

Evaluation the Effect of Auriculotherapy on the Clinical Signs of Single Girls with Polycystic Ovary Syndrome: A Single-Blinded Clinical Trial

Abstract

Context: Polycystic ovary syndrome (PCOS) is one of the most common endocrine abnormalities in women. This study aimed to evaluate the effect of auriculotherapy on the clinical manifestations of PCOS in single girls aged 18–35 years. **Setting and Design:** A single blinded parallel clinical trial. **Materials and Methods:** This study was performed on 60 single girls aged 18–35 years that randomly assigned into two groups including auriculotherapy and medication. The clinical symptoms, hirsutism score, laboratory tests and ultrasound were measured and both groups were treated for two months. **Statistical Analysis Used:** The results were analyzed in three stages and analyzed by *t*-test, Chi square and repeated measurement tests. **Results:** A significant reduction was observed in hirsutism score in auriculotherapy group ($P = 0.04$). There was a significant difference before and immediately after the intervention in auriculotherapy group ($P = 0.01$). Hair loss immediately after the end of intervention was significantly lower in auriculotherapy group ($P = 0.04$). There was a significant change in relative frequency of acne immediately after the intervention between two auriculotherapy and medication groups ($P = 0.01$). Acne recovery in auriculotherapy group was higher, and the relative frequency of acne was significantly different between the two groups after 3 months of intervention ($P = 0.005$). The irregularity of menstruation in auriculotherapy group was reduced more compared with medication group ($P = 0.02$). The mean weight 3 months after the intervention was significantly different between two groups ($P = 0.04$). **Conclusion:** Auriculotherapy can play a role in reducing the symptoms of hirsutism, hair loss, and acne in single girls with PCOS, and even can control weight gain.

Keywords: Auriculotherapy, hair loss polycystic ovarian syndrome, hirsutism, irregular menstruation

Introduction

Polycystic ovarian syndrome (PCOS) is one of the most common endocrine disorders in women.^[1] PCOS is defined as at least two out of three symptoms, including menstrual cycle disorders (amenorrhea and oligomenorrhea), clinical or biochemical hyperandrogenism, and polycystic ovulation in ultrasound. Obesity, infertility, and insulin resistance are other characteristics of PCOS that are related to increase the risk of endometrial hyperplasia and neoplasia.^[1–3]

The prevalence of PCOS in Iranian girls is lower 10%.^[4,5] In a national study in 1549, Iranian girls of high school students aged 16–20 years were reported 8.3%.^[5] Moreover, based on the another study in Isfahan, three different criteria were used to estimate the prevalence of PCOS including 7% based on the National Institutes

of Health criteria, 15.2% under the Rotterdam criteria, and 7.92% according to the Advanced Encryption Standard criteria.^[4] PCOS is the most common cause of hirsutism,^[6] as the most common manifestation of androgens in women.^[2] High levels of male hormones (androgens) mean as clinical hyperandrogenism and include hirsutism, male baldness, and acne.^[2,7,8] Hirsutism means male hair growth, which affects about 5%–8% of women's population.^[2,6] Another known characteristic of PCOS is androgenic alopecia, and 51% of hair losses often occur in the temporal areas.^[3,9] In addition, acne syndrome is another PCOS feature as one of the most common skin disorders and occurs in 11%–43% of PCOS women and varied among different age groups.^[10,11] The area started initially in the facial area, but in 50% of women with hyperandrogenism acne lesions are in the neck, chest, and shoulder.^[10,11] Menstrual disorders in PCOS

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patients varied from amenorrhea to oligomenorrhea.^[1,11] This disorder occurs during all life and begins with an irregular menstruation at puberty and continues with acne and hirsutism at adulthood.^[1] Obesity is another problem in PCOS women and affects $\geq 50\%$ of patients.^[2,12] Weight loss is the first step in obese PCOS patients to decrease insulin and androgen levels and causes ovulation to resume alone or with ovulation.^[2,13]

Various therapeutic methods such as pharmacological and nonpharmacological treatments are used for the treatment of PCOS, including conventional therapies such as spironolactone to suppress ovarian testosterone production.^[14,15] PCOS is a hormonal disorders in hypothalamus and pituitary level, and the PCOS consequences are reduced by taking drugs, but the symptoms appearing again by stopping treatment.^[16] Therefore, long-term medication is necessary which is often bothersome for patients and often feel tedious and complaints of side effects of drugs.^[3,16] Therefore, the use of nonpharmacological methods may be more acceptable due to pharmaceutical complications including chemical side effects, high drug costs, and family problems. Reflexology, acupressure and acupuncture, auriculotherapy are some common complementary therapies for the treatment of PCOS therapeutic.^[13,15,17,18]

Acupuncture modalities and reflection therapy can be used to stimulate ears (acupuncture) and hands. Other methods are acupressure and moxibustion.^[19] Acupuncture in China has been used for many years for treatment over 3000 diseases and treatment of various types of diseases.^[14,15,19] It is suggested as complementary alternative medicine in women with PCOS.^[14] Acupuncture is effective in modulating systems including the sympathetic nervous system, endocrine system, and neuropathic system.^[14,19,20] Acupuncture can be done in the entire parts of the body, as well as ears, that is defined as auriculotherapy. On the other hand, the stimulation of auricula or external ear is auriculotherapy and is used in various parts of the body.^[21,22] Since complementary therapies are less complicated and safer than medication methods, we aimed to evaluate the effect of auriculotherapy on the clinical signs of single girls with PCOS as nonpharmacological method for the treatment of PCOS.

Materials and Methods

This clinical trial study was conducted with 60 single girls aged 18–35 years referred to a private health center in an urban area of Iran. Sampling was conducted using a random method, and patients were divided into two groups of auriculotherapy and medication by block random allocation method. The patient number in each group was equal to 30 as the below formula. This research was approved by the Ethics Committee of Medical Sciences University (IRCT code: IRCT2013091614682N1). The

researcher obtained the written informed consent form before the study. The patients could refuse or accept the participation in the study.

$$n = \frac{(Z_1 + Z_2)^2 (2S^2)}{d^2}$$

Inclusion criteria were the absence of any systemic diseases, endocrine and neurological diseases, no drug use, the diagnosis of PCOS according to the Rotterdam criteria,^[2,3] no addiction, no hyperprolactinemia, and having at least one healthy ear. Exclusion criteria were drug treatment during treatment with auriculotherapy, absence for two sessions, discontinuing the drug, and the use of any hormonal and neurological drugs. For the diagnosis of PCOS, all hormone tests and ultrasound were performed for all eligible patients. According to the Rotterdam criteria,^[2] patients who had two criteria out of the following three criteria entered this study including clinical symptoms, laboratory tests, and ultrasound.

After the selection of samples, they were examined and consulted. Demographic characteristics (age, height, weight, education level, and occupation) and personal data were recorded, and they were asked to complete the checklist. The content validity method was used to assess the validity of the data collection tool. Reading books and articles published in this field helped with the development of checklist for observation and examination. Next, it was assessed by ten faculty members of nursing and midwifery faculty, which led to some modifications. According to the gynecologist's prescription, during three menstruation periods, the patients of medication group received cyproterone compound drugs or oral contraceptives, starting from 1 to 5 days of menstrual cycle for 21 nights, and discontinuation of the drugs for 7 days. They received drugs for three consecutive cycles. In auriculotherapy group, in two menstrual cycles from the end of cycle for 10 days in each cycle (a total of 20 sessions), they received treatment in every other day format.^[15] After auriculotherapy, ear seeds were used on especial areas of ears for 3 days. They were asked to put pressure on the seeds on their ears. Follow-up was performed to remain the women about the process of intervention. Ear seeds were tiny balls made from *Vaccaria* seeds from *Vaccaria* plant. Seeds also came in gold, silver, and magnetic beads. They were stuck to the cartilage of the ear using a small piece of adhesive tape. These seeds were carefully placed on selected acupuncture points to stimulate them. At each session, the Pointer-Plus^[23] device was applied on the body places of endocrine, uterus, ovaries, lungs, kidneys, liver, adrenal, skin, and appetite. The Pointer-Plus device was an accurate and easy to operate handheld trigger, or acupuncture point locator which incorporates an effective push button stimulation feature which might be used for the immediate treatment of the point or area right after its

detection. The severity of hirsutism was examined using Friedman Galway table and score 6 and above-indicated hirsutism.^[24] Hair loss, acne, and irregular menstruation were evaluated using a standard researcher-made questionnaire. During the study, the researchers were accessible by phone and asked from all patients to report any complications of intervention or medication. Moreover, the intervention continued to 10 days in patients who suffered from amenorrhea.

Finally, data were analyzed in three stages, namely before intervention, immediately intervention, and 3 months after intervention in both groups. Data analysis was done using the independent *t*-test, Friedman, and Chi-square tests by SPSS version 20 (SPSS Inc., Chicago, IL, USA).

Results

In this research, 60 single girls aged 18–35 years participated. The mean age of patients in two groups was 23.0 ± 3.08 and 24.13 ± 4.45 years ($P = 0.224$). The results of comparison of the mean score of hirsutism in both groups and between two groups were presented in Table 1. The mean of hirsutism in auriculotherapy group showed a significant decrease in terms of hirsutism score ($P = 0.04$). There was a significant difference in the mean of hirsutism score before and 3 months after the intervention in auriculotherapy group ($P = 0.007$). This comparison was also significant in the medication group ($P = 0.02$). Furthermore, there was a significant difference between before and immediately after the intervention in the auriculotherapy group ($P = 0.01$). This time difference was not statistically significant in medication group ($P = 0.65$). Comparison of time immediately and 3 months after the intervention showed no statistically significant difference in the auriculotherapy group ($P = 0.16$), but it was significant in the medication group ($P = 0.01$). However, the mean difference of hirsutism score was decreased as 0.83 in auriculotherapy group, while the mean difference of hirsutism score was increased 0.67 in medication group [Table 1].

Regarding hair loss [Table 2], there was no statistically significant difference in the percentage of hair loss before the intervention ($P = 0.3$). However, immediately after the intervention, the incidence of hair loss was significantly lower in auriculotherapy group compared with

medication group ($P = 0.04$). Three months after the end of intervention, it was less in auriculotherapy group than medication group, but the difference was not statistically significant ($P = 0.16$). The percentage of hair loss was significantly reduced in auriculotherapy group ($P \leq 0.001$), but it was not significantly different at three times in medication group ($P = 0.26$).

Table 3 shows the frequency distribution of acne immediately and 3 months after the end of intervention in both groups. There was a statistically significant change in the relative frequency of acne immediately after the intervention in the two groups ($P = 0.01$). Acne recovery was higher in the auriculotherapy group. Relative frequency of acne was significantly different in two groups after 3 months of the intervention ($P = 0.005$). Based on our results, the rate of full recovery of acne was 26.3% in auriculotherapy group and 18.7% in medication group. Moreover, the rate of relative improvement of acne in auriculotherapy and medication groups, 3 months after the end of intervention was 73.6% and 37.5%, respectively [Table 3].

The comparison of menstrual irregularities in both groups was presented in Table 4. Menstrual irregularities were not significantly different between two groups before intervention ($P = 0.56$). However, the irregularity of menstruation in both groups showed a significant difference 1 month after intervention ($P = 0.001$), but there was no significant difference between 2 months after the intervention ($P = 0.11$) and immediately after the intervention ($P = 0.16$). The irregularity of menstruation in both groups was significantly different at 3 months after starting the intervention ($P = 0.02$) and 3 months after the end of intervention ($P = 0.01$) and higher menstrual irregularities were reported in auriculotherapy group.

Regarding weight variations [Table 5], weight increased in the medication group, but it was not changed in the auriculotherapy group. The mean weight immediately after the intervention did not differ significantly between the two groups ($P = 0.322$). While the mean of weight 3 months after the intervention ($P = 0.017$) was significantly different between two groups.

Discussion

The results of the study regarding hirsutism indicated that auriculotherapy was associated with a higher reduction in

Table 1: Comparison of mean hirsutism score in two groups of auriculotherapy and medication before, immediately, and 3 months after the end of the intervention and between the two groups

Time	Mean±SD		P
	Auriculotherapy	Medication	
Before intervention	8.50±9.56	11.33±8.98	0.242
Immediately after intervention	7.73±8.89	11.70±9.41	0.099
Three months after the intervention	7.67±8.82	12.00±9.66	0.077
Repeated measurement P value	0.04	0.65	

SD: Standard deviation

hirsutism than medication method. As one of the causes of hirsutism is increase in androgens, acupuncture, and auriculotherapy are effective in modulating endogenous systems, including sympathetic nervous system, endocrine system, and neuropathic system.^[14,23,25,26] This problem can correct by balancing the hormones level balanced. Therefore, the treatment of hirsutism caused by this syndrome can have more efficacy than pharmacological methods. While no study was found on nonpharmacologic treatment, the results of medication studies are as follows.

The result of this study is in line with the results of Nazari *et al.*^[27] that examined the effect of metformin and concluded that metformin improved hirsutism after the

treatment. Conversely, Tavassoli *et al.*^[28] used metformin and Diane to improve hirsutism; and Salehpour *et al.*^[29] concluded that spironolactone with Diane was effective in treating hirsutism in women with PCOS, as well as in nonobese women with PCOS. These two studies had no follow-up and only investigated the effects of treatment immediately after the intervention.

The results of our research on hair loss showed that the use of auriculotherapy in reducing hair loss was significantly more effective than medication. Acupuncture and auriculotherapy by stimulating the blood flow and distributing energy in scalp area reduce hair loss. Acupuncture is a cost-effective alternative method. According to Frank's systematic review of alternative and complementary medicine in the treatment of alopecia, a number of complementary therapies can be effective in treating alopecia.^[30] For acne, both auriculotherapy and medication are effective in the treatment of acne due to PCOS. Auriculotherapy can be effective in treating acute compared with medication, and both methods have lasting effects.

According to our study results on acne, it can be concluded that auriculotherapy has a greater effect on acne than medication. This finding was in line with McKay's

Table 2: Distribution of relative frequency of hair loss in the two groups: auriculotherapy and medication, before, immediately after, and 3 months after the intervention, and between the two groups

	Auriculotherapy, n (%)	Medication, n (%)	P
Before intervention	18 (60)	14 (46.7)	0.30
Immediately intervention	5 (16.7)	12 (40)	0.04
Three months after the end of intervention	7 (23.3)	12 (40)	0.16

Table 3: Frequency distribution of acne immediately after intervention and 3 months after the intervention in two groups: auriculotherapy and medication

Time	Groups	Unchanged, n (%)	Relative improvement, n (%)	Full recovery, n (%)	Increased acne, n (%)
Immediately of intervention	Auriculotherapy	0	15 (78.9)	4 (21.1)	0
	Medication	5 (31.2)	7 (43.8)	3 (18.7)	1 (6.3)
3 months after the intervention	Auriculotherapy	0	14 (73.6)	5 (26.3)	0
	Medication	5 (31.2)	6 (37.5)	3 (18.7)	2 (12.5)
P		0.99	0.045	0.01	0.005

Table 4: Irregular percent of menstruation before intervention, 1 month after the intervention, 2 months after the intervention, 3 months after the intervention, and 3 months after intervention, in two groups of auriculotherapy and medication

	Does not have	Polymenorrhea	Oligomenorrhea	Amenorrhea	Oligomenorrhea and amenorrhea	P
Immediately of intervention						
Auriculotherapy	10	13.3	43.3	13.3	20	0.16
Medication	6.7	20	53.3	3.3	16.7	
1 month after the intervention						
Auriculotherapy	56.6	0	30	13.3	0	0.001
Medication	66.7	3.3	26.7	3.3	0	
2 months after the intervention						
Auriculotherapy	80	0	10	10	0	0.11
Medication	90	10	0	0	0	
3 months after the intervention						
Auriculotherapy	73.3	3.3	16.7	6.7	0	0.02
Medication	90	0	10	0	0	
3 months after the end of the intervention						
Auriculotherapy	63.3	6.7	23.3	6.7	0	0.01
Medication	33.3	20	46.7	0	0	

Table 5: Frequency distribution of weight before intervention, 1 month after intervention, 2 months after intervention, 3 months after the intervention, and 3 months after the intervention in two groups: auriculotherapy and medication

	Mean±SD		P
	Auriculotherapy	Medication	
Before intervention	57.61±9.62	59.86±7.79	0.322
Immediately after intervention	57.27±8.79	62.00±7.82	0.032
3 months after the intervention	57.31±8.98	62.67±7.91	0.017

SD: Standard deviation

research that ear acupuncture and auriculotherapy reduced acne. Jedel *et al.*^[26] also concluded that after 16 weeks of follow-up, electrical acupuncture had a great impact on acne. The result of this research was consistent with that study. Nazari *et al.*^[27] concluded that after treatment, metformin led to acne. The results of their research were in line with the current research. Other results showed that auriculotherapy was associated with a more severe menstrual irregularity than medication. Due to the continuous production of estrogen from ovaries and the absence of progesterone production, auriculotherapy can regulate the levels of hormones and neurotransmitters in the body and brain, which regulates menstruation.^[2,17,21] Stress is one of other factors that can affect menstruation irregularities and leads to the production of prolactin plenty and cortisol. Increasing these hormones causing irregular ovulation and has a direct impact on the production of estrogen and progesterone sex hormones in the body. Therefore, they can lead to irregular menstruation.^[2,17,22,26]

Since auriculotherapy stimulates reduction of stress, it creates a high level of satisfaction in participants compared to medication. The therapeutic outcomes may be a result of a stress-reduction approach in the patients that can control menstrual irregularities and other symptoms.

As shown in results, menstrual irregularities in auriculotherapy group decreased significantly compared to therapy at 3 months after the intervention. Therefore, it can be concluded that it has more survival viability. Medication helps connection of drugs to receptors during medication, though the effectiveness of drugs ends with stopping drugs. Therefore, considering the effects and benefits of auriculotherapy, it can be used as an over-the-counter method for the treatment of irregular menstruation due to PCOS.

In the current study, acupuncture was associated with decreasing androgen and improving menstruation in women.^[26] Pastore *et al.* also showed^[31] that acupuncture by normalizing the levels of luteinizing hormone and follicle stimulating hormone hormones led to reducing menstrual irregularities. Similarly, in this study, the pharmacological methods have been effective on reducing menstrual irregularities, but use auriculotherapy has been more effective in reducing menstrual irregularities.

Regarding changes in weight, the mean weight 3 months after the end of intervention was significantly different between two groups and weight loss and maintaining it in auriculotherapy group was more than medication group. Obesity is seen in 35%–60% of women with PCOS and is associated with a lack of or delayed response to various treatments such as clomiphene citrate, gonadotropins, and diathermia surgery through laparoscopy.^[11,13] There is some evidence that PCOS-related hyperandrogenism causes central obesity with a high back and hip ratio independent of body mass index (BMI). Ear acupuncture was introduced as a cure for obesity in mid-70s, and in recent decades, it has been a popular weight-loss method around the world. Technically, acupuncture is easy, relatively inexpensive and has minimal side effects, which have increased the use of this method of weight loss. Empirical and clinical evidence suggest that acupuncture stimulates the sympathetic system.^[11,13,19,23] However, the effects of sympathetic nervous system by stimulating ear acupuncture may play an important role for the treatment of obesity.^[13,19,20] In women with PCOS, the needle is placed along with meridian of acupuncture related to reproductive system. It helps to stimulate organs, improves blood flow in area, loses weight, improves endocrine profile, and increases the likelihood of ovulation and pregnancy. The normalization of menstrual cycles and ovulation can begin with a weight loss of 5% of the initial weight. Weight loss can improve both levels of androgen and glucose, and either rate of ovulation and pregnancy in obese women with PCOS.^[11,19]

According to Pastore *et al.*,^[31] acupuncture can maintain BMI of individuals with PCOS at normal levels. Furthermore, Lee *et al.* in a research that assessed the clinical effects of acupuncture on obesity in adolescents and its effects on blood lipid metabolism, it was found that acupuncture had a clear effect on simple obesity in teenagers.^[14,19,20] The above studies are consistent with results of this study. Considering the effect of drugs shown in other studies,^[28,29] this study showed that auriculotherapy was more effective than drugs, so it can be used as a nonharmful method for reducing symptoms of PCOS.

Conclusion

Auriculotherapy improves weight, hirsutism, hair loss, and acne and reduces the use of hormonal drugs that may have some side effects on the individual's health. This method is available in all health-care centers and can be utilized by a physician and midwife. Therefore, considering the impact of auriculotherapy on PCOS, this technique can be used as a branch of acupuncture or reflexology and has advantages over acupuncture. The use of medications takes a long time and with their discontinuation, symptoms may return. Auriculotherapy has a survival therapeutic effect up to 3 months. Therefore, further research on this syndrome

and this therapeutic approach in comparison with other nonpharmacological approaches are needed.

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Conflicts of interest

There are no conflicts of interest.

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