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Effect of oral saffron capsules on sleep quality in patients with diabetes at Zabol-Iran



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ABSTRACT

Introduction: People with diabetes have delayed sleep compared to ordinary people and do not have good sleep quality because of impaired glucose level. Saffron effect on insomnia in several studies on animals have checked, and beneficial results for it have observed.

Methods: This study was a quasi-experimental study aiming to determine the effect of oral saffron capsules on sleep quality in diabetic patients in the city of Zabol in 2016. This study conducted on 50 diabetic patients in Zabol city which were qualified for inclusion criteria for the study. The sleep quality of patients assessed with Pittsburgh Sleep Quality Index (PSQI). Then the intervention was done as a daily intake of one 300 mg capsule of saffron in the intervention

group and a placebo capsule in the control group, for a week, every day between hours 12 to 14 am and after taking lunch. After a week, sleep quality measured again.

Results: After the intervention, the comparison of the mean scores of two groups showed a significant difference ($P = 0.001$). Also, comparison of a total mean score of sleep quality in patients before and after intervention showed statistically significant difference in two groups ($p = 0.001$).

Conclusion: Results of this study showed that daily administration of saffron oral capsules improves sleep quality in diabetic patients. Saffron can use for improving sleep quality in diabetic patients along with other existing therapies.

Keywords: diabetes, saffron, sleep quality

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INTRODUCTION

Diabetes is one of the most prevalent diseases in human communities which, unfortunately, despite advances in medical science, its outbreak is not only not decreased but is increasing day by day.¹ Diabetes occurs due to relative or absolute lack of insulin or malfunctions in its functioning and it results in interference in the metabolism of carbohydrates, proteins, and fats.² Diabetes is the fourth death reason in the developed countries and it influences 6 percent of adult population.³ Diabetes is one of the greatest problems of global health, so that WHO calls it the silent epidemics. There are over 230 million people currently with diabetes worldwide, the meanwhile share of developing countries is more.⁴ Diabetes prevalence in the world is 1 to 2 percent and is estimated as 3 to 5 percent in Iran, and thousands of new cases annually added. 90 percent of current diabetic patients are patients with type II diabetes.⁵

Diabetes with complications such as retinopathy, nephropathy, and neuropathy, also creates several psychological and behavioral effects that widely affect patients' quality of life. This effect can be due to a change of diet, permanent dependence on medication, short or long-term complications of the disease and its related costs.⁶ Sleep is a

bio-dynamic and highly organized process which considered as an important part of life. The importance of sleep in health and disease from the time of Hippocrates has concerned, and disturbed sleep can consider as a major cause of suffering and sickness at any age.⁷ Sleep is one of the basic human needs to conserve energy, appearance, and well-being. In addition, sleep causes to reduce anxiety and stress and neural pressures.⁸ According to research works, indirect costs related to insomnia effects on a daily consciousness and behavior (accident and lack of efficiency) estimated as almost \$ 80 billion per year.⁹ Insomnia can have adverse effects on different aspects of human life, relationships with others, job and overall health of the patients and leads to depression, decreased immune function and heart disease.¹⁰ Diabetic people have a problem in night sleep due to disturbed glucose level, and over 80 percent of diabetic patients do not have good sleep quality.¹¹ People with diabetes have sleep duration less than normal amounts of sleep in the society.¹² Diabetes is a risk factor for drowsiness during the day and poor quality of sleep in patients.¹³ The prevalence of psychiatric disorders such as insomnia in diabetic patients is higher than normal individuals.¹⁴

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Drug treatment of sleep disorders must be considered as the last step because many of these sleep problems do not have aspects of the disease and consequences of medical treatment as well as their performance questioned.¹⁵ The use of synthetic drugs today is inevitable. Thus the scientists seek for effective drugs with fewer side effects in plant based medicine for the treatment of diseases. Given the rich history of traditional medicine in Iran, which stresses the use of medicinal plants in the treatment of diseases, extensive scientific research works are necessary to identify medicinal and pharmaceutical effects and consumption level of medicinal plants.¹⁶ Medicinal plants used as a replacement therapy which is useful regarding safety and tolerability.¹⁷ The medicinal plants have been considered today given fewer complications and attention of society to traditional medicine.¹⁸ Saffron plant with the scientific name *Crocus sativus* L., herbaceous, is a plant without stems, with 10 to 30 cm height, with hard bulbs, round, fleshy and covered with a thin and brown color membrane, and it is a resistant plant. The main compounds of saffron include crocin, picrocrocin, and Safranal. It is from Iridaceae family.^{19,20} Saffron is one of the medicinal plants which is known as the health flower, King of spices and red gold²¹ and its components play a preventive and medical role in diseases related to the nervous system, cardiovascular diseases, and gastrointestinal diseases.²² The saffron is used as an antispasmodic, sedative, helping digestion, carminative, diaphoretic, mucus stimulating, stimulating sexual desire, antispasmodic, increase in appetite, anti-depression, renal colic, anti-inflammatory, and pain reliever in traditional medicine.^{23,24} Saffron is also known as a powerful antioxidant.²⁵ The impact of saffron on the improvement of depression has identified in several studies.²³ Analgesic effects of saffron in various studies have confirmed.²¹ On the other hand, saffron effect on insomnia has been studied in animals, and beneficial results have been seen for it Hossein-Zadeh studied effect of saffron extract on mice, and it was found that saffron has positive effects on insomnia.¹²

The effect of saffron is similar to diazepam activity and like diazepam can be used as benzodiazepines, anxiolytic, analgesic, relaxant and hypnotic agent.¹⁸ Considering absence of a study for measuring saffron effect on sleep disorders in human subjects with diabetes as well as the prevalence of sleep disorders in diabetic patients, the current study was carried out to determine the effect of oral saffron capsules on sleep quality in diabetic patients in city of Zabol in 2016.

MATERIALS AND METHODS

Research Subject and Design

This study is a quasi-experimental study that aimed to assess the effect of oral saffron capsules on sleep quality in patients with diabetes conducted in the city of Zabol. The sample size was specified as 50 using Cochran formula and coefficient of confidence as 95 percent and accuracy as 0.07. Then, among patients qualified for research inclusion according to inclusion criteria, 25 ones were randomly assigned to the case and 25 ones in control group. Research inclusion criteria included the possibility of taking the drug orally, lack of cognitive impairment, tendency to participate in the study, aged 60-20 years, passing at least one year after diagnosis of diabetes, being literate and non-use of drugs or medicines that are influential in sleep quality.

Research Tool and Data Collection

Research tool included the demographic characteristics form and Pittsburgh Sleep Quality Index for investigating sleep quality in diabetic patients. Demographic characteristics form included such cases as age, gender, duration of suffering from diabetes, marital status, etc. Pittsburgh Sleep Quality Index measures such cases as sleep quality (as subjective and by the intended patient), the amount of night sleep and adequacy of sleep in the view of the individual according to 4-point Likert scale (no, once a week, twice a week, three times a week). It also investigates delays in getting to sleep more than 30 minutes, using sleeping pills to fall asleep, waking at night due to frequent urination, shortness of breath, feeling cold and heat, and waking due to pain in any of the subjects. The questionnaire has 19 items and 7 subscales. A score of each sub-scale varies between zero to three and score 3 in each of them, specifies the maximum sleep disorder in that part. Also, the overall score of this questionnaire is between zero to 21, and the total score of 5 or more indicates poor quality of sleep.

10 faculty members confirmed the validity of the demographic characteristics form in nursing and midwifery school of Zabol, and their corrective views were applied. The form's reliability was confirmed using retest method on 10 patients. Validity and reliability of Pittsburgh index were confirmed in the study by Hemmati,¹² and its reliability has been confirmed with a sensitivity of 89.6% and specificity of 86.5%. Reliability of Pittsburgh index was calculated in the study by Ebrahimi using halving method, and the Cronbach's alpha coefficient was obtained as 0.79.⁷

After obtaining permission from Ethics Committee of the Medical University of Zabol and the referral letter of the School of Nursing and Midwifery of Zabol and delivering it to the authorities of research environment, and following coordination with the authorities of Zabol Center for Special Diseases (diabetes center) to collect data, the research place was visited. The necessary clarifications about the research objectives were given to the selected individuals, for 10 minutes as face to face manner by the researcher, and written informed consent for participation in the research was taken, and the demographic characteristics form was filed using interviews with patients and reviewing their files. Firstly, the sleep quality before the intervention was measured using research tool. Then the patients in the intervention group were asked to take daily one oral saffron capsule containing 300 mg of saffron powder prepared in the School of Pharmacy, during the one-week day between hours 12 – 14 pm and after lunch.²¹ Placebo capsules also used in control group for one week. During one week, the author sent an SMS to the research subjects every day to remind intervention to patients. After one week, the researcher again went to the Zabol Center for Special Diseases and gave sleep quality measurement questionnaire to the patients to fill. It should note that the patients trained on the foods and practices which affect their sleep quality and they were asked to avoid consuming these materials and these activities during one week. The patients who did not meet these conditions and the have willingness to continue to cooperate in the study were excluded from the study and replaced by someone else.

Statistical Analysis

Data collected were analyzed using descriptive and inferential statistic methods and SPSS software version 22.

RESULT

The demographic characteristics revealed that 28 patients (56%) of the subjects were male and 22 (44%) were female. Age distribution was between 38 and 60 years. 48 patients (96%) of the subjects were married, and only 2 patients (4%) were single. Also, investigation of educational level showed that 13 patients (26%) had a high school diploma or below, 9 patients (18%) had an associate degree, 13 patients (26%) were undergraduate, and 15 patients (30%) had MA degree or higher. The mean duration of diabetes for every individual was 6 years.

Based on the data in [Table 1](#), mean score of sub-scales related to sleep quality in both case and

control groups showed impairments in this aspect of sleep quality. In a comparison of the mean score of mentioned sub-scales, No significant statistical difference was found using t statistical test ($p > 0.05$). But mean scores of each of subscales after intervention showed that patients in case group gained more optimal status in all aspects related to sleep quality, while control group patients had disorders in these sub-scales yet. Also after the intervention, comparison of the mean score of these scales in case and control group using t statistical test showed statistically significant difference ($p < 0.05$) ([Table 1](#)).

Also, data in [Table 1](#) indicates that before the intervention, a total score of sleep quality in case and control group was 7.46 and 7.01, respectively, which denotes disturbance in sleep quality of patients in both groups. On the other hand, comparison of a mean overall score of sleep quality in both groups did not show the significant statistical difference ($p = 0.17$). After the intervention, mean total score of sleep quality in case and control group was 4.91 and 7.41, respectively. This finding indicates that patients in control group had still disturbed sleep quality, while patients in case group experienced optimal sleep quality. Comparison of a mean total score of sleep quality of patients in case and control groups showed the significant statistical difference ($p = 0.001$) ([Table 1](#)).

The mean score of sleep quality in all subscales of Pittsburgh Sleep Quality Index and the mean score of sleep quality of patients before and after intervention in case and control groups compared using t-test ([Table 2](#)).

The results of this test showed that in all subscales of Sleep Quality Index, a significant difference exists before and after the intervention in case group ([Table 2](#)). Total score of sleep quality of patients before the intervention in case group was 7.46, and after intervention in this group it was 4.91, and their comparison showed a statistically significant difference ($p = 0.001$).

Comparing mean score of sleep quality of patients in the control group in all subscales of sleep quality index showed no significant difference before and after the intervention ([Table 2](#)). In control group, a total score of sleep quality of patients before the intervention was 7.01, and after the intervention, it was 7.41 and comparison of these means showed no statistically significant difference ($p = 0.72$).

Overall research results indicate an improvement of sleep quality in patients in case group after intervention compared to before intervention, and it supports an effect of the oral saffron capsule on the improvement of sleep quality in diabetic patients.

Table 1 Comparison of sleep quality and its subscales in case and control groups

Variable		Before Intervention		Before Intervention	
		(SD ± mean)	p-value	(SD ± mean)	p-value
Sleep subjective quality in the view of person	Case	0.63±1.12	0.52	0.81±0.07	0.03
	Control	0.44±1.099		0.52±1.02	
Delay in getting sleep	Case	1.02±2.06	0.09	0.92±1.17	0.04
	Control	0.09±2.02		0.72±1.98	
Duration of sleep	Case	0.74±2.49	0.83	0.22±1.24	0.001
	Control	0.68±2.39		0.18±2.01	
Sleep efficiency	Case	0.32±1.28	0.13	0.09±0.63	0.001
	Control	0.11±1.31		0.03±1.11	
Hypnotic drug use	Case	0.52±0.16	0.38	0.81±0.12	0.01
	Control	0.48±0.18		0.41±0.20	
Sleep disorder	Case	0.12±1.01	0.21	0.02±0.51	0.02
	Control	0.03±0.91		0.38±0.88	
Morning performance	Case	0.87±0.99	0.07	0.01±0.84	0.04
	Control	0.54±1.10		0.51±1.13	
Total Score of sleep quality	Case	3.32±7.64	0.17	2.02±4.91	0.001
	Control	3.92±7.01		3.39±7.41	

Table 2 Comparison of mean scores of sleep quality and its sub-scales before and after intervention in case and control group

Variable	Group	Before Intervention		After Intervention	
		(SD ± mean)	p-Value	(SD ± mean)	p-Value
Sleep subjective quality in the view of person	Case	0.63±1.12	0.12	0.81±0.07	0.02
	Control	0.44±1.099		0.52±1.02	
Delay in getting sleep	Case	1.02±2.06	0.07	0.92±1.17	0.04
	Control	0.09±2.02		0.72±1.98	
Duration of sleep	Case	0.74±2.49	0.11	0.22±1.24	0.01
	Control	0.68±2.39		0.18±2.01	
Sleep efficiency	Case	0.32±1.28	0.97	0.09±0.63	0.03
	Control	0.11±1.31		0.03±1.11	
Hypnotic drug use	Case	0.52±0.16	0.06	0.81±0.12	0.04
	Control	0.48±0.18		0.41±0.20	
Sleep disorder	Case	0.12±1.01	0.67	0.02±0.51	0.001
	Control	0.03±0.91		0.38±0.88	
Morning performance	Case	0.87±0.99	0.17	0.01±0.84	0.02
	Control	0.54±1.10		0.51±1.13	
Total Score of sleep quality	Case	3.32±7.64	0.72	2.02±4.91	0.001
	Control	3.92±7.01		3.39±7.41	

DISCUSSION

The current study conducted aiming at investigating the effect of oral saffron capsules on sleep quality in patients with diabetes in the city of Zabol. In this study, the sleep quality between the two groups after and before the intervention was compared using a t-test, and it found that significant differences exist

in sleep quality in patients in both groups after intervention ($P = 0.001$). Comparison of a total mean score of sleep quality of patients in the case group before and after intervention showed a significant difference ($p = 0.001$), and the results of this study showed that administration of oral capsules

of saffron, 300 mg daily for a week, improves sleep quality in patients with diabetes.

Extensive literature searches showed that there are no adequate studies with the subject of the effect of saffron capsules or other products of it on sleep quality in patients with diabetes. Most studies on the impact of saffron have been made on animals. Thus, it is necessary to carry out more studies on human subjects.

Hossein-Zadeh et al. conducted a study to determine the effects of the saffron extract on insomnia in rats using kit test and swim test, and it was found that the extract may reduce insomnia in rats and improve the quality of sleep.¹² Also, Azhari et al. concluded that saffron, like diazepam, has sedative and relaxant and hypnotic effects and leads to improved treatment of insomnia and increased satisfaction with sleep in patients.¹⁴ The results of the two research study are consistent with the current work.

Insomnia and poor sleep quality are among the factors that are closely related to pain, and the pain is among the factors that lead to insomnia and poor sleep in patients.³² According to this, it can be concluded that the patients' pain relief is an important factor for improving sleep quality in them. The analgesic effect of saffron has been identified in various studies by Izadi et al., Khodakarami et al., and Memarbashi et al.²¹ The results of these studies indicate that saffron-mediated analgesic effects and its effects on pain reduction in patients lead to improved sleep quality in them. Probably the reason for these effects of saffron is to its strong antioxidant activity and anti-inflammatory activity and reduction in its biochemical signs.²¹ Thus, it can be concluded that results of three studies are consistent with this study.

Taavoni et al. in their study found that 33 mg of saffron, as part of the Aphrodit capsule, with 27 mg ginger and 11 mg of cinnamon and 40 mg of the Tribulus Terrestris fruit reduce sleep problems in postmenopausal women including difficulty in falling asleep, difficulty in sleeping and getting up early.⁵ Findings of this study indicate that saffron leads to improvement of sleep quality in postmenopausal women, which is consistent with findings in the current study.

Saffron effects on sleep quality in patients with diabetics are probably due to the crocin and Safranal in it. Crocins as a compound soluble in water and Safranal as a fat-soluble operate by two different mechanisms, and possibly crocins is effective on the dopaminergic system and inhibiting reuptake of norepinephrine and Safranal is effective on the serotonergic system and the effect of saffron is like the activity of diazepam and the like diazepam, it

acts as a benzodiazepine, sedative, analgesic and hypnotic agent.¹⁹

CONCLUSION

According to other proven and useful effects of saffron in the treatment and prevention of many diseases and relieving many of the symptoms,^{5,12} saffron can use for relieving and preventing many complications and other disorders. Also, according to the results of this study and confirmed impact of saffron oral capsule on improving sleep quality in patients with diabetes and high prevalence of sleep disorders in patients with diabetes^{12,13,18,19} and the need to find solutions to improve this disorder, the saffron can be used as a very useful adjuvant therapy for improving sleep quality in patients with diabetes, along with other therapy.

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