Effect of Low-Level Laser Therapy versus Electroacupuncture on Postnatal Scanty Milk Secretion: A Randomized Controlled Trial

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Am J Perinatol

Abstract

Background Postnatal scanty milk secretion is a common complaint. Some physical and medical interventions were advocated to help milk production. These interventions should be effective and safe for the mother and the infant.

Objective To compare the effects of low-level laser therapy and electroacupuncture on postnatal scanty milk secretion.

Study Design A randomized controlled study conducted on 60 healthy primiparous mothers with insufficient lactation. They were randomly divided into three equal groups: group A (control), group B (those who received low-power He–Ne laser beam on both breasts), and group C (those who received faradic current stimulation at Spleen 6, Liver 3, and Small Intestine 1 acupuncture points on both sides). All participants received 10 mg Domperidone three times a day and were given advice about lactation, nutrition, and fluid intake. Evaluation was done before and after the treatment program.

Results The mean serum prolactin, infant weight, and visual analog scale (VAS) score were significantly increased in the three groups posttreatment when compared with their corresponding levels pretreatment. Posttreatment serum prolactin was significantly elevated in group C more than the other two groups ($p = 0.001$ and 0.012, respectively). Also, it was significantly elevated in group B more than in group A ($p = 0.001$). The mean value of infant weight was significantly elevated in group C when compared with its corresponding values in both groups A ($p = 0.001$) and B ($p = 0.029$). The VAS score was significantly increased in both groups B and C when compared with group A ($p = 0.001$).

Conclusion Electroacupuncture is more effective than low-level laser therapy in increasing postnatal scanty milk secretion.

Clinical Trial Registration NCT03806062.

Keywords
- scanty milk secretion
- prolactin
- low-level laser therapy
- electroacupuncture

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received
April 7, 2019
accepted after revision
June 6, 2019

DOI https://doi.org/10.1055/s-0039-1693428.
ISSN 0735-1631.

Human milk is unique in its structure. It is superior to other feeding options regarding infant growth, health, development, and all other short- and long-term outcomes for both mature and premature infants.[1]

Between 2000 and 2008, the exclusive breastfeeding rates of up to 6 months decreased in the Middle East and North African (MENA) region to 28%. These rates were 16% in Pakistan, 25% in Iraq, 31% in Saudi Arabia, 38% in Egypt, and 44% in Iran. This decline started from the early 1980s and raised the demand for a new intervention to stop it.[2]

Worldwide, only 40% of infants with less than 6 months of age are exclusively breastfed. Approximately 820,000 infants could be saved every year if breastfeeding was increased to near universal levels.[3]

Many women face problems with breastfeeding even after successful start. These problems can lead to failure of lactation.[4]

Breast milk has all the required nutrients needed for infants during their first 6 months of life. This well-balanced diet can promote both physical and psychological well-being.[5] Maternal benefits of breastfeeding include lowering the risk of postmenopausal breast cancer development and the risk of osteoporosis. Puerperal benefits include proper uterine involution, decreased bleeding, and increased weight loss.[6]

Low-level laser therapy (LLLT) is frequently used to deal with breast problems in parturient women as mastitis and nipple soreness.[7,8] It also has a positive effect in increasing serum prolactin level and the flow of milk in addition to its effect in suppressing any breast inflammation.[9]

Application of He–Ne Laser beam for 10 minutes on each side of the breasts per session for 12 sessions was found to be effective in increasing both the milk flow (quantity) and contents (quality).[10]

In the Traditional Chinese Medicine, the milk production deficiency is thought to result from loss of harmony in *qi* (the flow of energy throughout the body), spleen *qi* deficiency (*pi qi xu*) in which the breasts are soft with insufficient milk production, or liver *qi* stagnation (*gan qi stagnation*) in which the breasts are distended with no free flow of milk.[11]

Acupuncture influences energy flows by needling the acupuncture points which lie along the body meridians to achieve a harmonious balance between physical, emotional, and spiritual states. The same effect can be achieved without the use of needles. These needleless stimulations are noninvasive and nontraumatic and are useful for individuals who are scared of needles. They are also associated with decreased risk of infection or bruise.[12]

Acupuncture is an effective treatment for increasing mothers' breast milk production.[11] Electroacupuncture is commonly used in Western medical acupuncture units. The stimulation can be done through electrodes connected to the acupuncture needles or through simple (noninvasive) external electrodes.[13]

Unfortunately, we have limited literature reviews to identify and compare the nonchemical methods such as laser and electroacupuncture used for the treatment of postpartum lactation deficiency. So, the aim of our study was to compare the effects of electroacupuncture and LLLT on postnatal scanty milk secretion.

Materials and Methods

This randomized controlled open labeled study was conducted at the outpatient clinics of Cairo university hospitals, Egypt after approval of the Faculty of Physical Therapy Ethical Committee. All women have signed an informed consent for participation in our study. Sixty healthy primiparous mothers were included. Their age ranged between 20 and 35 years and their body mass index (BMI) ranged between 25 and 30 kg/m^2. They attended the breastfeeding clinic complaining of insufficiency of lactation within the first month after normal vaginal delivery and they were using mixed feeding (both breast and bottle feeding, between three and six bottles per day). They had approximately the same nutrition as well as education level (housewives with a middle level of education). Insufficient lactation was defined as failure to deliver sufficient breast milk that maintains the daily nutritional requirement of their infant. The exclusion criteria included lactating mothers who suffered from postpartum hemorrhage, cardiorespiratory disease, diabetes mellitus, breast cancer, previous surgeries in the chest, breast, or the surrounding area, and anemia, as well as those who had any causes that hindered their normal breastfeeding (retraced, cracked, inflamed, or inverted nipples) or receiving contraceptive pills. Infants with conditions that may affect the lactation process such as congenital abnormalities of the mouth (tongue tie, cleft palate) and congenital heart disease were also excluded.

Randomization was achieved through a random number generator that selects numbers contained in a sealed opaque envelope prepared by an independent person who was not involved in the trial and blinded to the research protocol .

To ensure that equal numbers were allocated to each group, randomization was restricted to permuted blocks of different sizes. The sequences assigned to the participants were placed in envelopes containing the allocation to each group.

The participants in all groups completed the treatment program. Group A (control); group B received low-power He–Ne laser on both sides of the breasts; and group C received faradic current at Spleen 6, Liver 3, and Small Intestine 1 acupuncture points.

All participants were evaluated through careful history taking and full examination. Serum prolactin level was measured as follows: the blood samples were collected at the beginning and after the end of treatment procedures to detect the level of serum prolactin for all groups. Blood samples were collected 30 minutes after the start of suckling[14] at around 9 to 10 o'clock in the morning from the dominant arm at a half-lying position with the head supported on a pillow, arms rested beside the body and another pillow placed behind the back, and another one below the knees for the lactating mother to be relaxed as much as possible; the lactating mothers were fasting for at least 8 hours.[15] The infants were weighed at the beginning and

after the end of the treatment procedures. Each infant in all groups was placed over the infant weighing scale wearing only the underwear and the infant diapers were removed.

Visual analog scale (VAS) is a psychometric scale used to measure subjective matters that cannot be measured directly in the form of questionnaires. The responders mark their degree of agreement to a specific question along a continuous line between two endpoints.[16] VAS is more sensitive to small changes in which symptoms are rated.[17] It was used for the assessment of the degree of improvement in the flow of milk in all groups before and after the treatment procedures (►**Fig. 1**).

Each lactating mother in all groups had a VAS form containing a straight horizontal line. Its ends are the extreme limits of the parameter to be measured (the flow of milk) oriented from left to right. The mother selected the suitable description of her milk flow before and after the end of the treatment procedures.

Women in group A acted as a control group and received only medical treatment in the form of 10 mg Domperidone three times a day after meals and were advised about lactation, nutrition, and fluid intake all through the treatment duration (4 weeks).

Each woman in group B was put in the supine position on the treatment table with protective eyewear and exposing her breasts out of her clothes, and then both breasts were cleaned with alcohol. The laser apparatus was directed perpendicularly 50 cm over the breast to be treated; all metal objects were removed from the range of action of laser. The laser scan beam was adjusted to the size of the breast to be treated and treatment was performed for 10 minutes with a wavelength of 632.8 nm and a power output of 25 MW, and then the same was applied to the other breast. Each woman received three sessions per week for 4 weeks (total: 12 sessions). A He–Ne laser (Bravo TrezaSerie) device was used. The equipment was designed in compliance with international technical standards UNI EN ISO 9002 and En 46002 and complied with the safety requirements. All women in group B received medical and educational treatments as those in group A.

Group C women were treated by faradic stimulation (Body Shaping System, model B-333, made in China), at the following acupuncture points on both sides: Spleen 6 (Sanyinjiao), Liver 3 (Taichong), and Small Intestine 1 (Shaoze) using surface electrodes in addition to medical and educational treatments applied to women in the other two groups.

The SP-6 acupuncture point lies on the medial aspect of the leg approximately 3 cm above the medial malleolus, along the posterior border of the tibia (►**Fig. 1**).

The LIV-3 acupuncture point is located on the dorsal aspect of the foot, between the first and second metatarsal bones, in the depression proximal to the metatarsophalangeal joints and the proximal angle between the two bones (►**Fig. 1**).

The SI.1 acupuncture point is located on the little finger, ulnar to the distal phalanx, at the intersection of the vertical line of ulnar border of the nail and the horizontal line of the base of the little fingernail (►**Fig. 1**).

Each woman in group C was asked to lie in the half lying position. After localization of the points, the electrodes were fastened securely with an adhesive tape or an elastic band to ensure their proper contact with the skin over the

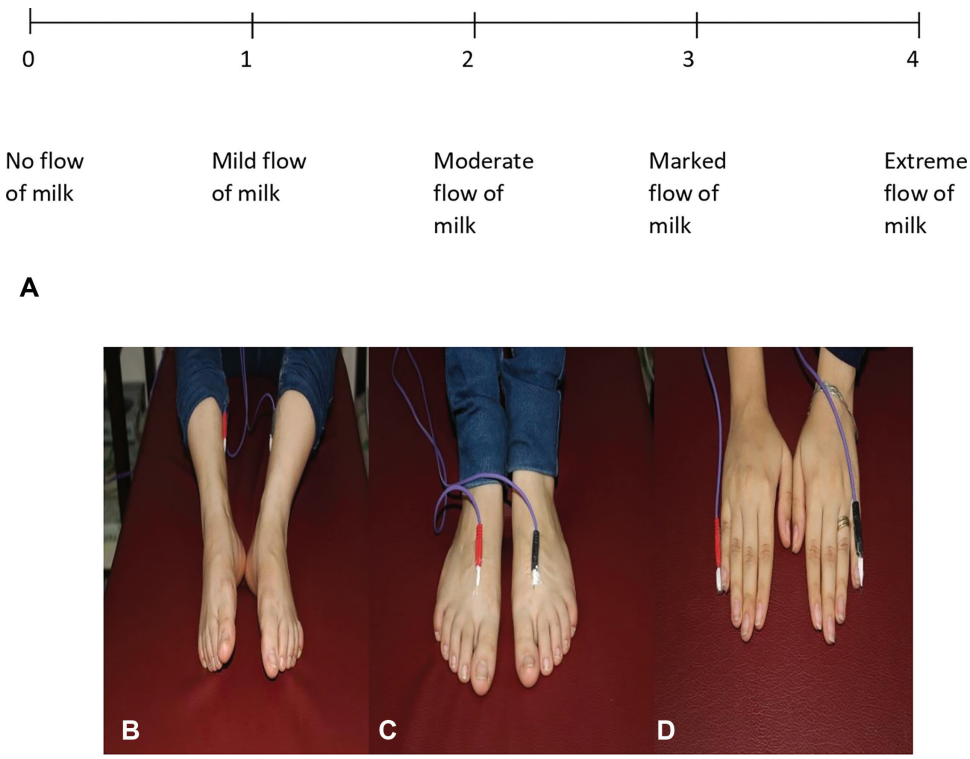

Fig. 1 (**A**) Visual analog scale for assessment of the flow of milk. Stimulation of (**B**) Spleen 6, (**C**) Liver 3 and (**D**) Small Intestine 1 acupuncture point by faradic current.

Table 1 Demographic features of the three studied groups

	Group A ($n = 20$)	Group B ($n = 20$)	Group C ($n = 20$)	F-value	*p*-Value
Age (y)	27.75 ± 3.31	27.45 ± 4.24	25.95 ± 2.80	1.520	0.228 (NS)
Weight (kg)	76.52 ± 5.43	76.15 ± 5.37	74.90 ± 4.05	0.581	0.563 (NS)
Height (cm)	163.98 ± 5.46	163.75 ± 6.54	163.15 ± 5.61	0.105	0.901 (NS)
BMI (kg/m^2)	28.45 ± 1.16	28.40 ± 1.08	28.19 ± 1.17	0.276	0.760 (NS)
Volume of bottle milk daily	452.7 ± 202.7	462.7 ± 223.5	461.1 ± 192.1	0.467	0.426 (NS)

Abbreviation: BMI, body mass index.
Note: Data are expressed as mean ± standard deviation. F = ANOVA test. NS = $p > 0.05$ = not significant.

acupuncture points. The intensity control of the stimulator was slowly increased until the patient could just feel the stimulation. The session lasted for 30 minutes. Each woman received three sessions per week for 4 weeks (total: 12 sessions).

Based on a pilot study, the sample size was calculated according to the difference in the mean value of serum prolactin between the three studied groups measured posttreatment, with an effect size of 0.42. Assuming $\alpha = 0.05$, a power of 80%, so a sample size of 20 patients per group would be required (GPower 301, http:www.psycho.uni-duesseldorf.de).

Statistical Analysis

Data were presented as mean ± standard deviation, median, minimum, and maximum. A test of normality, Kolmogorov–Smirnov test, was used to measure the distribution of pretreatment data. A comparison between normally distributed variables in the three groups was performed using one-way analysis of variance (ANOVA) followed by the least significant difference (LSD) test if significant results were recorded. Pairwise comparison (pre- vs. posttreatment) within the same group was performed using the paired *t*-test.

The comparison between nonnormally distributed variables in the three groups was performed using the Kruskal–Wallis ANOVA test followed by the Mann–Whitney test if significant results were recorded. A pairwise comparison was performed using the Wilcoxon signed-rank test.

The Statistical Package for Social Sciences (SPSS) computer program (version 19, windows) was used for data analysis. A *p*-value ≤ 0.05 was considered significant.

Results

In our study, all participants had completed the treatment program with no loss of follow-up cases.

There was no significant difference between the three study groups regarding maternal age or BMI (►**Table 1**).

At pretreatment duration, there was no statistical significant difference between the three groups regarding serum prolactin, infants' weight, and the VAS score (►**Table 2**).

Posttreatment serum prolactin showed a statistical significant difference between the three groups as it was

Table 2 Inter- and intragroup comparison between mean values of serum prolactin, infant weight (kg), and VAS score measured at pre- and posttreatment in the three studied groups

		Group A ($n = 20$) Control group	Group B ($n = 20$) Laser group	Group C ($n = 20$) Electroacupuncture group	F-value	*p*-Value
Serum prolactin	Pretreatment	19.66 ± 3.56	21.36 ± 4.65	20.44 ± 3.02	0.994	0.337 (NS)
	Posttreatment	21.66 ± 4.24	28.04 ± 6.24	31.91 ± 2.99	24.338	0.001 (S)
	p-Values vs. pretreatment	0.005 (S)	0.001 (S)	0.001 (S)		
Infant weight	Pretreatment	3.34 ± 0.36	3.37 ± 0.42	3.42 ± 0.56	0.187	0.830 (NS)
	Posttreatment	3.43 ± 0.37	3.61 ± 0.37	3.90 ± 0.50	6.590	0.003 (S)
	p-Values vs. pretreatment	0.001 (S)	0.001 (S)	0.001 (S)		
VAS score	Pretreatment	1.0 (0.0–1.0)	1.0 (0.0–1.0)	1.0 (0.0–1.0)	1.573[a]	0.455 (NS)
	Posttreatment	1.0 (0.0–2.0)	2.0 (1.0–3.0)	2.0 (1.0–3.0)	35.348[a]	0.001 (S)
	p-Values vs. pretreatment	0.025 (S)	0.001 (S)	0.001 (S)		

Abbreviation: VAS, visual analog scale.
Note: Data are presented as mean ± standard deviation. F = ANOVA.
[a]Kruskal–Wallis ANOVA test.

significantly elevated in group C when compared with its corresponding levels in the other two groups. Also, it was significantly elevated in group B when compared with group A ($p = 0.001$). Serum prolactin measured posttreatment was significantly increased in the three groups when compared with its corresponding levels measured pretreatment (►**Table 2**).

Posttreatment infants' weight was significantly increased in group C when compared with groups A and B. There was no significant difference between groups A and B. It was also increased in all women posttreatment when compared with its pretreatment measures (►**Table 2**).

The VAS score posttreatment showed a statistical significant difference between the three groups where its median value was significantly increased in groups B and C when compared with group A. However, there was no statistical significant difference between groups B and C. The posttreatment VAS score was significantly higher in all women when compared with its pretreatment measures (►**Table 2**).

Discussion

Electroacupuncture and LLLT are effective, noninvasive, cheap, and safe methods that can be used to improve milk flow in women with scanty milk secretion. The results of this study proved that electroacupuncture is more effective than LLLT on postnatal scanty milk secretion.

Campbell-Yeo et al (2010) studied the effect of Domperidone alone in preterm mothers experiencing lactation failure. They reported an increase in the milk volume without substantially altering its nutrient composition.[18] Domperidone increases prolactin secretion indirectly through antagonizing the action of dopamine. It should not be used as the first-line therapy unless all other factors that may result in insufficient milk supply have been dealt with first.[19]

Comparing the posttreatment results between the laser group and electroacupuncture group, we found a significant increase in the serum prolactin levels and weights of the babies in the electroacupuncture group more than the laser group with no significant difference in the VAS score (for degree of improvement in the flow of milk).

The results of this study agree with a study that was conducted to investigate the response of milk production to LLLT in scanty lactating ladies. This proves that LLLT improves both the quantity and quality of milk.[10]

It was also proved that the application of He–Ne laser combined with ultra-short wave could enhance the postdelivery lactation, milk ejection, and lower the incidence of mastitis.[20]

LLLT was used for 44 women with an early milk insufficiency. LLLT increased the quantity of the secreted milk associated with an increase of the serum prolactin level. Laser is applied successfully in milk insufficiency that results from stagnant and inflammatory changes in the lacteal gland.[9]

These results also agree with a study which was done to test the effectiveness of low-power He–Ne laser beam irradiation in rats. The authors reported enlargement of the mammary gland cell nucleolus, increased rough endoplasmic reticulum, further development of the Golgi complex, increased volume of cytoplasm and secretory granules, and enlargement of the mitochondria and an increase and lengthening of its margins, as well as the blood vessels between the mammary glands became more numerous in irradiated rats. The study also showed that the crowded appearance of lymphocytes and muscle silk of epithelial tissue were increased and lengthened.[21]

The primary mechanisms of laser are improvements in microcirculation and protein synthesis. It has been proved that nitrosyl complexes of heme proteins, such as hemoglobin and cytochrome c, are the essential chromophores of laser radiation. They can produce free nitric oxide, which relaxes blood vessel and enhances the mitochondrial respiration. This was observed through the use of low-intensity laser radiation.[22] LLLT increases ATP production, the mitotic activity of the cell, protein produced by mitochondria, and microcirculation (through the formation of new vessels from preexisting ones leading to increase in cell nourishment).[23]

The results of this study were supported by another study that measured the effect of electroacupuncture on milk supply. Their study group received electroacupuncture at the Small Intestine 1acupuncture point and the control group received electroacupuncture at the Large Intestine 1 acupuncture point. The degree of improvement was 97.8% in the study group and 24.3% in the control group.[24]

Also, the results of this study were supported by a study that randomized women with insufficient milk supply postpartum to either acupuncture ($n = 41$) or routine observation ($n = 43$). The study group received six sessions over 2 weeks. The main acupuncture point was Small Intestine 1. After 3 weeks, improvement occurred in 60 and 98% of the observation and acupuncture groups, respectively. At 3 months of age, exclusive breastfeeding was achieved in 15% of the observation group and 35% of the treated group.[25]

Acupuncture can stimulate milk secretion after delivery through increasing the serum prolactin level. So, it is used in the treatment of deficient milk secretion associated with depression and mental lability.[26]

Acupuncture point stimulation may alter the level of chemical neurotransmitters, the natural electrical currents, or electromagnetic fields in the body. The balance between the physical and mental health depends on a free flow of energy (*qi*) via the meridians of both sides of the body. If the speed of energy flow is altered or its channels are obstructed or blocked, this will lead to dysfunctions as pain, depression, and many other chronic or acute symptoms. Acupuncture stimulation releases certain hormones and chemicals that can regulate the function of endocrine and nervous systems.[27]

Applying the needles along the meridians to specific acupuncture points and stimulating them through rotation, heating, or electrical stimulation (electroacupuncture) will correct any malfunctions, treat illnesses, or relieve the annoying symptoms through accelerating the physiological functions of the body.[28]

As blood is the source of breast milk, excessive blood loss during labor may result in deficient lactation. A long and difficult labor leads to depletion of *qi* and this may result in scanty milk secretion when there is not enough *qi* to express the breast milk. Emotional problems such as worry, anger, frustration, or resentment cause stagnation of Liver-*qi*: the liver influences the breast and controls the nipple, and stagnant *qi* obstructs the connecting channels of the breast so that the breast milk cannot flow.[29] So electroacupuncture could reverse all these abnormalities, allowing free flow of milk.

Further studies are required to know the short- and long-term effects of other treating modalities such as mother's weight reduction and physical exercise on the milk production and infant growth. Also further studies are needed to compare the effect of exercise, breast massage, LLLT, acupuncture, and galactagogic medications on lactation process.

In the current study the primary limitation was the non-assessment of psychological status of the lactating women during the treatment period as well as the cooperation of participating women. To overcome these limitations the included participants were of the same social and economic standard (housewives with the same level of education). Within those limitations, the pioneer contribution of this study is that it compared the effects of LLLT versus electroacupuncture on postnatal scanty milk secretion, which had not been reported before. We think that the results of this work could add new guidelines for improving the flow of milk after delivery.

We concluded that both electroacupuncture and LLLT appeared to be effective, noninvasive, cheap, and safe methods of improving the flow of milk in women suffering from postnatal scanty milk secretion. The results of this study proved that electroacupuncture was more effective than LLLT on postnatal scanty milk secretion.

Authors' Contributions

A.M.M.: project development, data management, data analysis, manuscript writing and editing, and literature research. M.E.H.: project development, data collection, data analysis, manuscript writing, and literature research. W.M.K.: project development, data management, data analysis, manuscript writing, and literature research. A.H.A.: project development, data collection, data management, and literature research. M.A.: project development, data collection, and data management. A.N.A.: project development, data collection, data management, data analysis, manuscript writing, and literature research. A.E.-L: project development, data management, data analysis, manuscript writing, and literature research. M.N.F.: data analysis and manuscript writing. D.F.: data analysis and manuscript writing.E.A.H.: data analysis and manuscript writing.B.H.: data reanalysis and manuscript revision. All authors read and approved the final manuscript.

Note

Informed consent was obtained from all individual participants included in the study.

Ethical Approval

This study was approved by Kasr Alainy Ethical Committee of Cairo University People's Hospital. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Funding

None.

Conflict of Interest

None declared.

Acknowledgments

Many thanks to all women who participated in this study for their cooperation.

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