Original Article

The Effect of Auriculotherapy on the Stress and the Outcomes of Assistant Reproductive Technologies in Infertile Women

Mozhgan Saffari[1], Zahra Khashavi[2], Mahboubeh Valiani[3]

[1]Student Research Center, School of Nursing and Midwifery, Isfahan University of Medical Sciences, Isfahan, Iran, [2]Om-e-Leila fertility and infertility center, Bandar Abbas, Iran, [3]Department of Midwifery, Nursing and Midwifery Care Research Center, School of Nursing and Midwifery, Isfahan University of Medical Sciences, Isfahan, Iran

Abstract

Background: Infertility means failure to achieve pregnancy after one year of regular unprotected sexual intercourse. Infertile women may experience severe stress and depression. Numerous studies have indicated that auriculotherapy could reduce stress. Thus, the aim of the present study was to determine the effect of auriculotherapy on the stress and the outcome assisted reproductive technology in infertile women. **Materials and Methods:** The present study was a clinical trial that was conducted on 56 infertile women aged 20–45, who were assigned into two groups of intervention and control, from November 2014 to November 2015. The control group only received the routine treatments, while the intervention group, in addition to their routine treatment, received auriculotherapy for 8–10 sessions during menstrual cycle. Both groups completed Newton's Fertility Problem Inventory in three stages. The datasets collected for the study were analyzed using independent *t*-test, repeated-measures analysis of variance, and Chi-square test. **Results:** The mean score of stress in the intervention group decreased significantly, compared to the control group prior to the embryo transfer and pregnancy test stages. Although insignificant, the rate of pregnancy in the intervention group was higher than the control group. There was a significant increase in the rate of clinical pregnancy in the intervention group, compared to the control. **Conclusions:** The results indicated that auriculotherapy might be effective in reducing stress and improving the outcome of assisted reproductive treatment.

Keywords: *Auriculotherapy, infertility, Iran, stress*

Introduction

Infertility is defined as failure to become pregnant after 12 months of having regular and unprotected intercourse.[1-3] According to the statistics reported by the World Health Organization, infertility in women is ranked the 5th highest serious global disability.[3] Numerous studies have shown that the prevalence of infertility varies from 5 to 30% in different countries;[4] however, in Iran, the conducted studies have reported the prevalence of infertility rate between 10.90 % and 13.20%.[5,6] Infertility causes patients to experience emotional distress, lack of control and self-esteem, marital problems, anxiety, and depression.[7-9] To resolve their problem, infertile patients resort to assisted reproductive treatments. However, it must be noted that even patients who undergo such treatments would experience a great deal of mental stress,[10] because they often consider *in vitro* fertilization (IVF) as their last hope for having a successful pregnancy and a biologic child.[11] Numerous studies have indicated that the intensity and prevalence of depression among these patients tend to increase after each failed session of IVF treatment.[12] Such treatments are mostly a mere repeated experimental measure with little to no effect on the rate and chance of pregnancy,[13] and thus infertile patients, aiming at increasing their chance of having a successful treatment, tend to use complementary and alternative medicine that could be safer, more effective, and affordable.[14] Different methods of complementary and alternative medicine that could be used for treating infertility include herbal medicine, massage, acupressure, acupuncture, reflexology, etc.

The use of acupuncture as a complementary treatment for treating women's gynecological diseases has increased significantly in the last few years.[15] Also, numerous studies have shown that acupuncture could reduce stress by releasing internal opioids and adjusting

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Address for correspondence:
Dr. Mahboubeh Valiani, Department of Midwifery, Nursing and Midwifery Care Research Center, School of Nursing and Midwifery, Isfahan University of Medical Sciences, Isfahan, Iran.
E-mail: Valiani@nm.mui.ac.ir

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the performance of sympathetic nervous system.[16-18] Auriculotherapy (treatment through ears) is a form of acupuncture that has developed into a separate and unique method of alternative treatment in the last 60 years. This technique was first proposed by Dr. Paul Nogier in 1957 and was officially recognized by the World Health Organization in 1990.[19] In this method, noninvasive stimulation of certain points on the skin of the auricle (external ear) sends signals to the brain and other specific organs that would regulate and balance the physiologic performance of the body as a result.[20] This technique can be practiced through stimulation of the cranial, facial, cervical, and auditory nerves which are extended throughout the ear, and consequently have results on different body parts.[21] These points could be stimulated using different methods including needles, vaccaria plant seeds, probes or the tip of the fingers, electrodes attached to needles, or direct electrical stimulation; all of which are different types of auriculotherapy.[19,21] Auriculotherapy is an effective method with no side effects for treating acute and chronic diseases and decreasing mood and anxiety disorders.[22,23]

As mentioned earlier, the obtained results from the conducted studies on the infertile patients indicated that these patients deeply suffer from psychological problems.[7-10] This issue along with a host of other reasons of failure in assisted reproductive treatments could affect the success rate of patient's treatment. Hence, based on the evidence, patient's rate of success in treatments are directly affected by their psychological problems.[9,24] Therefore, in light of ample evidence on the effect of auriculotherapy as a branch of acupuncture in reducing psychological disorders, a number of research studies have been designed to evaluate the effect of complementary medicine on infertile patients suffering from anxiety disorders and the outcome of assisted reproductive treatment. One example of such studies was a research that was conducted in America in 2010, titled: "Evaluating the correlation between the perceived stress, acupuncture, and the pregnancy rate among patients undergoing IVF treatment." This study was conducted on 57 infertile women who were undergoing IVF treatment and were assigned into two groups of intervention and control. The obtained results indicated that acupuncture had significantly reduced patient's stress score prior to the embryo transfer stage, and had significantly increased the rate of pregnancy in the intervention group compared to the control group.[25] Another similar study in this regard was conducted in China (2014), titled: "Ear acupressure has reduced stress levels and improved the outcome of IVF treatment." This study was conducted on 305 women who were infertile due to the obstruction of the fallopian tubes and were randomly assigned into three groups of acupressure, placebo, and control. The results indicated that ear acupressure had significantly reduced presurgery anxiety score in patients undergoing IVF treatment, and has evidently increased the rate of clinical pregnancy in acupressure group compared to placebo and control groups;[26] it is worth noting that none of these studies were conducted in Iran. On one hand, in the methodology of these studies, the effect of auriculotherapy or acupuncture on patient's psychological disorders has been evaluated occasionally and merely during one stage of the procedure, for example, the day the embryo was transferred. In other words, the stress factor has not been taken into consideration throughout the whole therapy. On the other hand, there have not been sufficient studies to shade some light on the effect of auriculotherapy and the outcome of infertility. Therefore, considering the significant issue of infertility and its impact on personal, social, mental, and economic aspects of life, and the need to find complementary therapies which are safe, effective, and economic, the present study was conducted to evaluate the effect of auriculotherapy on the stress and the outcome of infertility treatment in patients undergoing assisted reproductive treatment.

Materials and Methods

The present study was a two-group three-stage clinical trial with the registration code IRCT20159182889N6, which was conducted on 56 infertile women who referred to Om-e-Leila fertility and infertility clinic in Bandar Abbas, Iran, from November 2014 to November 2015. By considering a 95% confidence interval and 80% test power, the estimated sample size for each group was 30 people. The participants in the present study were 20 to 45-year-old women who had infertility due to ovarian disorders, had at least one failed IVF treatment, had gone through IVF therapy for the second time, and participated in the study having full consent. At the beginning of the study (one menstrual cycle before IVF) through conducting interviews and close examination of their medical records, patient's nonmorbidity to uterine structural disorders, systematic diseases, and healthiness of the external ear were ensured. Further examination was also carried out to make sure patients have not been recently diagnosed or previously undergone any anxiety treatment. Interruption of the treatment during the intended menstrual cycle due to lack of embryo formation in the lab, occurrence of intense stressful situations, and patient's unwillingness to continue cooperation were among exclusion criteria in this study.

In the present study, participants were selected through convenient sampling. Nonsynchronized treatment sessions were arranged for both groups to avoid unintended conversations and observations between members that could eventually lead to the formation of wrong beliefs or unusual increase of anxiety among patients in the control group; thus, randomization was not conducted. Therefore, sampling was initially done for the control group, and when it was completed, it was done for the intervention group. After close examination of the inclusion criteria, 33 people entered the control group from whom 3 people

were eventually excluded due to lack of cooperation in completing the questionnaire, and thus the collected data from 30 people were finally analyzed. After the completion of this stage, according to the inclusion criteria, 32 people entered the intervention group from whom one person was excluded due to lack of cooperation, and five more people were excluded due to cancellation of the treatment for reasons such as lack of embryo formation in the lab, etc. Thus, the data collected from 26 people were finally analyzed. Data collection tools include demographic and fertility questionnaire plus Newton's Fertility Problem Inventory. Newton's Problem Inventory is a multidimensional, 46-item questionnaire that studies infertile women's concerns over five aspects in life. These aspects include social, sexual, interpersonal, a child-free lifestyle, and the need to be and experience parenthood. In Iran, the questionnaire reliability has been approved in the study of Alizade *et al.* with Cronbach's alpha coefficient of 0.91 for the total stress score. Prior to the present study, the questionnaire has been previously used in two other studies in Iran.[27,28]

Participants in the control group received only the routine procedure of fertility treatment (frozen embryo transfer , long and short protocols). This group completed the questionnaire at three stages: prior to their admission in the study, before the embryo transfer, and before performing the pregnancy test. In the first cycle of the treatment (one cycle before performing IVF), the intervention group received two sessions of auriculotherapy for 2 weeks. The total number of 6–8 sessions of auriculotherapy was conducted by the researcher. Also, in the second cycle of the treatment (the cycle of performing IVF), 2–4 sessions of auriculotherapy were conducted prior to embryo transfer stage. Eventually, the total number of 8–12 sessions was conducted for each patient. In this study, due to some reasons, auriculotherapy sessions were not proceeded any further after the embryo transfer stage. Firstly, comprehensive and sufficient documents could not be found to back up the project design on how auriculotherapy or acupuncture can affect the implantation and growth of the embryo after it has been transferred. Secondly, the general common belief among patients undergoing IVF is that after the embryo has been transferred, they should have full rest; whereas, conducting auriculotherapy sessions requires patients to visit the infertility center repeatedly. This plus other factors such as patient's lack of cooperation, the possibility of high-rate embryonic loss, the existence of stress in patients, and finally the possibility of partiality in the final results led to the cessation of intervention before the embryo transfer stage. Each auriculotherapy session lasted almost 30 min during which the associated points in the ovary, uterine, adrenal, endocrine system, brain, abdomen, pelvis, the immunity system, and the stress and relaxation points were stimulated for 10–15 seconds using Pointer Excel device. At the end of each session for the intervention group, the seeds were placed on specific points of the participant's ears, then they were trained on how to keep pressuring those points (every hour for 1 min). This group like the control group completed the Newton's Problem Inventory questionnaire at three stages. Patients were informed of the pregnancy test results through phone calls or visiting the center. If the result was positive, mothers were reminded of their next visit (next month) to have an ultrasound scan, performed by a specialist. In case of the negative test result, the study was considered finished for that person. After the completion of the sampling stage, the collected data were analyzed using independent *t*-test, covariance analysis, variance analysis with repeated measures, and Chi-square test.

Ethical considerations

An informed consent was obtained from all the participants of the study. Also, participants were free to leave the study at any stage if they did not want to continue.

Results

The obtained results of the study showed that there was no significant difference between the two groups in terms of age (p=0.50), duration of infertility (p=0.55), and frequency of infertility treatment (p=0.42). Also, the results showed no significant difference between the two groups regarding the cause of infertility (p=0.98) , and the type of infertility (p=0.57). Moreover, the obtained results revealed that there was a significant reduction in the stress score of the intervention group prior to embryo transfer and pregnancy test stages compared to the control group [Table 1]. The results also revealed that despite the higher rate of pregnancy in the intervention group than the control group, the difference was not significant; however, the frequency of clinical pregnancy in the intervention group was significantly higher than the control group [Table 2].

Discussion

The present study was conducted to determine the effect of auriculotherapy on stress and the outcomes assisted reproductive treatment. The results of the present study showed that auriculotherapy has been effective on stress and the outcomes of assisted reproductive treatment. Numerous studies have shown that stress and anxiety are prevalent factors among infertile patients particularly those undergoing IVF treatment, but the level of anxiety varies at different stages of IVF cycle; patients usually experience high levels of anxiety at egg harvesting, embryo transfer, and prior to pregnancy test stages.[24,25,29] The obtained results of the present study also confirmed that the participant's mean score of stress at the initial stages of the study, according to the stress score standings,[30] stood in a relatively high range. Similarly, the mean score of stress in the control group at embryo transfer and pregnancy test stages stood in a relatively high range. Numerous studies

Table 1: Comparing the mean scores of stress between the intervention and the control groups at different stages

Stage	Intervention group	Control group	Independent *t*-test	
	Mean (SD)	Mean (SD)	*t*	*p*
Beginning of the study	162.40 (31.30)	160.30 (34.70)	0.24	0.81
Embryo transfer	136.90 (35.90)	157.90 (35.90)	2.20	0.032
Pregnancy test	138.40 (33.50)	158.80 (36.90)	2.10	0.035
Analysis of variance with repeated measures				
F	53.68	0.24		
p	0.0001	0.78		

Table 2: Frequency distribution of pregnancy, gestational sac (GS), and fetal heart rate (FHR)[1] in the intervention and the control groups

Variable	Intervention group	Control group	Chi-square test	
	n (%)	*n* (%)	χ^2	*p*
Frequency of pregnancy	12 (46.20%)	10 (33.30%)	1.60	0.21
Frequency of GS and FHR	11 (42.30%)	7 (23.30%)	4.24	0.036

[1]One month after a positive pregnancy test

have indicated that auriculotherapy can reduce stress levels through regulating sympathetic activity and increasing beta-endorphin release in the body.[12,18,26]

The obtained results showed that 8–12 sessions of auriculotherapy, prior to the embryo transfer stage, had significantly reduced the stress levels in patients of the intervention group. The results of the present study are in line with the results of another study titled: "Ear acupressure have reduced stress levels and improved IVF treatment."[26] In the aforementioned study, patients received auriculotherapy at the interval between egg harvesting and embryo transfer stages which resulted in preoperative anxiety reduction in infertile patients, but in the present study, performing auriculotherapy from the menstrual cycle before IVF has significantly reduced the stress score in patients at embryo transfer and pregnancy test stages compared to the beginning of the study; whereas, the mean score of anxiety in the control group showed no significant change at these stages. Furthermore, conducting auriculotherapy until the embryo transfer stage could have been effective in reducing patient's stress, even at the pregnancy test stage, which confirms the durable effect of this method on patients; in this respect, the results of this study are in line with two other studies titled: "Acupuncture for infertility" and "Ear acupressure on pain, menstrual distress, and changes in the heart rate in cases of primary dysmenorrhea in stressful young girls."[12,31]

The results of the study in another section further indicated that there was no significant difference in the mean score of stress of the intervention group between embryo transfer and pregnancy test stages. This could probably be due to some reasons; firstly, there was an interval of 2 weeks between embryo transfer and pregnancy test stages. Considering the unknown effect of auriculotherapy on the implantation and growth of the embryo, intervention was not conducted. That might explain why patients stress score remained unchanged during this time period. Secondly, the interval from embryo transfer stage to pregnancy test stage is about 2 weeks; whereas, the interval time from the first treatment cycle (beginning of the intervention) until embryo transfer stage varies according to the treatment protocol, but it could last for almost 6 weeks. Therefore, different intervals could be another reason why patient's stress score has remained unchanged. This is in light of the fact that the total score of stress in the intervention group at the pregnancy test stage has significantly reduced compared to the beginning of the study [Table 1]. In search of finding associated studies on auriculotherapy and infertility anxiety, there has been no study so far to thoroughly examine and compare patient's mental state at different stages of IVF cycle and their response to auriculotherapy. There is considerable evidence which shows the psychological state of infertile patients affect their fertility conditions, and consequently the outcome of assisted reproductive treatment.[24,25] Evidence-based results on acupuncture and auriculotherapy further confirms the rewarding effects of using such methods in improving patient's psychological state, and reproductive system through increasing blood flow to pelvic organs and regulating endorphin release throughout the body.[13,32] The obtained results on the outcome of assisted reproductive treatment indicated that the intervention group had a higher rate of pregnancy compared to the control group, but the difference was not significant [Table 2]. Obviously, for achieving a successful pregnancy followed by IVF treatment, numerous factors such as the cause of infertility, gamete quality, physician's executive skills, and an ideal condition for embryo implantation are involved,[32] and naturally, having control over all these factors was not possible. Therefore, lack of significant difference could have been due to external factors which were not in control of the researcher. On the contrary, withholding intervention after embryo transfer stage due to executive and ethical reasons could have affected the results in this section of study. The obtained results in this part of the study are in line with two other studies titled: "Evaluating the correlation between perceived stress, acupuncture, and the rate of pregnancy in patients undergoing IVF therapy," and "Evaluating the effect of acupuncture on the outcomes

of IVF."[25,32] The results showed that the level of anxiety in patients undergoing IVF treatment was significantly lower than the control group, and there was a relatively higher rate of pregnancy in the intervention group compared to the control group, although the difference was not statistically significant. Considering the similarity between the results of the present study with the two aforementioned studies, we can conclude that performing intervention in the interval time from embryo transfer stage to pregnancy test stage can significantly increase the rate of pregnancy. Hence, conducting further studies in this area seems necessary.

The study titled, "Ear acupressure as an extra analogic before egg harvesting surgery in IVF therapy," showed that the rate of pregnancy in the group who received auriculotherapy using electrical device was significantly higher than the group who had auriculotherapy with needles, and the control group.[22]

However minor, there was a significant increase in the rate of pregnancy in the intervention group compared to the control group, and the cause of that could be related to implementing different methodologies in these studies.

Finally, the results of the present study showed that the observation of gestational sac and fetal heart rate (clinical pregnancy) one month after a positive pregnancy test in the intervention group was significantly higher than the control group, and this finding could indicate the comprehensive effect of acupuncture on body and it's physiologic stability.[11] These results are similar to the results of another study titled, "Ear acupressure can reduce stress levels and improve Assisted Reproductive Treatment."[26] According to the aforementioned study, performing auriculotherapy in the interval from egg harvesting surgery to embryo transfer stage could have effective results not only in reducing preoperative anxiety but also in increasing the rate of clinical pregnancy in the auriculotherapy group. Although the inclusion criterion of this study was cases diagnosed with infertility due to the obstruction of the fallopian tubes, all the participants were healthy in other aspects of fertility; even their husbands had normal spermogram. It seems that this matter could have potentially increased the chance of pregnancy in these patients.

However, in the present study, ovarian dysfunctions, and having at least one failed experience of assisted reproductive treatment were among inclusion criteria. Thus, considering the benefit of having different choices in selecting participants, we might conclude that performing auriculotherapy with the methodology used in the present study had more rewarding results in improving the outcome of IVF compared to the aforementioned study.

Eventually, it is worth mentioning that although auriculotherapy is an economic and safe technique, it requires trained practitioners plus auriculotherapy tools in order to have effective results on patients. Although attending auriculotherapy sessions on a regular basis could be difficult for patients, it could lead to better interaction between patients and practitioners; thus, further improve the results of the treatment. Having said that, midwives who work at infertility centers can learn the necessary skills to perform auriculotherapy on infertile patients. Lack of consistent and regular stimulation of seeds by patients, using different brands of drugs, lack of placebo group, and also lack of performing intervention after embryo transfer stage are among limitations of the present study.

Conclusion

The results of the study showed that auriculotherapy is probably effective in reducing stress and improving assisted reproductive treatment. This type of evidence can further clarify the necessity of implementing complementary medicine in infertility clinics. Therefore, considering the advantages and limitations of auriculotherapy, it is necessary to conduct more studies on the implementation of this method on infertile patients.

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Conflicts of interest

There are no conflicts of interest.

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