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Abstract

Background: Sleep disturbance is one of the symptoms of menopause, which occurs due to a decrease in sex hormones and dramatically affects the quality of life. This study was designed to compare the effects of relaxation and Valerian on insomnia of menopause women.

Methods: The study was a randomized clinical trial in 129 menopausal women with insomnia that were randomly allocated to three groups valerian, relaxation and control. After 1 month information obtained by demographic questionnaire and sleep quality Petersburg, then data analyzed in the software SPSS20 at a significance level of 0.05.

Results: The results showed there was significant difference in the level of education , age of marriage($p < 0.05$). Comparing average scores before and after treatment of sleep disorders were determined in valerian and relaxation group was significant difference ($p < 0.001$) and in the control group no correlation was found ($p > 0.05$).

Conclusion: This study showed that the herb valerian and relaxation techniques effective for menopausal insomnia and helps to increase the quality of their sleep.

Key words: relaxation, valerian, insomnia, menopause.

Introduction

Sleep disorder is one of the menopausal complications that takes place due to the reduction of sexual hormones and affects the quality of life of women significantly during this period. Sleep is the resting time of brain and body during which the consciousness reduces comparatively, person gets rid of stress and responsibilities resulting the psychical, mental and physical reinforcement (Benagiano G, Farris M., 2002). Of course, by increasing the age, some changes appear in sleep stages among which reduction of sleep duration, sleep output (the time percentage of sleeping after going to bed) and deep sleep are the most important ones which are categorized under the title of "Insomnia" (Roepke SK, Ancoli-Israel S., 2010).

Insomnia is defined as dissatisfaction from the amount or quality of sleep that continues for a long time. Sleeping late, remaining at sleep hardly and early awaking (light sleeper) are among the symptoms of Insomnia. About 30.0% of world population suffers from sleep disorders and its prevalence among menopause women has been reported to be 65.0% (Ohayon MM., 2002; Gooneratne NS., 2008).

The sleep disorders put negative physical, mental, cognitive, activity and social effects on individual's life. Sufferers are most probably more depressed than others and using medical services and hospitalization times at hospital has been reported more them. In 50.0-60.0% of menopause women, the complication severity is to such an extent that, treatment becomes necessary (Stone KL et al., 2009 ; Melanie K et al., 1999).

Therapeutic methods include: 1- Medicinal (hormonal and non-hormonal) and 2- non-medicinal like herbal complements, exercise, proper diet and avoiding from smoking cigarette (2). Medicinal methods consist of consuming Barbiturates, Analgesics and Antihistamines (Roepke SK, Ancoli-Israel S., 2010). which their side effects like sleepiness, drug resistance, memory disturbance, mouth dryness, constipation and Insomnia recurrence should be considered (Glass J et al., 2005). The American National Health Institute lay emphasis on the fact that, the drugs which are consumed normally to treat sleep disorders possess more risks comparing to their benefits and this therapeutic method in not recommended for olds especially this anxiousness is there that 81.0% of such Barbiturates are being consumed during day time and for the long period (Saddichha S., 2010; Mellinger GD et al., 1985).

Related to the non-medicinal treatment, it should be mentioned that, women have large propensity to follow this method of treatment especially using medicinal herbals to remove their sleep problems in such a way that 50.0% of middle aged women take the help of this method (Eisenberg DM., 2001). In the USA, 80.0% of menopause women apply herbal drugs and 60.0-70.0% of them believe that, these complements have removed their problems, are natural and without complication (Ness J et aj., 2005).

Valerian is one of the usable medicinal herbals which have been applied as relaxant, exhilarating and depression remover in traditional medicine of Iran (Ahmad M et al., 1979). The results of studies in animals have mentioned its relaxing effect which is related to its Volatile oil and

Valpotriat compounds and it has been specified that, Valernal and Valeneric acids are among the most powerful relaxant compounds in this plant (Sah SP et al., 2005; Wegner H et al., 1990).

Clinical studies have also proved the relaxation and barbiturate effects of Valerian in human being. The influence of this plant has been appeared among individuals with natural sleep as well as light sleepers and no complication has been observed in consumers (Hadley S, Petry JJ., 2003). In this respect, Andrew et-al. (2007) carrying out a double clinical trial on 405 patients with sleep disorder and prescribed Valerian for 14 days in comparison with placebo and reported the reduction in sleep disorder among herbal therapy group (Andrew, D et al., 2007).

Relaxation is another non-medicinal treatment method for sleep disorder. Suzanne et-al. (2012) in their study showed that, 23.0% of American adults with Insomnia symptoms applied relaxation techniques and 45.0% also used complementary medicine (Suzanne M et al., 2012). Raymond et-al. (2000) supported the value of drug therapy along with relaxation on Insomnia (Raymond C et al., 2000).

Relaxation is such an activity which results the change in psychical situation of human being and his/her deliverance from the thoughts connected with effort, work or tension. There is a general belief that, relaxation is an enjoyable activity that via increasing the secretion of Endorphin or analgesic hormone and reducing the secretion of Adrenaline in case of pain, birth, anxiety and Insomnia is supposed to be effective and causes individual to obtain his/her power of controlling feelings and behaviors (Payne RM., 2005; Bastani F et al., 2004). Nowadays, by increasing the process of health growth, the number of ladies who pass many years of their life in menopause condition and experience the complications of this period is increasing. Therefore, considering the importance and role of sleep in protecting the general health, mental and physical health and quality of life, the present research was planned as prescribing Valerian and using relaxation methods to reduce and treat the sleep disorder complications among menopause women.

Methods

This study was carried out as clinical trial on 129 menopause women referred to the Shiraz Therapeutic Health Centers (2013-2014). Seeking the help of studies, the sample size for each group (two experimental and one control group) was determined as 43 persons who were selected by random sampling.

Inclusion Criteria: being menopause, non-existence of skeletal diseases, Paralysis etc., nonuse of tranquilizer drugs, tobacco and alcohol, unaffected to liver, renal and digestive diseases, not having cancer history, nonuse of hormone therapy during recent 3 months and unaffected to hypertension.

Exclusion Criteria: Appearance of any type of disease resulting in sleep disorder, change in sleep condition (by journey, changing the place, using drug and additional materials), nonuse of Valerian for the continuous 7 days, nonperformance of relaxation and not having propensity to participate in the study.

At first, all three groups completed the informed consent form, demographic characteristic and sleep quality index of Petersburg (including 9 main questions) the validity and reliability of which have been evaluated in Iran with various studies (Malekzadegan A, Moradkhani M., 2010). Eight questions of sleep quality were scored as never=0 score, less than once a week=1 score, once or twice a week=2 scores and thrice or more a week=3 scores. The 9th question was considered as very good=0 score, comparatively good=1, comparatively bad=2 scores and very bad=3 scores. The total scores varied between zero to 21 and obtaining the score of 5 and more indicated sleep disorder. For the first experimental group, relaxation using Benson method was selected that two sessions of theoretical and scientific two hours classes along with presenting educational pamphlet were arranged. Thereafter, persons repeated the practices daily for 30.0 minutes for a period of 30.0 days at home. Valerian (the Sedamyn 530.0 mg, the product of Goldaro Company) and placebo capsule (containing 50.0 mg starch) were prescribed for the second and third group respectively and both groups consumed two capsules before going to bed for a period of one month.

The necessary trainings regarding the manner and time of consuming drug and performing relaxation practices were given to the persons of three groups. In continuation, in order to control the function of groups, monitoring was done every week via telephonic contact. The Petersburg questionnaire was recompleted by experimental and control groups one month after intervention. Collected data were then analyzed by statistical software of STATA, SPSS20 and descriptive statistic, t-test significant test, one way Variance analysis, suitable Post-hoc test and Pearson or Spearman correlation test at significant level of 0.05.

Results

The results showed that, under studied women did not have significant statistical difference with each other as far as age, marriage status and occupation were concerned ($P>0.05$) but from the view point of literacy, more educated persons were available in relaxation group that the difference was significant in this respect ($P=0.042$) (Table 1).

Also, from the view point of menstruation and menopause age, duration of marriage and midwifery history, no significant statistical difference was observed between under studied groups ($P>0.05$) and statistical difference was existed only in case of marriage age ($P<0.001$) (Table 2).

Comparing the score of sleep quality and its changes (before and after intervention) among Valerian and relaxation groups, the results indicated the improvement in sleep disorder ($P<0.001$) but such result was not observed among control group ($P>0.05$) (Tables 3 and 4).

Table 1: Frequency of demographic information the participants in the study groups

Variables		groups			Pvalue
		Relaxation	Valerian	Placebo	
Age		55.23±4.88	54.68±6.95	54.78±3.55	0.879
Marriage (married)		43(100)	43(97.7)	42(100)	1
Job	Housewife	37(86)	35(79.5)	37(88.1)	0.449
	Employee	6(14)	9(20.5)	5(11.9)	
Education	illiterate	4(9.3)	6(13.63)	8(19.04)	0.042
	Elementary	9(20.9)	16(36.39)	21(50)	
	Cycle	7(16.3)	6(13.63)	5(11.9)	
	Diploma	17(39.5)	10(22.72)	6(14.28)	
	Collegiate	6(13.95)	6(13.63)	2(4.74)	

Table 2: Frequency of obstetrics and gynecology history the participants in the study groups

Variables	Groups			P value
	Relaxation M±SD	Valerian M±SD	Placebo M±SD	
Mensutural age	13.44±1.45	13.97±1.57	13.38±1.44	0.129
Menopausal age	48.6±7.02	48.81±3.22	50.66±2.78	0.096
Marriage age	19.93±3.62	17.78±3.99	15.73±3.05	<0.001
Marriage duration	51.34±7.11	36.27±9.14	37.9±6.49	0.130
Gravida	3.86±1.76	4.57±2.22	4.57±1.48	0.136
Pariety	3.16±1.25	3.39±1.99	3.85±1.26	0.430
Abortion	0.69±1	0.61±0.86	0.71±0.86	0.811

Table 3: Comparison of the mean and standard deviation of sleep quality (before and after intervention) in the three groups

Groups	Relaxation	P-value	Valerian	P-value	Placebo	P-value	P-value
	M+/-SD		M+/-SD		M+/-SD		Intergroup
Before	13.02±2.07	<0.001	13.45±1.95	<0.001	13.73±2.02	0.261	0.261
After	7.83±2.86		8.13±2.77		13.69±2.07		<0.001

Table 4: Changes in sleep quality scores before and after intervention in the three groups

Changes in sleep quality scores	groups			P-value
	Relaxation	Valerian	Placebo	
before and after intervention	-5.19±2.85	-5.31±2.85	-0.04±2.18	<0.001

Discussion

The results of present study regarding demographic characteristic except in educational level and marriage age (P>0.05) in which there was difference between various groups (P<0.05), specified that, from the view point of other characteristic (Table 1 and 2) no statistical significant

difference was existed ($P>0.05$) and the similarity of groups caused the explanation of results to become possible. In this connection, some studies will be mentioned which obtained the similar results as our study.

Studied the influence of Valerian in order to treat sleep disorder among menopause women and reported that, persons had no statistical difference with each other based on age (Taavoni S ET AL.,2012; Diana M et-al.,2008). Also, in their studies reported the beginning age of menopause as 47-49 years (Rajaifard A, Mohamadbeigi A.,2012;Mortazavi Moghadam et al., 2001). Which has similarity with our results.

From the view point of mean age of beginning of menstruation, the results of researches in Iran and some other countries showed that, the mean age is between 12-14 years (Mohammad K, Zeraati H.,2003) that has similarity with our results. In connection with the distribution of educational level and occupation type also the results of our study is similar to that of Taavoni et-al (Taavoni et-al., 2012).

The results of present study regarding the influence of Valerian and relaxation on sleep disorder of menopause women were an indication of the reduction in sleep problem ($P<0.001$). In this respect, Farag NH and Miliis PJ (2003) in a double blind study evaluated the influence of two compound herbal tablets (Valerian, Pepper, Ginger, Liquorice, etc.) and Valeriana affinalis (Valerian 160 mg) on 20 women and 5 men (20-65 years old) with Insomnia. Applying the Petersburg questionnaire, the positive effect of Valerian as the reducer of mean score of sleep disorder was confirmed ($P=0.003$) and the drug had no any complication (Farag NH, Mills PJ., 2003). Also for 405 patients aging 18-75 years with Insomnia in the form of two interventional and control groups prescribed 3 Valerian tablets (3600 mg) and placebo respectively every night for a period of 14 days. Considerable improvement in the quality and sleep duration of individuals from experimental group was seen ($P=0.04$) and also no side effects were observed (Andrew D et-al.,2007). The results of this study were contrary to the results of our study from the view point of dose of drug and similar in connection with influence on sleep disorder.

There are also some studies with different results comparing with our study like the study in which 16 women with the mean age of 69 years with Insomnia were put in two experimental and control groups and prescribed 300 mg of Valerian root and placebo respectively for half an hour before going to bed. The results showed no significant difference between two groups from the view point of quality and sleep duration but the rate of awaking during sleeping reduced among experimental group ($P=0.02$) and no side effects were observed (Diana et-al.,2008).

Also, the studies on 270 patients (two groups) by daily consumption of 600.0 mg Valerian and placebo for a period of 8 weeks showed that, Valerian did not produce considerable improvement in sleep condition comparing with placebo (Jacobs BP et-al.,2005). The results of this study differ with the results of our study which may be due to the dose of medicine, intervention time and uncontrolled confounders.

In connection with the influence of relaxation, put 80 adult persons with Insomnia in two relaxation therapy and control groups. The influence of relaxation appeared after one year and even improved the Insomnia resulted problems like fatigue ($P=0.01$) (Lichstein L et-al.,2000). Also studied on 86 individuals of aging 16-88 years with chronic Insomnia and stated that, 87.0% of patients had considerable improvement after relaxation exercises (Morawetz D.,2003),and evaluated the daily function of 118 female and male students aging 17-44 years (57 persons with and 61 persons without sleep disorder) with relaxation therapy for a period of two weeks. The quality of sleep of individuals improved after intervention ($P<0.01$) but no significant difference was observed in their daily function (Melanie K et-al.,1999). The result of this study has similarity with the result of present study.

In a study carried out on 41 patients with Insomnia randomly in three therapeutic groups as 1-Acetazolame along with muscle relaxation, 2-Acetazolane along with mental imagination and 3- Acetazolane and sleep training and evaluated them 4 and 6 months after active treatment. The considerable improvement in sleep duration, awaking during sleeping and the time of going to sleep was observed (<0.001) but this result was more evident in group one. The quality of life of patients as well as their temper was also improved (Raymond et-al.,2000). The results of this study have similarity with our study. In the present study, the treatments were applied alone and the influence of each of them was judicious and explainable while the aforesaid study used geminate treatment and it is not specified that, which method (medicinal and non-medicinal) in each group is more effective.

Women experience numerous problems entering the menopausal period. Therefore, they need more attention to remove the complication which results from middle aged. Sleep disorder is among such problems that seeks noninvasive, cheap, simple, effective, and non-complicating treatments. On the other hand, reviewing and comparing the available studies is an indication of supporting non-medicinal methods especially herbal medicine in treatment of diseases that no complications have been reported. In this respect, the present study obtained acceptable result by prescribing Valerian capsule and applying relaxation for the treatment of sleep disorders which emphasizes on using non-medicinal accessible methods. It is worth mentioning that we did not observe any adverse side effects or events in our study group as a result of Valerian consumption or relaxation therapy. On the other hand, for controlling some invasive factors like dietary habits which are effective in creating Insomnia and supervising on the way of proper use of treatments, it is recommended to follow such studies among individuals living at olds house.

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