Original Article

Acupuncture to Boost Breast Milk in Postpartum Hypogalactia: Randomized Controlled Trial

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Background: Breast milk is appropriate and useful but the exclusive breastfeeding rate in Thailand was quite low at only 23.1%. Hypogalactia is one of the important barriers of breastfeeding. Studies in Asia and the west have shown that acupuncture could boost breast milk. However, some articles had controversial result. There has been no study to assess efficiency of acupuncture in early postpartum hypogalactia.

Objective: To compare the efficacy of acupuncture and conventional treatment for stimulating breast milk in early postpartum hypogalactia at 48 hours.

Materials and Methods: A randomized, prospective, clinical trial was used for the present study. Sixty postpartum hypogalactic women of term gestation in postpartum ward in Charoenkrung Pracharak Hospital between March 1, 2020 and February 28, 2021 were enrolled. They were randomized into acupuncture and control groups. In the study group, mothers received once a day acupuncture at 13 acupoints without electrode for three consecutive days by qualified Traditional Chinese Medicine practitioner other than conventional treatment. Breast milk quantity were measured at day 1, day 7, and day 14 after the intervention.

Results: Mean age of all participants was 29.72±5.96 year, mostly primigravida, delivered by vaginal route. Mean milk volume in the treatment group were significantly higher than the control group ($p<0.05$) with day 1 at 19.00±22.25 versus 5.97±6.08 mL, day 7 at 78.10±60.38 versus 40.17±28.82 mL, and day 14 at 128.33±64.86 versus 75.00±57.96 mL. The amount of breast milk in the treatment group were 3-fold, 2-fold, and 1.7-fold times more than the control group at day 1, day 7, and day 14, in respective order ($p<0.05$).

Conclusion: Accurate acupuncture intervention could boost breast milk production in early postpartum hypogalactia at 48 hours.

Keywords: Postpartum hypogalactia; Acupuncture; Traditional Chinese Medicine (TCM)

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Breast milk is the most appropriate food for newborn because it contains complete nutrition, immunization, and growth factors. The World Health Organization (WHO) and United Nations International Children's Emergency Fund (UNICEF) (2018) recommended that baby should receive exclusive breastfeeding for six months then accompany with complementary food until two years of age or more[1]. Although breastfeeding showed benefits for mother and baby[2,3], the global situation of exclusive breastfeeding at six months was 41% (UNICEF 2019)[4], and in Thailand the report of exclusive breastfeeding at six months was only 23.1% (2016)[5]. Barriers of breastfeeding can be from mother, baby, or environment. Hypogalactia, or the inadequate amount of breast milk or delayed breast milk production, is one of the major causes for non-exclusive breastfeeding[6,7]. In Thailand, one report from Srinagarind Hospital (2016) reported that low milk quantity at two weeks postpartum was the major reason for non-exclusive breastfeeding in 59.1%[7].

Moreover, the delay breast milk production causes stress and interfere with the oxytocin reflex, which motivates inadequate amount of breast milk. Treatment of hypogalactia is regular suckling or expression of breast milk every two to three hours and stress reduction. The other treatment of this condition are pharmacological treatment, herbs, and alternative medicine such as breast massage, Thai massage, or acupuncture.

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Acupuncture is one of the alternative medicines inherited from traditional Chinese medicine focusing on balancing the body. Traditional Chinese medicine classify hypogalactia into two groups. First group is Qi and blood deficiency. The symptom of this condition is inadequate breast milk along with fatigue, dry skin, loss of appetite, loose stool, and no tighten of breast, respectively. The other group is Liver Qi stagnation, which milk production is localizing in breast[8], is not included in these studies.

The aim of the present research was to solve the problem of hypogalactia in early postpartum period at 48 hours post-delivery.

Materials and Methods

The present study was approved by the Ethics Committee of the Bangkok Metropolitan Administration (S005h/62), with written informed consent form signed by all subjects. Sixty cases of postpartum hypogalactia in postpartum ward, Charoenkrung Pracharak Hospital, Bangkok, Thailand between March 1, 2020 and February 28, 2021 were enrolled. They were all post 48 hours after delivery, inpatient women in Qi and blood deficiency group, defined as the patients who had symptoms of inadequate breast milk without tightened breast. They had less than 5 mL of breast milk in one time of expression. All of them received conventional treatment for hypogalactia, which is stress reduction and baby suckling or breast milk expression every three hours, in respective order. Patients had written informed consent and were screened to define their eligibility for the present study. Participants were randomized to the control and the study groups, according to computer generated numbers.

Inclusion criteria were women 48 hours post-delivery, aged 18 to 50 years and who delivered 37 to 42 weeks gestational age by vaginal route or Cesarean section. Exclusion criteria included abnormal bleeding, coagulation defect, thrombocytopenia, anomaly of breast, extensive trauma of breast, history of breast surgery, effective on breastfeeding, and using contraindicated drugs for breastfeeding.

In the study group, the mothers received once a day acupuncture for three consecutive days by qualified Traditional Chinese Medicine practitioner. The location of thirteen acupoints[9,10] is shown in the Figure 1. The sterile copper head steel needles of Eacu brand (manufacture by Maanshan Bond Medical Instruments Co., Ltd., Anhui, China) of 0.18 mm in diameter and 25 mm in length were used. The needles were inserted 0.1 to 1.5 inch in depth until the patient felt irradiating sensation[11] and retained for 30 minutes before removed.

Amount of breast milk was collected by hand expression daily around 8 to 12 a.m., after last suckling or hand expression for two to three hours, measuring by 5 mL plastic syringe. Breast milk quantity of both groups were measured at day 1, day 7, and day 14, respectively.

Statistical analysis

Data were analyzed by parametric and non-parametric statistic using IBM SPSS Statistics, version 26 (IBM Corp., Armonk, NY, USA). Demographic data were expressed as mean ± standard deviation (SD). Continuous data was investigated for normal distribution (Kolmogorov-Smirnov test) before using the parametric statistics. The differences between continuous data were examined with unpaired t-test for the normal distributed data and Mann-Whitney U test for data not normally distributed. Repeated measurement of ANOVA was used for comparison of amount of breast milk and pain score after treatment. A p-value less than 0.05 was considered as significant.

Sample size[12] was estimated based on the study by Esfahani et al[13] as follows:

$$n_{trt} = \frac{(z_{1-\alpha/2} + z_{1-\beta})^2 \left[\sigma^2_{trt} + \frac{\sigma^2_{con}}{r}\right]}{\Delta^2}$$

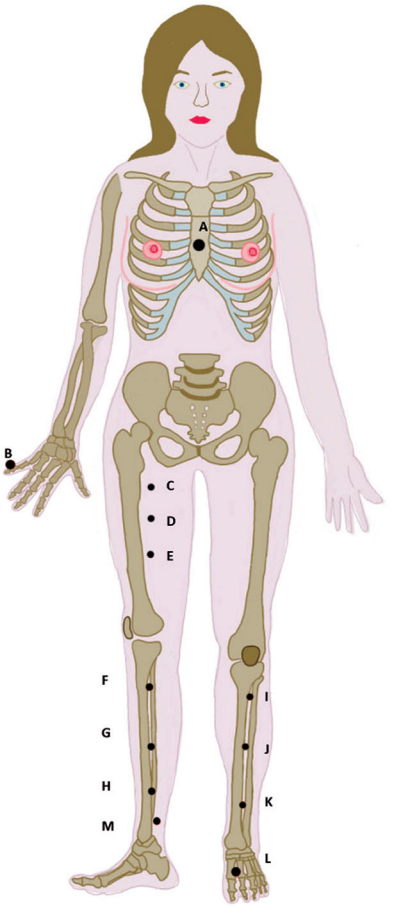
$$r = \frac{n_{con}}{n_{trt}}, \Delta = \mu_{trt} - \mu_{con}$$

Where n_{trt} was sample size of each group, Z_α and Z_β are Z-value of type I and type II errors, μ_{trt} and μ_{con} were amount of breast milk in acupuncture and control group, σ_{trt} and σ_{con} were SD in acupuncture and control group. According to Esfahani et al[13], amount of breast milk in acupuncture group was 33±13.44 mL, whereas 17.7±9.4 mL in control group. These studies considered α=0.01, β=0.10 (then $Z_{\alpha/2}$=2.58, Z_β=1.28) and ratio of n_{con}/n_{trt}=1. The authors obtained n=18. However, for accuracy data, the authors added 50% samples, so, each group required 30 patients.

Results

Sixty subjects attended the present study, 30 in the acupuncture group and 30 in the control group. Mean age of all patients was 29.72±5.96 years. They were mostly primigravida and delivered by vaginal route. The mean gestational age was 38.52±1.07 weeks.

Table 1 and 2 shows the demographic data and baseline values of the two groups. There was no significant difference between the two groups



A = Tan Zhong: CV17 (anterior midline, level of 4th ICS**)

B = Shaoze: SI1 (ulnar side 5th finger, 0.1 cun* from nail)

C = Tian Huang: ML88.13 (3 cun* proximal from D)

D = Ming Huang: ML88.12 (medial aspect of thigh, midpoint)

E = Qi Huang: ML88.14 (3 cun* distal from D)

F = Tian Huang: ML77.17 (medial aspect of leg, between the upper border of tibia and gastrocnemius)

G = Di Huang: ML77.19 (7.5 cun* proximal from medial malleolus)

H = Ren Huang: ML77.21 (3.5 cun* proximal from medial malleolus)

I = Si Hua Shang: ML77.08 (3 cun* distal from patella)

J = Si Hua Zhong: ML77.09 (7.5 cun* distal from patella)

K = Si Hua Xia: ML77.11 (12.5 cun* distal from patella)

L = Tai Chong: LR3 (on the dorsum of foot, between 1st and 2nd metatarsal bone)

M = Fu Liu: KI7 (anterior border of Achilles tendon)

* cun=Chinese unit of length

** ICS=intercostal space

Figure 1. Illustration of acupuncture points name[10,11].

Table 1. Demographic data of the mothers

	Acupuncture group (n=30); n (%)	Control group (n=30); n (%)
Age (year); mean±SD	28.87±5.91	30.57±5.98
Parity		
G1	17 (56.67)	12 (40.00)
G2	7 (23.33)	9 (30.00)
G ≥3	6 (20.00)	9 (30.00)
Gestational age (week); mean±SD	38.50±1.17	38.53±0.97
Pre-pregnancy BMI (kg/m^2); mean±SD	22.89±4.51	23.52±5.74
Hemoglobin level (g/dL); mean±SD	11.72±1.24	12.22±1.18
Route of delivery		
Normal delivery	17 (56.70)	15 (50.00)
Vacuum extraction	1 (3.30)	0 (0.00)
Cesarean section	12 (40.00)	15 (50.00)

SD=standard deviation; BMI=body mass index

Table 2. Demographic data of the babies

	Acupuncture group (n=30); n (%)	Control group (n=30); n (%)
Sex		
Male	16 (53.30)	11 (36.70)
Female	14 (46.70)	19 (63.30)
Birth weight (g); mean±SD	3,034.40±426.84	3,207.00±344.48
Early suckling		
Yes	15 (50.00)	13 (43.30)
No	15 (50.00)	17 (56.70)
Rooming in		
Yes	17 (56.70)	25 (83.3)
No	13 (43.30)	5 (16.7)

SD=standard deviation

in age, parity, gestational age, pre-pregnancy body mass index (BMI), mother's hemoglobin level, route of delivery, baby gender, baby's birth weight, early suckling, and rooming in.

Table 3 shows the comparison of breast milk quantity between the two groups. Mean breast milk

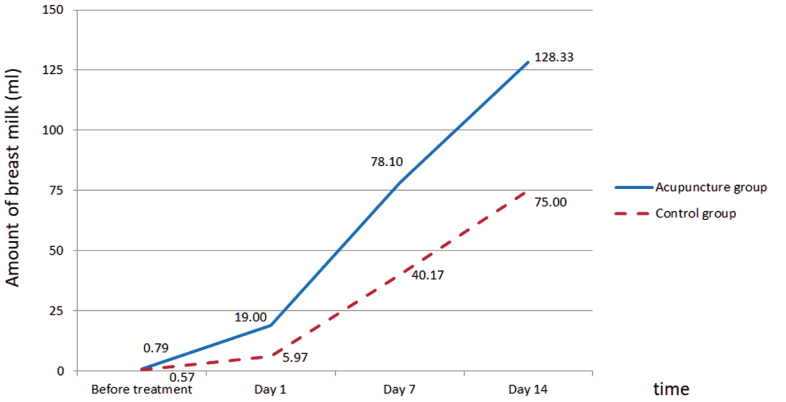


Figure 2. Amount of breast milk of 2 groups.

Table 3. Breast milk quantity in 1 meal

	Acupuncture group (n=30); mean±SD	Control group (n=30); mean±SD	p-value*
Before treatment	0.79±1.14	0.57±0.82	0.314
Day 1 after treatment	19.00±22.25	5.97±6.08	0.004**
Day 7 after treatment	78.10±60.38	40.17±28.82	0.001**
Day 14 after treatment	128.33±64.86	75.00±57.96	<0.001**

* Mann-Whitney U test, ** Highly significant difference

volume before treatment, day 1, day 7, and day 14 after the intervention were 0.79±1.14, 19.00±22.25, 78.10±60.38, and 128.33±64.86 mL, respectively, in acupuncture group and 0.57±0.82, 5.97±6.08, 40.17±28.82, and 75.00±57.96 mL, respectively, in the control group. Mann Whitney U test showed no statistical difference before treatment of the two groups, but the amount of breast milk was more in acupuncture group compared to control group ($p<0.05$) in day 1, day 7, and day 14 after intervention as shown in Figure 2.

Discussion

Breastfeeding has the advantages for both mother and baby[2,3]. Breast milk is recommended by WHO and UNICEF, that baby should receive exclusive breastfeeding for six months then accompany with complementary food until two years of age or more[1]. The rate of exclusive breastfeeding at six month was quite low, especially in Thailand, with only 23.1% in the year 2016[5]. One of the barriers of non-exclusive breastfeeding is hypogalactia[6,7].

Conventional treatment for hypogalactia consist of regular suckling or expressing of breast milk every two to three hours and stress reduction. Alternative treatment for hypogalactia added to the conventional treatment are pharmacological treatment, herbs, massage, or acupuncture and moxibustion.

Acupuncture and the others such as acupressure, acupoint massage, and electroacupuncture, are variant of Traditional Chinese Medicine (TCM). TCM has the principle of treatment to restore the balance of Qi, which is the body's vital life force or energy. Several authors published results of the effect of TCM on hypogalactia. In 2008, Lixin et al conducted randomized controlled study for hypogalactia. They had random patients with insufficient lactation of 2 to 5.5 days postpartum from Qi and Blood deficiency and Liver stagnation into two groups, electroacupuncture and control group. They found that, both groups increase the amount of breast milk after completing the treatment but the amount of milk in the electroacupuncture was increase more than in the control group ($p<0.01$). The electroacupuncture group could maintain prolactin level compared to the control group[14].

Concordance with the study from Neri et al 2011, which divided hypogalactic women at three months postpartum into acupuncture and observation groups. The results showed the exclusive breastfeeding rate at three weeks post enrollment and the third month of the infants' age were higher in the acupuncture group than in the observational group. This paper did not mention about breast milk volume[15]. The same result was also presented in the research of Esfahani et al in 2015. They conducted randomized clinical trial in the group of hypogalactia from ten days until six months post-delivery into acupressure and control groups. The result showed that mean breast milk volume in the acupressure group was significantly more than in the control group[13].

In 2019, Lu et al had randomized eighty 48-hour

Table 4. Results of previous study

Source	Year	Number of patients (case:control)	Method	Country	Type of hypogalactia	Lactational period	Result/outcome
Li[20]	2003	9:6:12	TCA:SA:Control	Australia	N/A	12 to 133 days postpartum	Infant of those mothers received TCA weighted 160.13 grams more than those whose mother received SA ($p<0.1$)
Wang, et al.[17]	2007	138:138	Electroacupuncture at Shaoze (SI1):Control-electroacupuncture at Shangyang (LI1)	China	N/A	N/A	Breast milk volume and prolactin level in Shaoze group more than control group ($p<0.01$)
He, et al.[19]	2008	Total 276 cases	Acupuncture at Tanzhong (CV17): Chinese drug (Tongre Decoction)	China	N/A	N/A	Neonatal body weight no difference in two groups
Lixin, et al.[14]	2008	46:46	Electroacupuncture:Control	China	Qi and blood deficiency, Liver Qi stagnation	2 to 5.5 day postpartum	Increase breast milk and maintain prolactin level in treatment group ($p<0.01$)
Neri, et al.[15]	2011	41:43	Acupuncture:Observation	Italy	Qi and blood deficiency, Liver Qi stagnation	Before 3 months postpartum	Exclusive breastfeeding rate at age 3 months in acupuncture group higher than in observation group ($p<0.03$)
Esfahani, et al.[13]	2015	31:29	Acupressure:Control	Iran	N/A	10 days to 6 months postpartum	Mean milk volume of acupressure group more than in control group ($p<0.001$)
Zhu, et al.[18]	2018	28:30	Acupoint massage:Control	China	N/A	3 days postpartum	Breast milk volume no significant difference in 1st and 2nd day, controversial result in 3rd to 5th day ($p<0.01$)
Lu, et al.[16]	2019	40:40	Acupoint massage:Control	China	N/A	48 hours postpartum	Breast milk production in acupoint massage group higher than control group ($p=0.000$)
Erfina, et al.[21]	2019	Total 80 cases	Acupressure:Control	Indonesia	N/A	24 hours postpartum	Breast milk volume in acupressure more than control group
Sulymbona, et al.[22]	2020	35:35	Acupressure:Control	Indonesia	N/A	N/A	Breast milk production in acupressure group increase more than control group
Maged, et al.[23]	2020	20:20:20	Electroacupuncture:LLLT:Control	Egypt	N/A	Before 1 month postpartum	Infant weight and prolactin level more elevated than other 2 groups
The present study	2021	30:30	Acupuncture:Control	Thailand	Qi and blood deficiency	48 hours postpartum	Breast milk volume in acupuncture group higher than control group ($p<0.05$)

TCA=Traditional Chinese Acupuncture; SA=Sham Acupuncture; LLLT=low-level laser therapy

postpartum women who underwent Cesarean section and had suffered from insufficient milk production into two groups, the acupoint massage and the control group. The results revealed breast milk production in the acupoint massage group was significantly higher than in the control group at 24-hour and 48-hour post intervention by 13-fold and 10-fold, respectively ($p=0.000$)[16]. Wang et al (2007) displayed the effect of electroacupuncture st Shaoze (SI1) and Shangyang (LI1) points, to the treatment and control groups, respectively. The result showed higher breast milk volume and prolactin level in the treatment group than in the control group ($p<0.01$)[17].

On the other hand, a controversial study by Zhu et al (2018) revealed no significant difference of breast milk volume between treatment and control groups at three day postpartum for the first and second day ($p>0.05$)[18]. In addition to the comparing study between Traditional Chinese Acupuncture (TCA) Tanzhong (CV17) point and Chinese drug (Tongre Decoction), He et al (2008) found no significant difference of neonatal body weight[19].

The present study performed a randomized controlled trial of early postpartum period at 48 hour, which is a critical time for non-exclusive breastfeeding. The authors selected only Qi and blood deficiency mother that indicated delayed breast milk production without stagnation. The results revealed breast milk volume was increased in both groups at day 1, day 7, day 14 post-TCA. The amount of breast milk in treatment group were 3-fold, 2-fold and 1.7-fold times more than control group in day 1, day 7, and day 14, in respective order ($p<0.05$). No complication was observed in all studied patients (Table 4).

Conclusion

Acupuncture intervention could boost breast milk production in hypogalactic women in early postpartum period at 48 hours, under qualified Traditional Chinese Medicine practitioner and using specific acupoints. Further studies of larger population combining other alternative treatment such as massage or herbs, are encouraged.

What is already known on this topic?

Studies about acupuncture and other Traditional Chinese Medicine were shown to solve the problem of postpartum hypogalactia. Type of hypogalactia, onset, and duration of condition were different between studies. The results of the studies were varied, with some stimulating production and others having no significant difference. There is still no definite alternative method to treat hypogalactia in early postpartum at 48 hours, which is the critical period for successful exclusive breastfeeding.

What this study adds?

The present study used acupuncture to stimulate breast milk production in early postpartum at 48 hours. This is different from the previous studies. The subjects of delayed breast milk production were in the Qi and Blood deficiency group and used specific groups of acupuncture points. The study defined the outcome of treatment by showing the accurate increase in quantity of breast milk production at day 1, day 7, and day 14, after three consecutive days of acupuncture, in terms of fold time number of breast milk volume.

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Conflicts of interest

The authors declared no conflicts of interest in this article.

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