ORIGINAL ARTICLE

Efficacy of Steamed Ginger Extract Capsule on Breast Milk Flow Rate Among Primiparous Women Following Normal Vaginal Delivery: A Randomized, Double-Blind, Placebo-Controlled Trial

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Background: Inadequate milk production is common after delivery. In Thai traditional medicine, steamed ginger is used to promote lactation, and recently its extract has been developed in capsule form as a convenient and standardized preparation for postpartum women.

Objective: To study the efficacy and side effects of steamed ginger extract capsule and placebo for promoting milk production in postpartum primiparous women after normal vaginal delivery.

Materials and Methods: The study was conducted using a double-blind, two-group design. Sixty-six women who had spontaneous vaginal deliveries were divided into two groups. The control group received a placebo, and the intervention group received the steam ginger extract capsules three times a day for three days, with the first dose starting two hours after delivery. The Numerical Rating Scale of milk flow rates was used for milk production assessment.

Results: Demographic and obstetric characteristics between the two groups showed no significant differences. In terms of milk flow, the ginger extract group outperformed the placebo group. The difference was statistically significant ($p<0.05$). On the right breast after 24 and 48 hours, the mean scores in the groups receiving ginger extract were 0.73±0.12 and 3.55±0.09. While those in the groups receiving placebo were 0.70±0.11 and 1.82±0.13. On the left breast after 24 and 48 hours, the mean scores in the ginger extract group were 0.85±0.13 and 3.73±0.80, whereas the mean scores in the placebo group were 0.91±0.08 and 1.79±0.10, respectively.

Conclusion: Steamed ginger extract could improve milk flow rate in Postpartum primiparous women after normal vaginal delivery. Furthermore, no significant adverse effects were reported during the study period.

Keywords: Steamed ginger extract; Milk flow rate; Postpartum women

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Inadequate breastmilk production is one of the breastfeeding problems. Breastfeeding is extremely beneficial to infants and mothers. Breast milk contains important antibodies and nutrition for babies. Breastfeeding triggers contractions of the uterus[1]. Insufficient milk supply can reduce maternal breastfeeding confidence and contribute to early formula supplementation and breastfeeding cessation[2,3]. In the Thai traditional scripture for women's health, the Mahachotharat scripture, it is found that ginger is widely used as a food and medicinal plant after delivery, in treatments to enhance breastmilk production. A previous study of ginger has been reported, which showed high total phenolic content[4]. The 6-gingerol and 6-shogaol were marker compounds of the 95% ethanol extract of steamed ginger by the high-performance liquid chromatography (HPLC) technique[5], and it has been shown that 6-gingerol and 6-shogaol have efficacy as antioxidants, anti-inflammatories[4,6-8],

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vasodilation, and hyperthermia[9]. In addition, ginger also has the property of warming up the peripheral temperature, possibly by the effect of vasodilatation[9], a mechanism that may explain its possibility to boost the milk production through increased blood supply of the lactating breasts[10].

For these reasons, researchers undertook to compare steamed ginger extract with a placebo by using milk flow rate to identify the breast milk production of postpartum primiparous women after normal vaginal delivery.

Materials and Methods

Study design

A randomized controlled clinical trial of a two-arm parallel-group design was conducted to compare the efficacy of steamed ginger extract and placebo for promoting milk flow rate of postpartum primiparous women after normal vaginal delivery. Sixty-six women who were admitted to the postnatal ward at Thammasat University Hospital were enrolled in the study. The allocation sequence was concealed using a centralized, web-based randomization system. Investigators entered participant details into the system, which automatically generated the group assignment only after enrollment was confirmed.

Inclusion and exclusion criteria

The population consisted of postpartum primiparous women after normal vaginal delivery. The procedure was explained to the participants, and written informed consent was obtained.

The inclusion criteria: participants were being 20 to 34 years of age, first normal labor, healthy, had no history of pregnancy toxemia, no liver disease, no kidney disease or gastrointestinal bleeding during pregnancy, not participating in other research project, no postpartum hemorrhage, willing to sign the consent form, do not take a medication regularly, no smoking, and no drinking alcohol during pregnancy.

The exclusion criteria: participants were allergic to herbal remedies and did not follow treatment correctly.

The discontinuation criteria: volunteers are allergic to ginger extract, do not follow the instructions of the researcher, have adverse reactions or serious danger, such as swelling, nausea, vomiting, and chest discomfort, will discontinue the study.

Termination criteria: volunteers receiving ginger extract capsules showed serious side effects.

Sample sizes

Sample sizes were based on the necessity to demonstrate a significant difference between steamed ginger extract and placebo. The sample size was calculated to be at least 30 women per group. This calculation was based on a population significance level of 0.05 and a power of 0.8[11]. With an adjustment for 10% dropout rate, the sample size becomes 33 cases in each group. The sample selection consisted of simple random sampling by population criteria and dividing sample into the following two groups: group 1 as an experimental group who received 100 mg ginger extract in capsules after meals, to take two capsules per time (200 mg), three times a day for three days, and group 2 as the control group who received 500 mg placebo capsules after meals, to take two capsules per time, three times a day for three days.

Raw materials and drug preparation

Raw materials:

Fresh ginger rhizomes used in the study were from plants grown under Good Agricultural Practice (GAP) at Nam Nao District, Phetchabun Province, Thailand. The ginger rhizomes were cleaned, washed, air-dried, and steamed with autoclave at 121°C and 15 psi for 15 minutes and ground into powder. The powder was macerated in 95% ethanol for three days and filtered through Whatman No. 1 filter paper. The filtrate was dried by rotary evaporator. The percentage yield of 95% ethanol extract of steamed ginger (ginger capsule) was 4.71%. The 95% ethanol extract of steamed ginger (ginger capsule) had an inhibitory effect on prostaglandin E_2 (PGE_2) and nitric oxide (NO) release with IC_{50} values of 0.40±0.06 and 13.47±0.20 μg/mL[4], respectively, and high total phenolic contents with 108.60±1.14 GAE mg/g[4]. The 6-gingerol and 6-shogaol were marker compounds of the 95% ethanol extract of steamed ginger extracts by the HPLC technique[5]. The 95% ethanol extract of steamed ginger had the content of 6-gingerol and 6-shogaol with 65.42±4.23 and 48.12±2.54 mg/g of extract, respectively[6]. The 95% ethanol extract of steamed ginger passed the standard of quality tests, including loss on drying, total ash, acid insoluble ash, extractive value, total aerobic microbial count, and heavy metals according to the standard values set by The Thai Herbal Pharmacopoeia[4].

Preparation of steamed ginger extract and placebo capsules:

1) Preparation of steamed ginger extract capsules: The excipient for preparation of steamed ginger extract to be packed in capsules contains the

diluent Avicel® PH 102 (microcrystalline cellulose PH 102). Lubricants include magnesium stearate. From the earliest days of direct compression until the present, a glidant has been required to enhance the flow of powder, and AEROSIL® colloidal silicon dioxide is the material of choice. Each capsule has 100 mg ginger extract. The ginger extract was blended by gliding Avicel® PH 102 past strainer number 80 and then mixing. A mortar was used to roll them together. The mixture was then glided again through strainer number 80 and then 100, until the powder was uniform. The lubricant was then mixed into the final product before entering the capsule-filling machine. The capsules were prepared in the Center of Excellence in Applied Thai Traditional Medicine Research (CEATMR), Thammasat University, Thailand.

2) Preparation of placebo capsules: Placebo capsules were filled with lactose monohydrate and were labelled "0" (500 mg/capsule).

Medication administration; dose calculation

The dose in the study is a Reference Dose (RfD), which is the appropriate dose a person can ingest every day, according to the United States Environmental Protection Agency (EPA) and the U.S. Food and Drug Administration (FDA). It is found by probabilistic multiplication of the NOAEL (no-observed-adverse-effect-level), which is primarily established experimentally with small laboratory mammals and correlated with body weight. Uncertainty factors (UF) are applied as powers of 10 (i.e., tenfold reductions of the NOAEL) to allow for interspecific variability (UFs) and intraspecific variability (UFH) where other animals and individual people differ from each other, respectively[12]. This is then multiplied by the average body weight of pregnant women in the delivery room (being 63.8 kg in Thailand)[13]. The result indicated that a drug dose equal to 638 mg can be taken daily with no expectation of adverse drug reaction.

$$\text{RfD} = \frac{\text{NOAEL}}{\text{UFs} \times \text{UFH}} \times \text{Av. weight pregnant woman}$$

$$= \frac{1{,}000 \text{ mg/kg}}{10 \times 10} \times 63.8 \text{ kg}$$

$$= 638 \text{ mg/day}$$

Intervention

Data collection followed randomization using even weeks or odd weeks to establish treatment and control grouping. After the allocation sequence was established, the researcher enclosed ginger extract and a placebo in the sequentially numbered sealed envelopes. These envelopes were kept with the midwife, who opened each envelope when a new participant was recruited at the time of her delivery. All women received the enclosed capsules three times a day for three days postpartum, with the first dose starting two hours after their delivery.

Ethical approval

The study was approved by the Ethics Committee of the Faculty of Medicine, Thammasat University, Thailand, with code MTU-EC-TM-4-057/58. All subjects were informed of the study details and were free to leave at any time.

Data collection

The questionnaires, demographic and data delivery records, were designed by the researcher with content and construction validated by five experts, and were tested for internal consistency by the Cronbach alpha coefficient. The estimated reliability coefficient was 0.952.

1) Demographic data questionnaire was designed by the researcher to record the personal characteristics of the postpartum primiparous women after normal vaginal delivery, including age, weight, height, and body mass index.

2) The delivery record form included gestational age, progression of labor, type of perineum trauma and episiotomy, the maternal condition assessment data for two hours after delivery, such as temperature, pulse, systolic blood pressure, diastolic blood pressure, blood loss, gestation age, uterine contraction, bleeding per vagina, weight of newborn, and APGAR score.

3) Milk flow rate: Using the milk flow rate form to investigate milk injection in the left and right breasts at 24 and 48 hours.

4) Adverse drug reactions form was designed to record adverse drug reactions that occur almost daily in health care institutions and can adversely affect a patient's quality of life, often causing considerable morbidity and mortality. Much attention has been given to identifying the patient populations most at risk, the drugs most commonly responsible, and the potential causes of ADRs.

Statistical analysis

The data was analyzed by a computer program and the steps of analysis followed are as for nonparametric statistics.

The demographic data of the postpartum

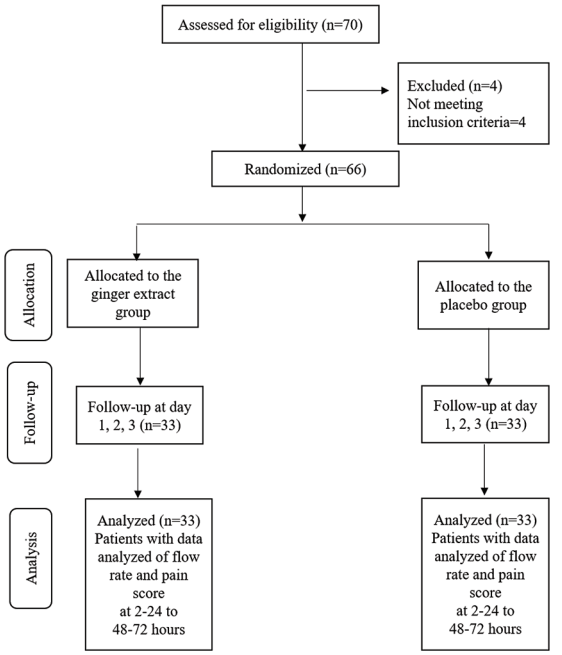

Figure 1. The consort diagram of participants, enrollment, allocation, and follow-up (n=66).

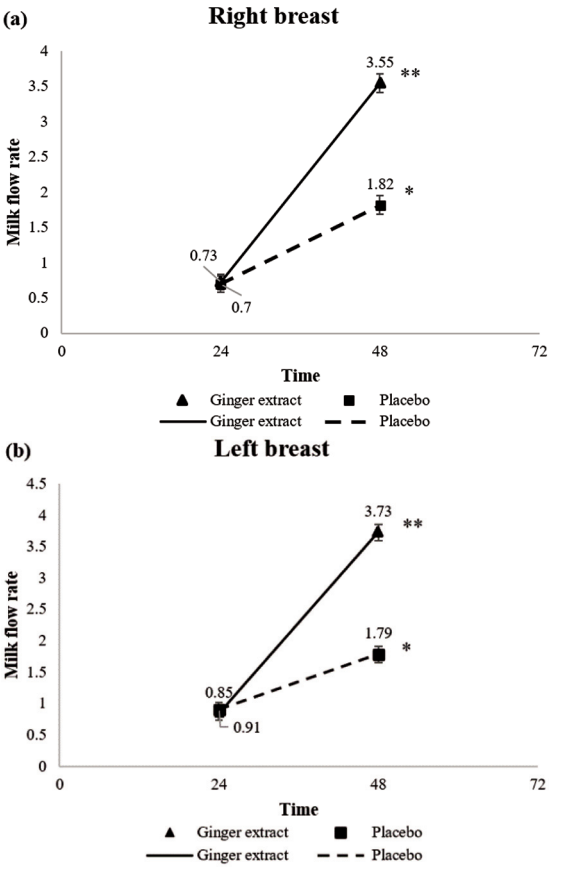

Figure 2. Milk flow levels in the ginger extract and placebo groups measured at 24 and 48 hours postpartum: (a) right breast and (b) left breast. * $p<0.05$ and ** $p<0.001$ indicate statistical significance in comparison with 24 and 48 hours (Wilcoxon signed-rank test).

primiparous women after normal vaginal delivery: The maternal conditions were assessed for two hours after birth such as temperature, pulse, systolic blood pressure, diastolic blood pressure, blood loss, uterine contraction, vaginal bleeding, perineum wound, receiving of standard synthetic drug, weight of newborn, APGAR score, and gestational age. Data were arranged by using median and interquartile range (IQR). Comparison was made between the baseline characteristics and obstetric data for the experimental and the control groups by using a Mann-Whitney U test and independent t-test.

Milk flow rate measurement: Milk flow rates mean the assessment of milk ejection in postpartum women. Using milk flow rate to investigate milk injection in the left and right breasts. Milk flow rate refers to milk volume from nipple squeezing that is divided to 5 levels.

Level 0 means no milk expressed on nipple compression.

Level 1 means Minimal milk oozing from the nipple on compression, without dripping.

Level 2 means One to two drops of milk expressed from the nipple on compression.

Level 3 means More than two drops of milk expressed from the nipple on compression, not in a forceful steam.

Level 4 means Milk squirts from the nipple on compression.

Comparisons between the 24-hour and 48-hour were performed using the Wilcoxon signed-rank test.

Results

Demographic and obstetric information

Sixty-six postpartum primiparous women after normal vaginal delivery were divided into two groups (steamed ginger extract and placebo), as shown in Figure 1.

The results indicated no significant difference between the two groups in terms of demographic information, such as age, weight, height, and body mass index, as shown in Table 1.

Comparison of the level of milk flow (left and right breasts) between ginger extract group and placebo group at 24 and 48 hours after birth

There was a significant difference of ginger

Table 1. The Demographic, maternal condition data, and obstetric data after delivery of the postpartum primiparous women

Demographic information	Population group		p-value
	Ginger extract (n=33)	Placebo (n=33)	
Age (years); median (min-max)	24 (22 to 28)	24 (22 to 28)	0.559[a]
Temperature (℃); median (min-max)	36.80 (36.60 to 37.00)	36.70 (36.50 to 36.90)	0.623[a]
Pulse (bpm); median (min-max)	86 (80 to 92)	82 (76 to 88)	0.549[a]
Systolic blood pressure (mmHg); median (min-max)	120 (115 to 130)	120 (110 to 120)	0.235[a]
Diastolic blood pressure (mmHg); median (min-max)	70 (60 to 80)	70 (60 to 78)	0.375[a]
Blood loss (mL); median (IQR)	100 (100 to 200)	150 (100 to 200)	0.160[a]
Uterine contraction: normal; n (%)	33 (100)	33 (100)	1.000[a]
Vaginal bleeding: normal; n (%)	33 (100)	33 (100)	1.000[a]
Perineum wound; n (%)			0.172[a]
Normal	33 (100)	30 (90.90)	
Edema	-	3 (9.10)	
Other	-	-	
Paracetamol 500 mg: not received; n (%)	33 (100)	33 (100)	1.000[a]
Weight of newborn (g); mean [SD]	3,004.55 [358.17]	2,912.88 [399.89]	0.463[b]
Apgar score; median (IQR)			0.316[a]
1 minute	8.78 (5 to 9)	8.90 (6 to 9)	
5 minutes	10 (10 to 10)	10 (10 to 10)	
Gestation age; median (min-max)	39 (38 to 39)	38 (38 to 39)	1.000[a]

IQR=interquartile range; SD=standard deviation

Comparison between groups: (a) p-value from the Mann-Whitney U test; (b) p-value from the independent t-test

Table 2. Comparison of the level of milk flow (left and right breasts) between ginger extract group and placebo group at 24 and 48 hours after birth

	After birth (hours)	Milk flow score; mean [SD]		p-value
		24 hours	48 hours	
Ginger extract (n=33)	Right breast	0.73 [0.12]	3.55 [0.09]	<0.001**
	Left breast	0.85 [0.13]	3.73 [0.80]	<0.001**
Placebo (n=33)	Right breast	0.70 [0.11]	1.82 [0.13]	0.002*
	Left breast	0.91 [0.08]	1.79 [0.10]	0.002*

SD=standard deviation

* $p<0.05$ and ** $p<0.001$ indicate statistical significance compared with values at 24 and 48 hours (Wilcoxon signed-rank test)

extract group and placebo group related to milk flow right and left breast at 24 and 48 hours after birth ($p<0.05$), as shown in Table 2 and Figure 2.

Adverse drug reactions between steamed ginger extract group, placebo group, and SSD group at 24 and 48 hours after delivery

There are no adverse drug reactions between steamed ginger extract group and placebo group at 24 and 48 hours after delivery as shown in Table 3.

Table 3. Adverse drug reactions between steamed ginger extract group and placebo group at 24 and 48 hours after delivery

Symptoms/side effects	Population group (number)	
	Steamed ginger extract (n=33)	Placebo (n=33)
1. Itchy, rash	-	-
2. Muscle pain, muscle weakness	-	-
3. Wrist pain, ankle pain	-	-
4. Facial swelling, lymphadenitis, lid swelling, angioneurotic edema, glossitis, hand-foot syndrome, swollen feet	-	-
5. Dyspnea	-	-
6. Chest pain	-	-
7. Palpitation, tachycardia	-	-
8. Dizziness	-	-
9. Nausea, vomiting	-	-
10. Flatulence	-	-
11. Constipation	-	-
12. Diarrhea	-	-
13. Insomnia	-	-
14. Anorexia	-	-
15. Bladder irritability	-	-
16. Dysuria	-	-
17. Fatigue	-	-

Discussion

The active component in fresh ginger is 6-gingerol, a phenolic ketone that provides several therapeutic advantages to ginger. Dehydration changes from 6-gingerol to 6-shogaol when exposed to 121℃ and 15 psi for 15 minutes[14].

This heat-induced transformation eliminates a hydroxyl group and introduces a double bond, resulting in 6-shogaol, which possesses enhanced anti-inflammatory, vasodilatory, and antioxidant activities[15,16]. Consequently, steaming is a regulated method to modify the phytochemicals in ginger extracts, enhancing their efficacy. Moreover, in Thai traditional medicine, ginger is classified as a hot herb that has been documented to demonstrate vasodilatory properties and enhance peripheral blood circulation, thereby increasing blood flow to the mammary glands to support Stage II lactogenesis[17]. The result from the study suggests that ginger increases breast milk volume in the early postpartum period. The authors measure the breast milk volume on the third day (48 hours), as the period represents the average timing of stage II lactogenesis[18]. These results are consistent with previous studies, which have reported that on day 3 postpartum, women in the ginger group produced significantly greater milk volumes than those in the placebo group, suggesting a short-term stimulatory effect[19]. The 24-hour breast milk volume in the placebo group is comparable with the previous study[6]. However, such a mechanism may not explain how ginger increases breast milk volume. How ginger increases breast milk supply is not well understood. The authors hypothesize that ginger induces systemic vasodilatation and increases blood supply to the mammary glands, based on previous evidence that ginger increases peripheral body temperature in humans[11,20] and induces vasodilation through multiple mechanisms, including inhibition of calcium channels and stimulation of nitric oxide production[21-23]. The authors suggest that additional studies with larger sample sizes and more stringent measurement of breast milk volume in the later phase of lactation are needed to confirm the efficacy of ginger on increasing breast milk volume in postpartum primiparous women after normal vaginal delivery. Furthermore, the evaluation in this study was based on individualized assessment and may involve some degree of subjectivity. Objective methods, such as test-weighing (measuring infant weight before and after feeding to estimate milk intake), could provide a more precise assessment of milk transfer[24,25].

Conclusion

Ginger can promote the breast milk flow rate in the 48 hours after delivery without adverse drug reactions. However, more studies with larger sample sizes and more rigorous methods of measuring milk production are needed to determine the effect of ginger at greater than 48 hours postpartum before it can be recommended for use in clinical practice.

What is already known about this topic?

Inadequate milk production is the most common symptom after delivery. Thai traditional medicine uses steamed ginger to promote milk production, but there is no report to study milk flow rate in post-partum primiparous women after normal vaginal delivery.

What does this study add?

The research indicated that steamed ginger can markedly improve breast milk flow rate within the first 48 hours postpartum, suggesting its efficacy as a natural galactagogue for new moms. No adverse medication reactions were detected among participants, indicating that steamed ginger is a safe and well-tolerated herbal strategy for promoting early lactation.

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Authors' contributions

SP and NJ conceptualized the study. NR and PW collected the data. SP and NR performed the statistical analysis. SP and NJ wrote the first draft of the manuscript. AI acquired funding for the study. All authors reviewed and approved the final manuscript.

Data availability statement

The data is not publicly accessible due to ethical constraints; however, it is available from the corresponding author upon reasonable request and with the approval of the Institutional Review Board.

Ethics approval and consent to participate

The study was approved by the Ethics Committee of the Faculty of Medicine, Thammasat University, Thailand, with code MTU-EC-TM-4-057/58. Written informed consent was obtained from all participants prior to enrollment.

Clinical trial registration

This study was registered at ClinicalTrials.gov (Identifier: NCT03617900).

Use of artificial intelligence

The authors used QuillBot (AI-assisted language editing tool) to improve the clarity and grammar of the manuscript. The authors take full responsibility for the content of the manuscript.

Conflicts of interest

The authors have no conflict of interest.

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