care setting. Moreover, systematic reviews have found inconsistent results and wide variation in the design of the trials.[30,31] Nine randomized, placebo-controlled, double-blinded clinical trials published through 1999 were systematically reviewed by Stevinson and Ernst.[30] Two of these trials focused on older poor sleepers. These two studies and one additional study of younger adults were the only studies that evaluated valerian administration for more than 7 days.[31] As such, and because there were no studies investigating the effect of valerian on postmenopausal women, we examined the effect of valerian on insomnia in 50- to 60-year-old women with menopause.

METHODS

Study design

A randomized, controlled, triple-blind study was conducted. Participant recruitment and data collection were done between February 2009 and July 2010. A sample of postmenopausal women experiencing insomnia according to their self-reported symptoms were recruited for the study. The inclusion criteria were as follows: generally healthy women aged 50 to 60 years who were menopausal for at least 1 year and not using HT, no medical or psychiatric conditions that would cause sleep disturbance, and a score of 5 in the Pittsburgh Sleep Quality Index (PSQI). The exclusion criteria were as follows: sleep disorders such as sleep apnea, restless legs syndrome, periodic limb movement during sleep, or severe self-reported insomnia; night shift work or an unstable sleep schedule; transmeridian travel (three time zones) within the past 4 weeks; current major illness such as cancer or fibromyalgia; currently using sleep medications; tobacco or alcohol use; more than two caffeinated drinks per day; and not using valerian (Sedamin) capsules for 7 days.

Ethical issues

This study was approved by the ethics committee of Tehran University of Medical Sciences.

Data gathering

Two surveys were used in this study. The first was a demographics collection questionnaire of 11 items: age, age at onset of menopause, marital status, education status, occupational status, economic status, age difference of partner, number of pregnancies, number of children, number of married children, and family size. The second was the PSQI. The PSQI is a self-rated questionnaire that assesses sleep quality and disturbances over a 1-month period. The questionnaire has 19 items that are used to generate seven composite scores. The composite scores provide information about subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medication, and daytime dysfunction. The scores from the seven components are then summed to yield a final PSQI score. When the final PSQI score is greater than 5, it is nearly 90% sensitive and specific for diagnosing "poor" sleep. The post hoc cutoff score of 5 on the PSQI produced a sensitivity of 89.6% and a specificity of 86.5% of participants versus control participants. In this study, decreasing PSQI score or a score of less than 5 was defined as improvement after intervention.

Each supplement capsule (Sedamin) used in this study contained 530 mg of valerian root extract and was made in an Iranian pharmacy factory. The placebo had the same appearance as the herbal supplement, and the two types of capsules were labeled A (valerian) and B (placebo). The study was triple blind, and participants and investigator as well as statistician were blind to the study groups until the analysis was completed. During the study, only the pharmacist knew the identity of each type of capsule. Participants used capsules orally twice a day for 4 weeks. All participants were followed weekly by telephone and requested to fill out the PSQI again after completing the intervention.

Sample size was calculated based on 80% power and 5% type 1 error, and it was determined that 50 participants were needed for each group. Therefore, we delivered the PSQI questionnaire to 250 volunteer women who met the inclusion criteria. Of the 250 women surveyed, 100 gave informed consent and were randomly assigned to 2 groups (A and B). Participants were involved in the study until the end of week 4. During the follow-up visit, participants were informed of their actual treatment.

Descriptive statistics (including frequency measures of central tendency and variance) and inferential statistics (*t* test) were used to analyze the data using SPSS version 14.

RESULTS

The results of the initial PSQI, which assessed sleep quality and disturbances over a 1-month period, showed a frequency of sleep disturbance of 70%.

The average (SD) age was 52.6 (3.3) years in the valerian group (group A) and 53.1 (3.5) years in the control group. The

TABLE 1. *Demographic characteristic*

Group	Valerian n	Valerian %	Control n	Control %	Valerian, mean ± SD	Control, mean ± SD
Age, y						
50-52	33	66	27	54	52.6 ± 3.3	53.1 ± 3.5
53-55	7	14	13	26		
≥56	10	20	10	20		
Menopause age, y						
40-44	23	26	6	12	49.9 ± 3.9	48.0 ± 3.6
45-49	25	50	29	58		
≥50	12	24	15	30		
Age difference with partner, y						
0	1	2	4	8	4.02 ± 6.17	4.45 ± 6.2
1-4	18	36	11	22		
5-9	12	24	15	30		
10-14	10	20	9	18		
No partner	9	18	11	22		
Marital status						
Married	41	82	39	78		
Single	9	18	11	22		
No. of pregnancies						
0-2	7	14	2	4	4.74 ± 2.3	5.3 ± 1.72
3-4	17	34	13	26		
5-6	17	34	22	44		
≥7	9	18	13	26		
Family size						
1-2	6	12	11	22	4.4 ± 1.8	4.56 ± 2.3
3-4	23	46	16	32		
≥5	21	42	23	46		
No. of children						
0-2	8	16	3	6	4.62 ± 2.3	5.1 ± 1.7
3-4	22	44	15	30		
5-6	20	40	32	64		
No. of married children						
0	5	10	5	10	2.52 ± 2.1	2.94 ± 2.06
1-2	25	50	17			
3-4	14	28	19	38		
≥5	6	12	9	18		
Educational status						
Illiterate	24	48	27	54		
Primary school	18	36	22	44		
Secondary school	8	16	1	2		
Occupational status						
Employed	2	4	1	2		
Housewife	48	96	49	98		
Economic status						
Good	7	14	3	6		
Moderate	28	56	31	62		
Bad	15	30	16	32		

TABLE 3. *Improvement rate in two groups*

	Groups			
	Valerian		Placebo	
Improvement	n	%	n	%
Yes	15	30	2	4
No	35	70	48	96
χ^2 Test Analyze	$\chi^2 = 11.9$	df = 1	$P < 0.001$	

age of onset of menopause was 49.9 (3.9) years in the valerian group and 48 (3.6) in the control group. The age difference with their partner was 22.8 (36.2) years in the valerian group and 26.6 (39.06) years in the control group; the number of pregnancies was 4.74 (2.3) in the valerian group and 5.3 (1.72) in the control group; family size was 4.4 (1.8) in the valerian group and 4.56 (2.3) in the control group; the number of children was 4.62 (2.3) in the valerian group and 5.1 (1.7) in the control group; and the number of married children was 2.52 (2.1) in the valerian group and 2.94 (2.06) in the control group. Demographic characteristics are shown in Table 1.

The mean (SD) score on the sleep scale before intervention in the valerian group was 9.8 (3.6), and after intervention, it was 6.02 (2.6). The placebo group's initial sleep scale score was 11.14 (4.3), and after using the placebo, it was 9.4 (3.9). There was a significant difference between the valerian and placebo groups' mean PSQI scores ($P < 0.001$; Table 2); due to the effect of treatment on sleep score in both groups, we analyzed different mean sleep score in two groups. Mean sleep scores (PSQI scores) was 3.8 ± 1.7 in the valerian group and 1.7 ± 1.3 in the placebo group. There was a significant difference between the two groups ($P = 0.04$) and a test showed more effects after using the valerian capsules ($P = 0.001$).

About 30% of the participants in the valerian group and 4% in the placebo group reported an improvement in their sleep quality. There were significant differences between the two groups ($P < 0.001$; Table 3).

DISCUSSION

This study examined the effect of valerian on insomnia among 50- to 60-year-old postmenopausal women. Previous studies on valerian have generally shown inconclusive results.[32-35] Although participants reported an improvement in sleep among older persons who used valerian, statistical tests

TABLE 2. *Pittsburgh Sleep Quality Index scores before and after intervention in 60- to 50-year-old postmenopausal women*

	Group											
	Valerian						Placebo					
	Before			After			Before			After		
Sleep scale	n	%	Mean (SD)	n	%	Mean (SD)	n	%	Mean (SD)	n	%	Mean (SD)
1-4	0	0		20	40		0	0		6	12	
5-9	20	40		22	44		23	46		18	36	
10-14	18	36	9.8 (3.6)	8	16	6.02 (2.6)	22	44	11.14 (4.3)	20	40	9.4 (3.9)
15-21	12	24		0	0		5	10		6	12	
Total	50	100		50	100		50	100		50	100	
T-Test	T = 5.02			df = 98		$P < 0.001$						

were not used to compare the results between the valerian and placebo groups in one study,[36] and another study reported the proportion showing improvement rather than the actual ratings of sleep quantity and quality.[37] Two other studies on older persons using valerian reported no significant difference in self-reported or PSG sleep outcomes.[38,39] However, valerian use in this study showed improvement of insomnia, which is consistent with previous findings of greater improvements in poor sleepers than in good sleepers after nightly use of 400 mg of aqueous valerian.[28]

Although some studies have reported improvement in sleep quality with valerian administration over time,[36,38,40] there are few studies that have mentioned significant improvement in any of the sleep outcomes when valerian is compared with a placebo. Despite evidence from in vitro studies of valerian's effect on neuropeptide systems involved in sleep mechanisms,[41,42] Vitiello et al[43] reported moderately disrupted sleep on PSG recordings in older healthy women who did not complain of sleep problems, but this pattern was not observed in healthy older men. More research is needed to explore moderators between objective measures and perceptions of sleep, especially in older women and men.

Participants did not report any adverse effects from this herbal supplement.

A potential limitation of this study is the absence of compliance monitoring. Pre-bedtime activities can significantly affect women's sleep. Although we instructed the participants to avoid drinking caffeine and alcohol, there was no way to be certain of their compliance.

CONCLUSIONS

Valerian improves the quality of sleep in postmenopausal women experiencing insomnia, and findings from this study support the effectiveness of valerian in the clinical management of insomnia. In addition, the absence of negative side effects, which are commonly seen with prescribed hypnotics, suggests that traditional herbal supplements may be a suitable alternative for treatment of insomnia. In conclusion, the herbal supplement used in this study led to measurable improvements in sleep for postmenopausal women.

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