# **Original Article**



Website: www.jehp.net

10.4103/jehp.jehp\_243\_22

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> Received: 13-02-2022 Accepted: 04-04-2022

Published: 28-12-2022

# The effect of auriculotherapy on improving sleep quality in postmenopausal women aged 45-60 years: A clinical trial study

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#### **Abstract:**

BACKGROUND: Menopause is one of the developmental stages of women. One of the most common problems during this period is sleep disorders. Sleep disorders can affect the quality of life of these people. To improve sleep disorders, auriculotherapy has received less attention due to its low cost and effectiveness, and side effects. Therefore, the aim of this study was to determine the effect of auriculotherapy on improving sleep quality in postmenopausal women aged 45-60 years.

MATERIALS AND METHODS: The present study is a clinical trial study that was performed on 82 postmenopausal women aged 45-60 years under the auspices of health centers in Mahshahr city, Iran from 2021-2022. Women with inclusion criteria were randomly divided into two groups (intervention and control). The intervention group underwent auriculotherapy for 4 weeks. The St. Petersburg Sleep Quality Questionnaire was completed by both groups at the beginning and 4 weeks after the start of the intervention. Finally, the data were analyzed by SPSS software version 22 and independent t-test, paired t-test and Chi-square test.

**RESULTS:** At the beginning of the study, both groups were homogeneous in terms of demographic variables. The results of data analysis using independent t-test showed that before the intervention, mental quality (P = 0.513), length of incubation period (P = 0.285), sleep duration (P = 0.121), sleep efficiency (P=0.513), sleep disorders (P=0.685), use of sleeping pills (P=0.530), daily functioning (P=0.60), and overall sleep quality score (P = 0.30) in the control and intervention groups were not statistically significant. However, comparing the mean scores after the intervention in the control and intervention groups showed that mental quality (P < 0.001), incubation period (P < 0.001), sleep duration (P < 0.001), sleep efficiency (P < 0.001), sleep disorders (P < 0.001), use of hypnotics (P = 0.002), daily functioning (P = 0.001), overall sleep quality score (P < 0.001), sleep duration (P = 0.822), sleep efficiency (P = 0.889), sleep disorders (P = 0.889), use of sleeping pills (P = 1.00), daily performance (P = 0.767), overall sleep quality score (P = 0.69) were statistically significant between the two groups. In-group comparison using paired t-test in the control group showed that mental quality (P = 0128), length of the incubation period (P = 1.00), and before and after the intervention did not differ significantly in the mean scores. However, a within-group comparison in the intervention group showed that mental quality (P < 0.001), incubation period (P < 0.001), sleep duration (P < 0.001), sleep efficiency (P < 0.001), sleep disorders (P = 0.003), use of sleeping pills (P = 0.007), daily functioning (P < 0.001), and overall sleep quality score (P < 0.001) before and after the intervention had a significant difference in the mean scores.

CONCLUSION: The results showed that auriculotherapy has significant effectiveness in improving the quality of sleep, and its dimensions and can be used as an effective method in this area that can be implemented at a low cost and easily. According to reports from participants and previous studies in this field, auriculotherapy did not have any side effects and can be used as a safe way to improve sleep quality.

Auriculotherapy, ear acupressure, menopausal women, postmenopause, sleep quality

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How to cite this article: Eidani M, Montazeri S, Mousavi P, Haghighizadeh MH, Valiani M. The effect of auriculotherapy on improving sleep quality in postmenopausal women aged 45-60 years: A clinical trial study. J Edu Health Promot 2022;11:422.

# Introduction

In recent decades, due to advances in medical science Land increasing life expectancy worldwide, countless women are entering menopause. In the 17th century, however, only 28% of women reached menopause. The population of postmenopausal women is projected to reach 1.2 billion by 2030, with an annual increase of 47 million new cases per year.[1] Menopause is a physiological phenomenon caused by the decreased ovarian function that occurs after menopause in women.[2-4] Menopause is one of the developmental stages of women that all of them experience with age and this phenomenon exposes women to wide changes. [5] Due to decreased levels of body hormones during menopause, women experience many changes including hot flashes, night sweats, palpitations, headaches, dizziness, fatigue, and irritability. Among these, one of the most common problems is sleep disorders.<sup>[1]</sup> With estrogen deficiency in the postmenopausal period, the hormone serotonin, which is one of the important factors in causing sleep, decreases. [6] Sleep is the resting time of the brain and body, during which consciousness is relatively reduced. The phenomenon of sleep frees a person from stress and responsibilities. It also rejuvenates the mind and body. Although it is not clear exactly how sleep can be beneficial to the body, sleep has always been mentioned as one of the most basic human needs. [7] Sleep disorders in postmenopausal women may be chronic or temporary and are more likely to be difficult to fall asleep, with frequent awakenings during the night, and difficulty falling asleep again and waking up early. [8] Sleep is essential for physical and mental health in such a way that if a person is deprived of sleep, she/he becomes irritable.[9-12] Menopausal sleep disorders do not necessarily reduce the amount of sleep, but they do affect the quality of sleep. Many women experience sleep problems during menopause more than during periods, and 61% of women report insomnia symptoms such as frequent waking, falling asleep late, and staying in bed for more than half an hour after menopause. [13] Also, as women get older, their sleep becomes lighter, and hot flashes and night sweats exacerbate these problems. Magnesium, which promotes muscle relaxation and night sweats, lowers estrogen levels, and low estrogen lowers serotonin levels, which in turn reduce the amount of melatonin that is essential for sleep.[14] Medical treatments used for sleep problems include hormone therapy and the use of sedatives. [1,15] Hormone therapy, which is one of the treatments for menopausal sleep disorders, eliminates menopausal hot flashes within 2 weeks and improves sleep patterns. [16] However, it increasingly increases complications such as breast cancer, blood clots, stroke, and heart disease. [17] Sedatives and hypnotics are also considered treatment options and cause harmful side effects such as aggravation of sleep

disorders, drowsiness, dry mouth, and constipation in middle-aged and elderly people.[18] In contrast, a variety of complementary therapies, including music therapy, touch therapy, aromatherapy, relaxation, yoga, acupuncture, and herbs, have been offered to treat postmenopausal women's sleep problems that are less expensive, have no side effects, or have a few side effects. [1] Among the available treatments, acupuncture has been considered to treat insomnia. Acupuncture has been used in the treatment of various physical and mental diseases including migraine headaches, anxiety, and depression, and has been effective. [19,20] Auriculotherapy is a branch of acupuncture and a branch of reflexology that eliminates the disease by applying pressure to different parts of the ear with a needle, electric current, laser, heat, and sieve. Auriculotherapy is a safe and non-invasive method that seeks to diagnose and treat diseases to maintain health in different parts of the body following stimulation of the orifice or outer ear<sup>[21]</sup>. Accordingly, each anatomical unit of the body has a point of reflection on the surface of the ear in each of the body organs. [22] The ears are the closest and most sensitive organs to the brain due to the rapid transmission of stimuli, which are directly or indirectly connected to the 12 meridians. Thus, the conditions and changes that occur in the body of individuals and their physiological systems. It can appear as normal and abnormal shapes in parts of the ear. Acupuncture uses these points on the ear, which are also easy to access and improve the condition of the body by pressing the points. [23] Numerous studies have been conducted on the effectiveness of acupuncture or auricular therapy on sleep disorders, which in some cases has been associated with good effects on sleep quality, sleep delay, sleep duration, sleep function, and daily dysfunction.[24-28] Numerous mechanisms have been proposed to justify the effects of acupuncture on sleep status, including increased gamma-aminobutyric acid secretion and subsequent inhibition of central nervous system overexpression after acupuncture treatment. The effect of increasing melatonin secretion improves sleep duration and quality.[29]

In this regard, the results of Chueh's study reported an improvement in sleep quality after auriculotherapy. [30] Suen *et al.* [31] also showed that auriculotherapy improves sleep quality and sleep disorders. However, the results of the study of Salles *et al.* [32] (2017) showed that auriculotherapy has no effect on sleep quality. Avis *et al.* [33] also reported in their study that auriculotherapy had no effect on sleep quality. Due to the current trend of increasing the elderly population and consequently the increase in the population of postmenopausal women, the health of this group of people has a special place in health services. One of the most common menopausal disorders is sleep disorders, which reduce the quality of life and increase the dysfunction of women. Hormone

therapy is not accepted by these women and its use has many side effects; also, repeated use of sleeping pills leads to drug dependence. As a result, considering that auriculotherapy is a non-invasive and low-complication method and the results of studies in this field are contradictory, the aim of this study was to determine the effect of auriculotherapy on improving the sleep quality in postmenopausal women aged 45–60 years.

## **Materials and Methods**

# Study design and setting

The present study was a single-blind clinical trial study that was performed on postmenopausal women aged 45–60 years under the auspices of Mahshahr health centers (Health No. 3, Qudusi 1 and 2, and Azadegan alley) from 2021 to 2022.

# Study participants and sampling

Inclusion criteria were conscious written consent to participate in the study, women aged 45–60 years, no menstruation for at least 12 months, get a score of 5 or higher from the Pittsburgh Sleep Quality Tool, and organ health in the earlobe area. Exclusion criteria were having known underlying diseases (heart, kidney, thyroid, blood pressure, diabetes, etc.), the emergence of any physical or mental illness during the research, use of hormone therapy, aromatase inhibitors, clonidine, and antidepressants during the last 3 months and during the study, use of alcohol and addictive drugs, severe uterine bleeding, loss of a relative in the last 6 months and during the study, using other traditional therapies and complementary medicine in the last 4 weeks and during the study, lack of access to samples in the follow-up stages (migration, etc.), withdrawal from continuing cooperation during the study, failure to comply with the criteria regarding the number of times and duration of pressure on the sides during the week of intervention (every hour for 1 min except sleep time), glue allergy (allergy, redness, etc.), COVID-19 infection (due to pandemic conditions).

The sample size, considering the variable of sleep quality based on the study of Ozgoli *et al.*<sup>[34]</sup> considering the power of 95%, and 95% confidence, using the following formula and taking into account the 20% probability of sample loss, was estimated as 41 people in each group.

$$n = \frac{\left(Z_{1-\frac{\alpha}{2}} + Z_{1-\beta}\right)^2 (S_1^2 + S_2^2)}{(\overline{X_1} - \overline{X_2})^2}$$

#### Data collection tool and technique

The data collection tool in this study was questionnaires that included demographic characteristics questionnaire and a sleep disorder questionnaire. The demographic information questionnaire included age, weight, level of education, employment status, economic status and marital status, place of residence, having children, insurance coverage, and type of insurance coverage.

The Pittsburg Sleep Quality Index (PSQL) is a 19-item questionnaire that assesses a person's sleep quality based on their sleep status over a 1-month period. [35] This questionnaire has seven areas that are subjective sleep quality, sleep latency, sleep duration, sleep efficiency, sleep disturbances, use of sleep medications, and daytime dysfunction. The validity and reliability of this questionnaire have been confirmed in internal studies. [36,37]

This study was performed after approval by the Research Ethics Committee of Ahvaz University of Medical Sciences with the code IR.AJUMS.REC.1399.230 and registration in the National Experimental System of Iran with the code IRCT20200613047756N1. To conduct the research, first, an official letter of introduction from Ahvaz Jundishapur University of Medical Sciences was submitted to Mahshahr Health Center. Then, health centers (Health No. 3, Qudusi 1 and 2, and Azadegan alley) were randomly selected by the director of the health center. Menopausal women in the age range of 45–60 years were extracted through the apple system. After making a general explanation about the study, they were asked about the inclusion criteria and their willingness to participate in the study. The Pittsburgh Sleep Quality Questionnaire for 230 people was completed by telephone through a researcher interview with 148 people who obtained the word criteria for the study (Pittsburgh Sleep Quality Score above 5). Due to the COVID-19 pandemic conditions, 12 eligible individuals were contacted by telephone daily and participants were asked to attend the health center at various intervals whenever possible. Then, by observing the hygienic protocols of the interview, the researcher was instructed about the goals and method of conducting the research, basic information, how to take care of the sides, and the possibility of being in one of the intervention and control groups, and the sleep quality questionnaire was completed. Out of 148 eligible people, 107 were excluded due to unwillingness to participate in the study. Finally, 82 people consented to participate in the study, written informed consent was obtained from the participants and a demographic questionnaire (including age, weight, level of education, employment status, economic status, and marital status) was completed. After obtaining consent to participate in the study, the samples were randomly assigned in block form in the form of quadruple blocks in two groups intervention and control. The researcher had passed the introductory course of

Auriculotherapy (theory-practice) under the supervision of an auricle therapist. After learning the general theory of method and point-finding using a map of points on the ear, using a point-finding device, the points related to both intervention and control groups were identified. Finally, the correctness of the pointing done by him was confirmed by the instructor. According to the corona pandemic conditions, the intervention was performed by observing health protocols, maintaining social distance, providing a mask at each visit, and disinfecting the research site. To perform the intervention, the patient was placed in a semi-sitting position. In the intervention and control groups, auriculotherapy was performed once every 6 days for 4 weeks. Before the intervention, the right ear was sterilized with 75% alcohol. After the alcohol had dried, the researcher used a Hong Kong-made EXCEL2 POINTER point detector to stimulate the main points of the sleep protocol (includes master cerebral, Shenmen insomnia 1, insomnia2, lung1, lung2, and thalamic) for 15 s (15 s each) [Figure 1]. Grain or Vakaria plant labels were then affixed to each of the stimulated sites by the researcher. There were no restrictions on personal matters such as bathing. The patient was also instructed in what group he or she was in without being aware of the fact that, according to the schedule, the siders applied gentle pressure for 1 min every hour during the day, with the exception of bedtime. To be more effective, it was recommended to sleep on the right side. [38] To blind the specimens in the control group, the auriculotherapy method was used with similar instructions, but on false points (including master cerebral and fingers) behind the ear and using seeds without beads [Figure 2]. At the end of each session, warning signs were given, including sensitivity to the adhesive (inflammation, edema, redness, etc.), headache, dizziness, any intolerance, and exposure to severe stress. Participants could contact the researcher if they had any of the warning signs. In the event of sepsis separation during the 6-day period, participants were notified to the researcher by telephone, and, with the patient's consent at the health center, the seizures were reattached. Participants who regularly pressed the sidewalls for 1 min every hour and visited regularly for 4 consecutive weeks remained in the study. During the intervention, participants visited the health center once a week (every 6 days) with the prior notice of the researcher, and the previous slices were removed using forceps, and the eardrum was examined for any inflammation, sores, or edema. If there is no problem, the earlobe was sterilized with 75% alcohol and after drying, the desired points were stimulated again with the device and new sutures were attached to them. The Pittsburgh Sleep Quality Questionnaire was completed by the researcher through a telephone interview before the start of the study and 4 weeks after the end of the intervention for both groups. The study steps are shown

in Figure 3. Finally, the collected data were analyzed by SPSS software version 22 and descriptive and analytical statistical tests.

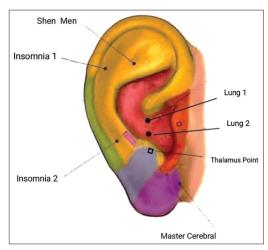


Figure 1: Stimulated points in the intervention group

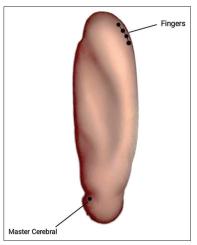


Figure 2: Stimulated points in the control group

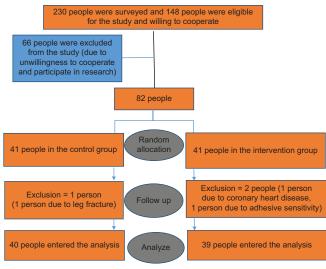


Figure 3: Study diagram

#### **Ethical consideration**

This study was conducted after obtaining permission and a letter of introduction from the Vice Chancellor for Research of Ahvaz University and School of Nursing and Midwifery and with the consent of the Ethics Committee (code: IR.AJUMS.REC.1399.230) in the research of Ahvaz University of Medical Sciences. This project was registered in the National Experimental System of Iran with the code IRCT20200613047756N1.

The objectives of the research were explained for each of the research units and informed written consent was obtained from them. Research units were reassured about the protection of their private and personal information. No additional costs were imposed on participants.

#### Results

The results of data analysis showed that the mean age of participants in the control group was  $54.33 \pm 4.11$  years and in the intervention group was  $54.77 \pm 3.82$  years. The majority of participants in the control group (79.5%) and the intervention group (85%) were married. Most of the participants had primary education and were housewives. A comparison of the mean and percentage of demographic variables between control and intervention groups using an independent t-test and Chi-square test did not show a statistically significant difference (P < 0.05).

In accordance with the findings presented in Table 1, the results of data analysis using independent t-test showed that before the intervention, mental quality (P = 0.513), length of incubation period (P = 0.285), sleep duration (P = 0.121), sleep efficiency (P = 0.513), sleep disorders (P = 0.685), use of sleeping pills (P = 0.530), daily functioning (P = 0.60), overall sleep quality score (P = 0.30) in the control and intervention groups were not statistically significant. But comparing the mean scores after the intervention in the control and intervention groups showed that mental quality (P < 0.001), incubation period (P < 0.001), sleep duration (P < 0.001), sleep efficiency (P < 0.001), sleep disorders (P < 0.001), use of hypnotics (P = 0.002), daily functioning (P = 0.001), overall sleep quality score (P < 0.001), sleep duration (P = 0.822), sleep efficiency (P = 0.889), sleep disorders (P = 0.889), use of sleeping pills (P = 1.00), daily performance (P = 0.767), overall sleep quality score (P = 0.69) were statistically significant between the two groups. In-group comparison using paired t-test in the control group showed that mental quality (P = 0128), length of the incubation period (P = 1.00), and before and after the intervention did not differ significantly in the mean scores. But within-group comparison in the intervention group showed that mental quality (P < 0.001), incubation period (P < 0.001), sleep duration (P < 0.001), sleep

Table 1: Comparison of average sleep quality scores and their dimensions before and after the intervention between the control and intervention groups

between the control and	-	intervention groups	
	Control group	Intervention group	<i>P</i> , intergroup
Subjective sleep quality	group	group	intergroup
Before intervention	0/84±2/23	0/76±2/35	0/513
After the intervention	0/64±2/23 0/75±2/05	0/76±2/35 0/80±0/625	<0/0001
P interagroup	0/128	<0/001	<0/000 I
0 1	0/120	<0/0001	
Sleep latency Before intervention	0/49±2/74	0/67 - 0/60	0/285
After the intervention	0/49±2/74 0/49±2/74	0/67±2/60	<0/0001
	0/49±2/74 1/00	0/76±1/22	<0/0001
P interagroup	1/00	<0/0001	
Sleep duration	0/00 0/50	0/47 0/77	0/404
Before intervention	0/82±2/53	0/47±2/77	0/121
After the intervention	1/04±1/38	0/31±0/05	<0/0001
P interagroup	0/822	<0/0001	
Sleep efficiency			0/= 4.0
Before intervention	1/01±1/41	1/17±1/57	0/513
After the intervention	1/04±1/38	0/31±0/05	<0/0001
P interagroup	0/889	<0/0001	
Sleep disturbances			
Before intervention	0/50±2/10	0/50±1/89	0/685
After the intervention	1/04±1/38	0/57±1/32	<0/0001
P interagroup	0/889	0/003	
Use of sleep medications			
Before intervention	1/23±0/71	1/13±0/55	0/530
After the intervention	1/25±0/71	0/31±0/50	0/002
P interagroup	1/00	0/007	
Day time dysfunction			
Before intervention	0/55±0/28	0/97±0/62	0/60
After the intervention	0/56±0/30	00/00±0/0	0/001
P interagroup	0/767	<0/0001	
Overall score of sleep quality			
Before intervention	2/51±12/02	2/58±12/62	30/0
After the intervention	2/49±11/61	2/38±4/60	<0/0001
P interagroup	0/69	<0/0001	

efficiency (P < 0.001), sleep disorders (P = 0.003), use of sleeping pills (P = 0.007), daily functioning (P < 0.001), overall sleep quality score (P < 0.001) before and after the intervention had a significant difference in the mean scores.

# Discussion

The results of this study showed that at the beginning of the study, the two groups of control and intervention did not have significant changes in terms of the overall score of sleep quality and its dimensions. However, after the intervention, the intervention group showed significant changes. Also, changes within the group in the intervention group showed significant changes in the overall score of sleep quality and its dimensions. But in the control group, the changes were not significant. In this regard, the results of a study by Arai *et al.*<sup>[39]</sup> (2013) showed that 4 weeks of use of ear acupressure, which exerts pressure on the Shenmen point, improves sleep

quality, anxiety, and depressed mood in students with sleep disorders. The results of a study by Lan et al.[40] (2015) also showed that acupressure increased total sleep time, increased sleep efficiency, lowered scores for sleep disorders, reduced sleep latency, and reduced the number of awakenings compared with placebo or sham interventions. A systematic review study by Ren et al.[41] (2015) showed that auriculotherapy could be an effective method to improve primary insomnia. The results of the study of Pourmohammadi et al.[42] (2021) also showed that auriculotherapy is effective in improving the sleep quality of the elderly with chronic low back pain. In addition, the results of the study of Garner et al. (2018), Yeh et al. (2016), Suen et al. (2017), Wu et al. (2014), and Wang et al. (2021) confirmed the results of the present study.<sup>[43-47]</sup> In other words, in confirming the results, it can be stated that auriculotherapy is based on the idea that the outer ear has a somatotropin pattern with an inverted embryonic pattern, and that each part of the ear corresponds to a specific part of the human body or organ, by stimulating specific points in a particular ear, can have detrimental effects on sleep disorders and improve the sleep quality by rebalancing the central nervous system and reducing various pathological conditions.[48] According to studies, acupressure may improve sleep disorders by lowering the level of inflammatory cytokines in the blood and improving the inflammatory status.[49] Another study suggests that acupressure may improve sleep quality by increasing changes in the heart rate as well as lowering blood pressure and heart rate. [50] One study reported that stimulation of microcurrents at the Shenmen acupuncture point could enhance EEG changes associated with drowsiness and positive mood. [51] Another study showed that acupuncture can significantly increase the secretion of endogenous melatonin at night, which may be one of the mechanisms to improve sleep quality. To this end, future research should focus more on objective measurements of sleep quality to further reveal the possible mechanism of acupressure in improving sleep disorders.<sup>[52]</sup> Complementary and alternative therapies have been accepted by an increasing number of people suffering from sleep disorders due to certain benefits such as comfort, cheapness, and fewer side effects. As a result, this treatment can be used as a complementary and alternative treatment in clinics.

However, a number of studies have reported conflicting results with the results of the present study. A study by Yeh *et al.*<sup>[53]</sup> (2016) reported that auriculotherapy had no effect on sleep quality. In addition, in the study of Salles *et al.* on people with chronic diseases, auriculotherapy could not improve the mental quality of sleep. <sup>[32]</sup> It should be noted that the reported results of Chung *et al.*'s<sup>[54]</sup> study also showed that auriculotherapy has no effect on sleep quality. In explaining the observed

differences between the results in the present study with the mentioned studies, we can point to the differences in the points of stimulation, time and frequency of stimulation, as well as demographic differences between different studies. The present study investigated the effect of adjuvant auriculotherapy treatment on improving the sleep quality of postmenopausal women, which showed the positive effect of auriculotherapy on the sleep quality of postmenopausal women. One of the strengths of the study was the improvement of sleep disorder in the intervention group, which was reported by the participants several months after the end of the intervention. It is also economically viable and avoids imposing an additional financial burden on the health system and does not have the side effects of some sleeping pills.

# Limitations and recommndation

This study also faced limitations. Because the process of sampling, intervention, and final evaluation is performed by the researcher, the lack of blindness can be considered one of the most prominent limitations. Other limitations of this study include excluding samples with chronic diseases. For this purpose, it is recommended that this study be performed by blinding the researcher to greatly reduce the possibility of bias. In contrast, it is recommended that this study be performed on different groups of postmenopausal women with diseases and other underlying problems to increase the generalizability of the results.

## Conclusion

The results showed that auriculotherapy has significant effectiveness in improving the quality of sleep and its dimensions and can be used as an effective method in this area that can be implemented at a low cost and easily. According to reports from participants and previous studies in this field, auriculotherapy did not have any side effects and can be used as a safe way to improve sleep quality.

# Acknowledgments

The present study is the results of the master's thesis in midwifery approved by the Vice Chancellor for Research of Ahvaz Jundishapur University of Medical Sciences with the code IR.AJUMS.REC.1399.230. For this purpose, we would like to thank the Vice Chancellor for Research of Ahwaz Jundishapur University of Medical Sciences for providing credit for this research and all the people who participated in the study.

# **Declaration of patient consent**

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient(s) has/have given his/her/their consent for his/her/their

images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

# Financial support and sponsorship Nil.

#### **Conflicts of interest**

There are no conflicts of interest.

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