

Research Paper

Effect of Auriculotherapy on Sleep Quality in Elderly With Chronic Low Back Pain: A Single-blind Randomized Clinical Trial



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ABSTRACT

Objective One of the common problems that leads to poor sleep quality in the elderly is low back pain. This study aims to evaluate the effect of auriculotherapy (ear acupuncture) on the sleep quality of elderly people with chronic low back pain.

Methods This single-blind randomized clinical trial was conducted in 2019 on 70 older adults with chronic low back pain in Kashan, Iran, who were selected using a convenience sampling technique. After obtaining a written informed consent, they were assigned into intervention and sham groups using the block randomization method. In the intervention group, the pressure was applied to ShenMen, sympathetic, subcortex and low back points of the ear, while in the sham group, the pressure was applied to the points that were not associated with the low back pain. The Pittsburgh Sleep Quality Index (PSQI) and McGill Pain Questionnaire (MPQ) were completed at the beginning of the study, at the end of intervention, and one month after the end of intervention. Six patients from the Sham group and 2 patients from the intervention group were excluded from the study. The data of 62 elderly (in sham group 29 and in intervention group 33) according to Per-Protocol (PP) and data of all samples as Intention to Treat (ITT) were analyzed using covariance analysis and repeated measures ANOVA.

Results There was a statistically significant difference between the intervention and sham groups in terms of the duration of disease at baseline ($P=0.012$). The interaction effect of time and group on the sleep quality was significant ($P<0.0001$). Sleep quality in the intervention group was significantly better than in the sham group at the end of the intervention and also during the one-month follow-up period ($P<0.0001$). Within-group comparison results reported a significant difference in the sleep quality between three evaluation times in the intervention group ($P<0.0001$).

Conclusion Auriculotherapy can improve sleep quality in the elderly with chronic low back pain. It is recommended to use auriculotherapy as a complementary therapy for treating these elderly groups.

Extended Abstract

1. Introduction



One of the most common forms of chronic pain in the elderly is low back pain [2-4],

which in many cases is associated with sleep disorders [6] and can endanger the physical and mental health of the sufferer [2, 7-9]. In recent years, non-pharmacological methods [14-17] have been increasingly considered by researchers and health professionals to treat chronic low back pain and its secondary problems. Among these non-pharmacological methods introduced to reduce pain, auriculotherapy

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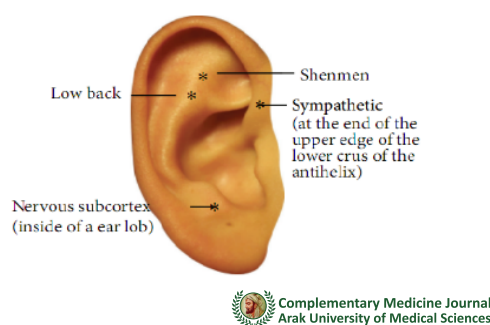


Figure 1. Pressure points on the ear of patients in the intervention group

or ear acupressure is effective in balancing hormone levels and increasing the release of neurotransmitters such as serotonin. It also improves blood circulation and brain function and induces deep relaxation [18]. In some studies, its effect on inflammatory processes has been proven; it has been reported that it can increase anti-inflammatory compounds [19, 20]. Therefore, it is expected that these mechanisms may be effective in reducing pain intensity and sleep disorders in patients with chronic low back pain. Some studies have shown that auriculotherapy reduces the severity of low back pain and improves sleep quality [21, 27]. However, not all previous studies indicate its positive effects in patients with chronic pain [19-23]. In addition, these studies face some limitations and disadvantages in terms of methodology or perspective on how to address the issue of pain [9, 19-27, 30]. On the other hand, in most related studies, the cognitive status of the elderly and behavioral manifestations of pain such as changes in sleep quality have not been considered [11, 20], while they are very important for the elderly people. In this regard, the present study aims to investigate the effect of auriculotherapy on the sleep quality of the elderly with chronic low back pain.

2. Methods and Materials

The present study is a single-blind clinical trial conducted in 2019 on the elderly aged ≥ 60 years with chronic low back pain in Kashan, Iran, divided randomly into two intervention and sham groups using the block randomization method. They were selected based on the inclusion criteria and the scores of Cognitive State Test (COST) and Visual analogue Scale (VAS). In the intervention group, auriculotherapy was performed for 4 weeks, 5 days a week, 3 times per day during having pain. In this group, Vaccaria seeds were applied on the shenmen, sympathetic, subcortex and low back points of the ear [11] and the elderly were instructed to press these seeds with their index and middle fingers for three minutes at a scheduled time (Figure 1). In the sham group, auriculotherapy was also applied with similar instructions but on the kidney, stomach, mouth and

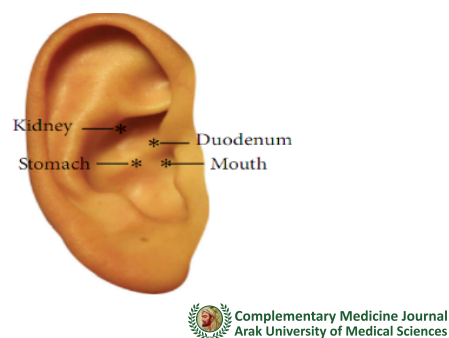


Figure 2. Pressure points on the ear of patients in the sham group

duodenum points [11] (Figure 2). In both groups, during the 4 weeks of the intervention, Vaccaria seeds were alternately applied to both ears every other week. Seeds were placed on the ear for 5 days each week, and subjects were told to separate them at the end of the 5th day. During the intervention period, each week, subjects were visited and their pain intensity was assessed with the short form of McGill Pain Questionnaire (MPQ) and new seeds were attached to their ears. If the mean number and duration of pressures on the seeds were at least 2 times a day and 2 minutes each time, the sample would be remained in the study. Application of seeds was continued for 4 weeks and subjects were followed up for 4 weeks after the intervention. MPQ and Pittsburgh Sleep Quality Index (PSQI) were completed at the beginning of the study and at the end of the first, second, third and fourth weeks of the study as well as 4 weeks after the intervention (follow-up period). Data analysis was performed in SPSS V.16 software using repeated measures ANOVA and ANCOVA. Data were analyzed in two stages: in the first stage based on a Per-Protocol (PP) approach and in the second stage based on an Intention-to-Treat (ITT) approach. Six patients from the Sham group and 2 patients from the intervention group did not complete the study.

3. Results

There was a statistically significant difference between the intervention and sham groups in terms of duration of disease at baseline. In PP approach, the interaction effect of time and group on low back pain intensity score was reported to be significant by controlling the confounding effect of the duration of disease ($F=270.17$, $P<0.0001$). In the intervention group, the effect of time on the low back pain intensity was significant ($P<0.0001$), but its effect in the sham group was not significant ($P=0.17$). After removing the confounding effect of the duration of disease, ANCOVA results showed that at the beginning of the study, the first week and the second week, the difference between the two groups was not significant in terms of low back pain intensity, but in other time periods, the difference between

Table 1. Comparing the sleep quality scores of patients in two groups at three evaluation times

PSQI Score	Mean±SD		Test Results		Within-group Comparison**
	Control (n=29)	Intervention (n=33)	Time×Group		
			Mauchly's test	Greenhouse-Geisser	
Baseline (T ₀)	11.83±3.22	12.06±3.53			F= 1.07 P=0.30
week 4 (T ₁)	11.52±3.49	4.00±0.75	χ ² = 201.82 P<0.0001	F= 141.87 P<0.0001	F= 121.88 P<0.0001
Follow-up (T ₂)	11.52±3.49	3.94±0.70			F= 124.78 P<0.0001
Time		F=1.62 P=0.21	F= 225.45 P<0.0001		
Within-group comparison*	Bonferroni statistic	T0 vs T ₁	P<0.0001		
		T0 vs T ₂	P<0.0001		
		T1 vs T ₂	P=0.97		

* Repeated measures ANOVA; ** ANCOVA.

the two groups was significant (P<0.0001). The interaction effect of time and group on the sleep quality score was also significant by controlling the confounding effect of the duration of disease (F=141.87, P<0.0001) (Figure 3). The effect of time on the sleep quality was also significant in the intervention group (P<0.0001), but not in the sham group (P= 0.21). ANCOVA results showed that at the beginning of the study, the difference between the two groups was not significant in terms of sleep quality, but the difference between the two groups was significant in other time periods (P<0.0001) (Table 1). In ITT approach, the results were similar to the results reported In PP analysis stage.

4. Conclusion

The present study revealed the positive effects of auriculotherapy on reducing the severity of low back pain in the elderly with chronic low back pain under ITT and PP analysis. The findings of our study are consistent with the results of some previous studies [11, 20] and are against the findings of some other [19, 28]. This discrepancy, regardless of differences in the target group or their characteristics, may be related to insufficient sample size in the mentioned studies. The positive role of auriculotherapy in reduction of pain intensity can be explained by the effect of this treatment on Qi flow, improving blood flow, and the production of endorphins [11] and hormones such as cortisol and serotonin [20].

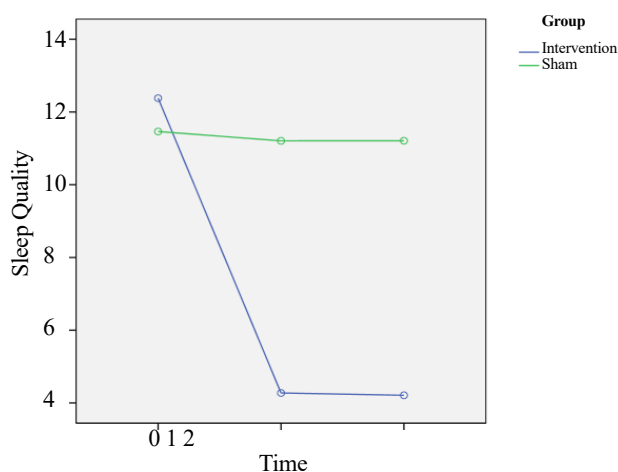


Figure 3. The sleep quality scores of patients in two groups at baseline, after intervention, and at follow-up period



In the present study, both PP and ITT analyses showed a positive effect of auriculotherapy on improving sleep quality in the elderly with chronic low back pain. This finding confirms the findings of other researchers [6, 29, 38] but is not in line with the findings of Yeh et al. [39]. Due to the two-way relationship between pain and sleep disorders, it is expected that auriculotherapy can also improve sleep quality by raising the level of pain threshold [32, 34], in addition to inducing muscle relaxation following Qi circulation, improving blood flow in the meridians [18], and increasing serotonin production [41].

Although performing ITT analysis and obtaining findings similar to PP analysis support the validity of the results, we should be somewhat cautious about generalizations of the results due to insufficient blinding, the use of younger elderly, and the fact that most of them were female. It is suggested that further study be conducted with a double-blind design, a larger sample size, and data analysis based on gender and age.

Ethical Considerations

Compliance with ethical guidelines

The research proposal was approved by the Vice Chancellor for Research and Technology and the Ethics Committee of Kashan University of Medical Sciences (Code: IR.KAUMS.NUHEPM.REC.1397.064). The design was registered on the clinical trial site (Code: IRCT20190303042891N1).

The participants were informed of the purpose of the research and its implementation stages. A written consent has been obtained from the subjects. They were also assured about the confidentiality of their information and were free to leave the study whenever they wished, and if desired, the research results would be available to them.

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Authors' contributions

Conceptualization and supervision: Zahra Tagharrobi, khadigeh Sharifi, Zahra Sooki; Methodology: Zahra Tagharrobi, Maryam Pourmohammadi, Fatemeh Zare-Joshaghani; Investigation, writing – original draft, and writing – review

& editing: Zahra Tagharrobi, Khadigeh Sharifi, Zahra Sooki, Maryam Pourmohammadi; Data collection: Maryam Pourmohammadi; Data analysis: Zahra Tagharrobi, khadigeh Sharifi, Zahra Sooki; Funding acquisition and Resources: All authors.

Conflicts of interest

The authors declares no conflict of interest

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