

Comparing the Effect of Auriculotherapy and Vitamin B6 on the Symptoms of Premenstrual Syndrome among the Students who Lived in the Dorm of Isfahan University of Medical Sciences

Abstract

Background: Premenstrual syndrome (PMS) is a series of physical and psychological symptoms before menstruation which its prevalence around the world has been reported to be 80%. Consumption of vitamin B6 is a common treatment for this syndrome, and this study was conducted to compare the effect of auriculotherapy and vitamin B6 on the symptoms of premenstrual syndrome. **Materials and Methods:** This study was a clinical trial. Eighty-four female students who lived at the university dorm were randomly selected and allocated into two groups of 42. The first group received auriculotherapy (10 sessions) for two menstrual cycles and the second group consumed 40 mg of vitamin B6 daily from a week before their menstruation for two menstrual cycles. The severity of symptoms was recorded for both groups during two cycles before the intervention and two cycles after the intervention. Data gathering tool was a 28-question, questionnaire to assess the severity of symptoms of premenstrual syndrome based on DSM-IV. **Results:** The mean score of symptoms in the auriculotherapy group in the first and second cycles was 26.70 (19.49) and 24.76 (17.07), respectively, and in the vitamin B6 group, was 22.60 (10.87) and 24.17 (14.15), respectively, which showed a significant difference compared to before the intervention ($P = 0.001$). However, comparing the total score of symptoms in the first and second cycles after the intervention between both groups showed no significant difference. **Conclusions:** Auriculotherapy, similar to vitamin B6, decreases the severity of PMS symptoms.

Keywords: Auriculotherapy, Iran, premenstrual syndrome, Vitamin B6

Introduction

Premenstrual syndrome (PMS) includes physical, mood, and behavioral changes that would happen periodically during the luteal phase of menstruation cycle. These symptoms would gradually disappear by the start of menstrual bleeding or after that, following which an asymptomatic period starts.^[5]

According to previous studies, the prevalence of this syndrome worldwide is 80%, among women in USA is 70–90%, in Chinese women is 92%, among Japanese teenagers is 64.60%, and in the French population is 30.4%.^[1,18] In a study that was conducted from 2009 to 2011 among 18–35-year-old Iranian women, 52.9% of the participants suffered from PMS, and the intensity of the syndrome in 34.5% of them was severe.^[18] In 2008, the prevalence of PMS among working women was reported to be 67.8%, of which 27.6% of them had a moderate to severe PMS.^[20] No results have

been reported regarding the prevalence of PMS in Isfahan.

The symptoms of this syndrome include fatigue, irritability, edema, anxiety, and sore breasts. The cause of PMS is unknown and is considered a multi-factorial disorder.^[5] Its complications could cause marital disputes, mother–child conflicts, social isolation, missing school and work, academic failure, poor performance, decreased concentration, increased complaints of psychosomatic diseases, suicide, legal problems, and social consequences such as committing a murder or crime.^[16]

Many therapeutic measures including medicinal treatment, surgery, nonmedicinal, and alternative treatments as well as consuming supplements, vitamins, and minerals have been suggested. Because of the chronic condition of the disease and the side effects of the drugs, patients mostly

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prefer food supplements, herbal drugs, and complementary medicine methods.^[3,21]

Consuming vitamin B6 is one of the common treatments for PMS. On the one hand, this drug would enhance the levels of serotonin and dopamine, and on the other hand, it would affect the level of prostaglandin and necessary fatty acids that would improve the symptoms of premenstrual syndrome.^[3] Vitamin B6 as a medium effect and low-complicated supplement is commonly used in low doses (less than 150 mg per day) to treat mild cases of this disease.^[3]

One of the nonmedicinal methods for treating PMS is ear acupuncture (auriculotherapy), which is one of the branches of acupuncture.^[9,4] In auriculotherapy, certain points on the external ear are stimulated with electricity or seeds, which confirms the noninvasive nature of this method compared to acupuncture.^[10] Auriculotherapy could control pain and adjust the level of hormones and neurotransmitters in the body and brain.^[11,6,22]

Considering the high prevalence of premenstrual syndrome, the role and importance of this syndrome on women's personal and social problems, the necessity of finding the best way for the least hurt by this disease to women, its side effects, the cost of medicinal treatments, and increasing popularity of complementary and alternative medicine, as well as lack of researches regarding the effectiveness of auriculotherapy in comparison to medicinal treatments to find a practical way of controlling the symptoms of premenstrual syndrome by nonmedicinal methods, the researcher decided to determine and compare the effect of auriculotherapy and vitamin B6 on the symptoms of premenstrual syndrome among female students who lived in the dorm of Isfahan University of Medical Sciences during 2014–2015.

Materials and Methods

The present study was a clinical trial (IRCT code of IRCT201509182889N5) that was conducted in 2015–2016 among 84 female students who lived in the dorm of Isfahan University of Medical Sciences. The sample size was calculated to be 42 for each group based on a 95% confidence interval and an 80% test power. Before the intervention, questionnaires were distributed to students. From 120 students who voluntarily completed the questionnaire, 84 met the inclusion criteria. The inclusion criteria were being 18–35 years old, having regular menstruation cycles with equal intervals (22–35 days), not having a history of psychological or chronic physical diseases and depression, not having a history of using anti-depressant, sedatives, and hormonal drugs as well as drugs that have interactions with vitamin B6, and not having any kind of mass, infection, or scar on the external ear (in the auriculotherapy group). The occurrence of any undesirable incidence or death, not presenting for all the auriculotherapy sessions correctly

and completely (more than two consecutive absences), not pressuring the seeds in the auriculotherapy group, and not completing the table of symptoms' severity recordings were the exclusion criteria. The form for evaluating the severity of PMS symptoms based on DSM-IV has been used in different books and articles with a 92% correlation. Also, Pakgozar *et al.* in 2004 approved the scientific validity and reliability of this tool through content validity and a reevaluation, approved its reliability with a Pearson correlation of $r = 0.92$.^[13] Beck *et al.* in 1996 calculated the test–retest reliability coefficient of these tools to be 93% and 91%. Among national studies, the studies of Tashakori (1994)^[2] with a reliability coefficient of 0.78 and also Partovi (1975), Vahab Zadeh (1973) and Chegini (2002) with a coefficient of 70% to 90% could be mentioned.^[2]

Data collection tools were personal information and menstruation characteristics questionnaire, an evaluation form for symptoms of PMS based on DSM-IV, general health questionnaire (GHQ-28), table for recording daily symptoms, and Beck's depression inventory (for making sure of not having any mental disorders or depression before entering the study). Measurement tools in this study were Pointer Plus Exel II device, a digital scale, and a stadiometer.

After the initial completion of the questionnaires and confirming the syndrome in the participants, its symptoms were determined after two menstruation cycles. The order of random allocation of participants into one of the groups (B6 and auriculotherapy) was that all of the names (84 participants) were written on separate papers and then randomly selected for allocation to each group. The intervention in the auriculotherapy group was executed in 10 weekly sessions during two menstruation cycles (except for the 7 days of menstrual bleeding). Each session lasted about 20 minutes and was conducted by the researcher at the dorm in a private place that was considered for this matter. At each session Shenmen, zero, endocrine, ovary, uterus, adrenal, kidney, external genitalia, liver, brain, and brainstem points were stimulated [Figure 1]. At the end of each session herbal seeds were placed on specified points and were retained for at least 3 days; seeds had to be pressured by the participant for a whole minute every hour except for the time of sleep. Phone calls were made for reminding. The receivers of vitamin B6 were asked to take 40 mg vitamin B6 (made by Iran Hormone Company), which was given to them daily from a week before the start of menstrual bleeding. This group continued the consumption of B6 during the two months that the other group did not have any auriculotherapy sessions. Collected data were analyzed using SPSS 16 (version 16, SPSS Inc, Chicago, IL) with independent *t*-test and variance and covariance analysis. Both groups signed informed consent forms before the start of the study.

Ethical considerations

All the volunteers who had complaints of having PMS but did not meet the inclusion criteria were guided based on their needs. All the participants were assured of the confidentiality of their information. Results of the study were given to the research council of the Isfahan University of Medical Sciences and the head of the school of Nursing and Midwifery. This study was approved by ethics committee of Isfahan University of Medical Sciences by No. 394342.

Results

Results of this study showed that the mean age of participants in the auriculotherapy and B6 groups was 23.12 (3.65) and 22.86 (3.84) years, respectively. The mean age of the first menstruation in the auriculotherapy and B6 groups was 13.43 (1.45) and 12.90 (1.42) years, respectively; the mean of their BMI was 36 (2.03) and 21.04 (2.91), respectively. The longest interval between two cycles was 22–35 days, and the duration of bleeding was 3–8 days, which had no significant difference between both groups.

Independent *t*-test showed that the mean score of the symptoms of PMS had no significant difference between two groups before the intervention. However, the mean score of the symptoms of PMS had a significant difference

in both groups after the intervention compared to before the intervention; while the difference between both groups after the first and the second cycles was not significant [Table 1].

Variance analysis with repeated measures showed that the mean score of symptoms of premenstrual syndrome was not similar between the auriculotherapy and vitamin B6 groups at different time intervals (before, after the first and after the second cycle). Post-hoc LSD test showed that the mean score of symptoms of premenstrual syndrome before the intervention in both groups was significantly higher than the other two time intervals but the difference between both groups at the other two time intervals (one cycle and two cycles after the intervention) was not significant [Table 1].

Discussion

The present study was conducted to study and compare the effect of auriculotherapy and vitamin B6 on the symptoms of premenstrual syndrome in 84 female students living in the dorm of Isfahan University of Medical Sciences. Results showed that auriculotherapy and vitamin B6 were both effective in decreasing the symptoms of premenstrual syndrome in physical and psychological dimensions. As shown in Table 1, the highest decrease in physical and psychological symptoms in the first month after the intervention in the auriculotherapy was respectively allocated to symptoms such as the desire for sweets (25%), weakness and energy reduction (23.7%), pain and the tenderness of the breasts (23.1%), desire to stay at home (35.8%), lack of concentration, isolation and depression (32.9%), and irritability (21.9%), and in the vitamin B6 group was, respectively, for symptoms such as pain and tenderness of the breasts (46.2%), feeling cold (32%), weakness and energy reduction (15.8%), irritability (39.7%), lack of concentration, isolation and depression (30.5%), and boredom (30%).

In the second cycle of the intervention, the highest decrease in physical and psychological symptoms in the auriculotherapy group was, respectively, allocated to pain and tenderness of the breasts (36%), acne, and greasy skin (28.3%), weakness and energy reduction (26.3%), desire to stay at home (35.8%), lack of concentration, isolation and depression (32.9%), and irritability, (21.9%) and in the vitamin B6 group was, respectively, in symptoms

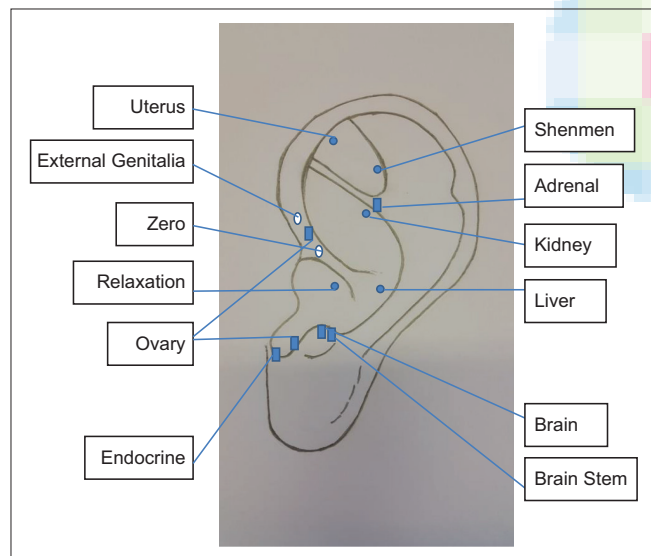


Figure 1: Points selected for stimulation

Table 1: Comparison of symptoms of premenstrual syndrome (100) before and after intervention

	Mean(SD)			Analysis of variance with repeated (ANOVA)
	The mean total score of the pre- intervention	The mean total score first cycle after intervention	The mean total score second cycle after intervention	
Auriculotherapy (Group)	43.12 (17.75)	26.70 (19.94)	24.76 (17.07)	0.001
B 6 (Group)	43.12 (17.75)	22.60 (10.86)	24.17 (14.15)	F=18.10 0.001
<i>t</i> -test	P=0.93; <i>t</i> =0.09	P=0.18; <i>t</i> =1.34	P=0.86; <i>t</i> =0.17	F=26.73

such as feeling cold (30.7%), weakness and energy reduction (25%), pain and tenderness of the breasts (17.5%), irritability (49%), anger (35.1%), and boredom (34.2%).

According to the results of the present study, auriculotherapy and vitamin B6 were both similarly effective in relieving the symptoms of PMS. The effect of auriculotherapy was long-term, and despite stopping the technique, its effect remained, whereas consuming vitamin B6 must be continued to get the desired results. Hence, auriculotherapy is preferred over consuming vitamin B6 because it could also prevent the relapse of the disease after stopping the treatment.

No studies were found in Iran to compare the effects of auriculotherapy and B6 on the symptoms of premenstrual syndrome.

Su Hee Jung (2014) reviewed 19 studies regarding the effect of acupuncture and herbal drugs on PMS. Their results showed that acupuncture and all the herbal drugs could significantly reduce the symptoms of PMS up to 50% and even in some cases to 100%.^[6] These results confirm the results of the present study. Auriculotherapy as a part of acupuncture has an important role in adjustment and regulation of the mood by interfering with the production of opioids. In addition, by affecting cytokines (oxytocin and cortisol) and strengthening the immune system, it would exert its autonomic and somatic effects,^[6,7] which could be an explanation for the efficacy of this method on relieving the symptoms of premenstrual syndrome.

In another study conducted by Abdollahi Fard *et al.* (2013), the effect of foot reflexology on physical and psychological symptoms of PMS was evaluated. Results showed that foot reflexology was effective in the intervention group in improving the symptoms of premenstrual syndrome.^[12] Because auriculotherapy is considered as a branch of acupressure, it has the same anti-inflammatory, anti-spasmodic, and blood circulation stimulation effects;^[12] considering that blood and fluid stasis and imbalance in hormones is one of the reasons for this syndrome,^[6,13] auriculotherapy could relieve the symptoms by balancing the hormones (by affecting mediated hormonal receptors) and regulating the energy.^[6] Therefore, this study also confirms the results of the present study.

Valiani *et al.* (2013) by studying the effects of auriculotherapy on hormonal changes caused by polycystic ovary syndrome showed that auriculotherapy has been more effective in regulating hormones in comparison to drugs.^[10] Results of this study also confirm the effect of auriculotherapy on hormone regulation along with the results of the present study.

In a study by Yeh Mei-Ling *et al.* (2013), the effect of auriculotherapy by itself and along with online training was evaluated in 107 students with primary dysmenorrhea. Selected points were Shenmen, liver, kidney, and internal genital. Auriculotherapy decreased dysmenorrhea, and this effect was

more obvious in the group who received online training.^[14] Considering the etiology of dysmenorrhea, auriculotherapy would affect the treatment of dysmenorrhea by its regulating effect on hormones and anti-inflammatory, anti-spasmodic, and blood circulation stimulation effect and also by following the theory of pain threshold control.^[7,9,12] Back pain and the pain under the stomach are the common symptoms of PMS and dysmenorrhea and the present study also found similar results which indicate conformity of these two studies.

In another study that was conducted on 150 students who lived in a university dorm, Hasani *et al.* (2014) compared the effect on symptoms of PMS between the three groups of body relaxation, B6, and control. Results showed that body relaxation and vitamin B6 (240 mg per week) were both effective in reducing the psychological symptoms of PMS. But vitamin B6 was more effective in reducing physical symptoms than body relaxation.^[3] Comparing these results with the results of the present study, the difference in the effect of B6 on physical symptoms could be due to the differences in the consumption method or dose of B6 or maybe auriculotherapy had a more significant effect on physical symptoms than body relaxation which made it comparable to consumption of vitamin B6. This study also confirmed the effect of the complementary medicine on symptoms of PMS, which present study is in line with the results of this study.

Hyo Jaeng Bae *et al.* (2014) reviewed the effects of ear acupuncture on reducing anxiety symptoms before surgery. Results showed that acupuncture interventions in comparison to sham acupuncture (stimulating points other than the real points) had a significant effect on reducing the anxiety symptoms before surgery.^[8] By effecting neurotransmitters including endorphin, serotonin, norepinephrine, and cortisol, auriculotherapy could control mood symptoms including anxiety.^[9,17] In the present study, auriculotherapy in comparison to vitamin B6 was more effective in reducing anxiety as one of the psychological symptoms of PMS.

It must be noted that this technique is inexpensive, low risk, and easy to apply and would happen in a shorter time with a good communication between the therapist and the patient; it could be conducted at general health centers by trained therapists including midwives. The effectiveness of this technique in treating this disease has been proposed as a holistic technic on the general health of the body.

The limitations of this study were students' communications and interactions about the two studied methods and lack of a placebo group.

Conclusions

In this study, the effects of auriculotherapy and vitamin B6 on general relieving of the physical and psychological symptoms of PMS were significantly obvious. According to the results, both methods could be effective in improving the symptoms of PMS. Therefore, auriculotherapy could be

a good replacement for drugs in treating the symptoms of this syndrome, and its even comparable with vitamin B6 which is commonly used.

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Conflicts of interest

There are no conflicts of interest.

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