

# The Effects of *Lysiphyllum strychnifolium* Tea on Breastmilk Volume and Nutrient Composition of Human Milk: A Randomized Controlled Trial

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**Background:** Poor breastmilk production in mothers is a major concern worldwide. Galactogogues are increasingly being used as treatments that help to initiate and sustain adequate breast milk production.

**Objective:** To determine the clinical effects of *Lysiphyllum strychnifolium* (Craib) A. Schmitz (LS) tea in terms of breastmilk volume, nutrition in the milk content, and the infant weight among nursing women with normal delivery.

**Materials and Methods:** A randomized controlled trial was conducted in nursing women with normal delivery in Kut Chum and Loengnoktha Crown Prince Hospitals, Thailand. Eighty-four participants were randomly divided equally into two groups. The intervention group received LS tea while the control group received only warm water before each meal three times a day for seven days. Breastmilk volumes were measured, recorded on day 4 and 10 and analyzed for nutrient composition. Infant weight and adverse effects were also recorded.

**Results:** The mean breastmilk volumes were 62.86±44.90 mL/time in the LS group, which were higher than those of the control group at 47.38±32.18 mL/time, without statistical significance ( $p=0.073$ ) between groups on day 4. All the participants in the intervention group started secreting breastmilk, while five participants in the control group could not give sufficient breastmilk supply on day 4. Fat, carbohydrate, and mean differences of infant weight increased significantly, and protein decreased significantly in both groups. However, there was no significant difference between both groups. Moreover, adverse effects of LS were not observed in the present study.

**Conclusion:** LS tea has the potential to function as a galactogogue in mothers by increasing breastmilk volume and initiating lactation.

**Keywords:** *Lysiphyllum strychnifolium* (Craib) A. Schmitz; Galactogogues; Ya-Nang-Daeng; Breastmilk; Nutrition content

Received 2 August 2021 | Revised 17 January 2022 | Accepted 17 January 2022

J Med Assoc Thai 2022; 105(2):127-33

Website: <http://www.jmatonline.com>

Breastmilk is the best nutrient for infants. Previous research showed that breastfeeding has short-term health benefits including a reduction in morbidity and mortality from infectious illnesses in children<sup>(1-3)</sup>. Currently, the World Health Organization

(WHO) supports 6-month exclusive breastfeeding<sup>(4)</sup>. In Thailand, the percentage of infants exclusively breastfed for the first six months of life increased from 5.4% in 2005 to 12.3% in 2012. However, such percentage in Thailand is among the lowest exclusive breast-feeding rates in Asia<sup>(5,6)</sup>. The most essential reason behind this situation was poor breastmilk production in mothers and half of mothers have problem with insufficient breastmilk supply especially in the first week after delivery<sup>(7,8)</sup>. Galactogogues are the treatments that help to initiate and sustain adequate milk production by using pharmaceutical and herbal compounds<sup>(9,10)</sup>. Through brief pharmacological action, some herbs could function as phytoestrogens, which have estrogenic effects on mammary epithelial cells proliferation<sup>(11-13)</sup>.

*Lysiphyllum strychnifolium* (Craib) A. Schmitz (LS) has been utilized as a cure for various illnesses

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## How to cite this article:

Maenpuen S, Sriyakul K, Tungsukruthai P, Srikhao N, Kietinun S. The Effects of *Lysiphyllum strychnifolium* Tea on Breastmilk Volume and Nutrient Composition of Human Milk: A Randomized Controlled Trial. J Med Assoc Thai 2022;105:127-33.

DOI: 10.35755/jmedassocthai.2022.02.13267

such as poisoning, pesticides, poisonous mushrooms, alcohol poisoning, and a therapy for breast milk stimulation among women after delivery, health promotion, nutrition, and less fatigue<sup>(14,15)</sup>. In addition, LS also contains quercetin, which acts as phytoestrogen in the previous study<sup>(16)</sup>. Besides, traditional medicine in the Northeast of Thailand has used LS in the form of decoction or herbal tea to stimulate breast milk production<sup>(14)</sup> and it has been used in a hospital in Yasothon Province for five years to stimulate breastmilk production in nursing women without any side effects. However, there is no known study to prove the efficacy of this herb. Therefore, the present study aimed to evaluate clinical effects of LS tea in terms of breastmilk volume, nutrition in the milk content and the infant weight among nursing women with normal delivery.

## Materials and Methods

The present study was a single-blind randomized controlled trial. The study was a multicenter trial. The randomization technique used was a randomized experiment in which the assessor was blinded. Throughout the study, the assessor was the same nurse, and it was unknown whether the participants were given herbal tea or warm water. The present study was conducted in the Kut Chum Hospital and Loengnoktha Crown Prince Hospitals, Yasothon Province, Thailand between March and September 2019. Both hospitals offered the same standards of postpartum care after giving birth. All the participants in both areas shared similar culture and belief in food consumption for mothers after giving birth. A nurse/hospital was trained to be an assessor who taught the participants how to do the breast pump and to collect the milk sample. So, there were two nurses in both hospitals as assessors in the present study. They were assigned to prepare and give medicines at both hospitals and at home according to the research procedures.

The inclusion criteria were females aged 20 to 40 years with normal delivery, exclusive breastfeeding, no postpartum hemorrhage, no history of drug use, no food or herb allergy, and with full term and healthy neonates. The exclusion criteria were those who had chronic illness, breast problem, history of smoking or any drug use for improving breast milk production, twin delivery, any participants who received blood test during pregnancy with positive finding of hepatitis B, AIDS, or syphilis, low birth weight of less than 2,500 g, low APGAR scores of less than 7, or intrauterine growth retardation.

The sample size was calculated by the researchers using the formula of difference between mean values from a similar study by Turkyılmaz et al<sup>(12)</sup> and had 80% power to detect a difference between conditions at the 0.05 level. The minimum number of participants in each group was estimated to be 38, with a projected dropout rate of 10%. As a result, 42 participants were chosen for each group. Eighty-four participants fulfilled the inclusion criteria. They were randomized by a computer-generated list into two groups with 42 participants in each group. Allocation cards were placed in opaque, sealed, and stapled envelopes by a nurse who did not participate in the research. The treatment group received 2 g of LS tea mixed in 200-mL warm water and the control group received only 200-mL warm water before each meal, three times a day for seven days.

LS tea was prepared by the pharmacist and the product quality was controlled according to GMP. The herb was collected and gathered from Na-So Subdistrict, Kut Chum District, Yasothon Province in November 2017. It was verified for its identity with BK No. 069394 at The Plant Varieties Protection Office, Department of Agriculture. The LS leaves were washed to be clean from any contamination. The leaves were air dried at 40°C to 50°C for five days, and grinded to a coarse powder. The ground powder was produced in a form of 2-g tea per sack by an herbal production factory with GMP standard in the Kut Chum Hospital.

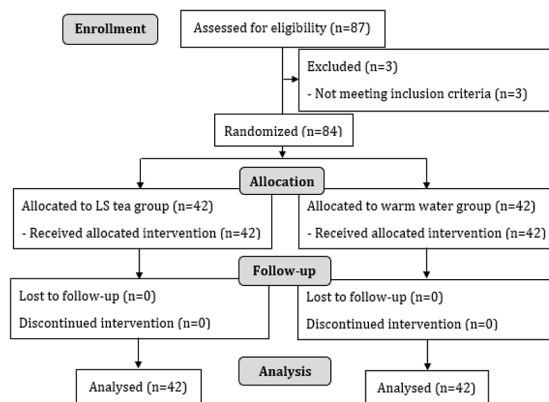
All the participants who met the inclusion criteria received information sheets. After the researchers informed them about the present study, the volunteers willing to participate in the present study had to sign their informed consents and follow all the research protocols. The participants started to take the LS tea as an intervention six hours after giving birth. The intervention group received 2 g of LS tea mixed in warm water 200 mL and the control group received only 200 mL of warm water before meal three times a day for seven days. After giving birth, all participants were given advice on how to breastfeed their babies based on the standard maternity care provided by hospitals. The advice included how to prepare the breasts, how to clean them, how to breastfeed properly, how to place the babies in the right positions during breastfeeding, and how to have adequate rest. Furthermore, the nurses taught and demonstrated how to use an automatic breast pump, as well as advise the participants the appropriate time to breast pump. During their stay at both hospitals, all participants were given food prepared by nutritionists. When they

stayed at home, their family members prepared the food for them. All the participants were instructed to avoid consuming the food that stimulated breast milk such as spicy foods, supplementary foods, and herbal liquor.

The breast milk of all the participants were collected by an automatic breast pump (Medela® Latiana, Pump in Style Advanced Double Breast Pump, Canada), which pumped both breasts simultaneously for 15 minutes after 2-hour breastfeeding. Lai et al discovered that a 15-minute breast pump could be used to measure milk volumes in an hour. The milk volumes were not different whether the breasts were pumped from hour 2 to hour 7<sup>(17)</sup>. The milk volumes collected by the automatic breast pump were then weighed using a measuring cylinder, and 40 mL of milk samples were collected to determine the nutrient volumes in the breast milk. Forty mL of the milk sample was placed in sealed bags and stored in a freezer at -20°C. AMARC company tested the milk samples for nutrient volumes in breast milk (Bangkok). The milk samples were collected every week and delivered by air. The milk samples were frozen at -20°C, placed in a foam box covered by a freezing cool pack, and tightly sealed according to the AMARC company's instructions. Breastmilk samples were analyzed for nutrient composition at Asia Medical and Agricultural Laboratory and Research Center (AMARC) Co., Ltd., Thailand. The detection of the nutrient volumes in the breast milk was performed by using an AOAC (2012) method.

Infant weights were measured using a sensitive digital scale (ZEPPER® EB-20, accurate to 5 g) at birth, on day 4 and day 10 after birth by the same nurses. They did not know whether the infant was in the intervention or the control group. Before breastfeeding, each infant was weighed. The infant weights were measured three times, the first at birth, the second on day four, and the third on day ten after birth. All the infants were weighed during the same period, which was between 9.00 and 11.00.

On days 4 and 10 after giving birth, the researchers asked the participants to recall the foods and beverages they had consumed in the previous 24 hours. Throughout the study, all participants were asked to record their daily food consumption while staying in the hospitals and at home. The participants were assessed for mental health by the stress questionnaire (ST-5) form of the Department of Mental Health, Thailand<sup>(18)</sup> on day 0 and 10 after the delivery. The stress questionnaire (ST-5) form has a total of 15 scores. Scores 0 to 4 indicate no stress or a



**Figure 1.** CONSORT flow diagram of the participants throughout the study.

mild level of stress, scores 5 to 7 indicate a moderate level of stress or discomfort, and scores greater than 8 indicate a severe level of stress. Moreover, the researchers interviewed participants with their infants about adverse effects. The present study was approved by the Human Ethics Committee of Thammasat University, Faculty of Medicine, Approval number MTU-EC-00-6-087/61. It was also registered in the Thai Clinical Trials Registry (Trial registration number: TCTR20190716001).

Statistical studies were performed by using SPSS Statistics for Windows, version 10.0. The results were presented as numbers (n), frequencies (%), and means with standard deviation (SD). To compare within groups, quantitative data and paired t-tests or Wilcoxon signed ranks tests were used, while independent samples t-tests were used to compare between both groups. A repeated measure analysis of variance was used to compare the differences throughout study. Qualitative data were presented as proportion and chi-square test was used to evaluate the significance. A statistically significant p-value of 0.05 was used.

## Results

In the present study, 87 mothers and infants were paired and assessed for eligibility. Three volunteers did not meet the inclusion criteria. Eighty-four participants completed the study (Figure 1).

### Baseline demographic and clinical characteristics

In Table 1, both groups were not statistically different in terms of mother's age, body mass index (BMI), mean corpuscular volume (MCV), hematocrit (Hct), parity, abortion, gestation age infant, infant birth weight, and infant gender.

**Table 1.** Baseline general of the intervention and control groups

Characteristics	Intervention (n=42)	Control (n=42)	p-value
Mother's age (years); mean±SD	27.64±5.50	27.83±4.94	0.480 <sup>a</sup>
BMI (kg/m <sup>2</sup> ); mean±SD	22.24±3.30	22.51±4.54	0.765 <sup>a</sup>
MCV (fL); mean±SD	79.97±9.16	79.39±7.81	0.762 <sup>a</sup>
Hct (%); mean±SD	36.00±3.62	35.19±3.36	0.294 <sup>a</sup>
Parity; n (%)			0.595 <sup>b</sup>
Primiparous	8 (19.0)	10 (23.8)	
Multiparous	34 (81.0)	32 (76.2)	
Abortion; n (%)			0.450 <sup>b</sup>
No	30 (71.4)	33 (78.6)	
Yes	12 (28.6)	9 (21.4)	
Gestational age (weeks); mean±SD	38.29±1.04	38.64±1.16	0.143 <sup>a</sup>
Infant birth weight (g); mean±SD	3,095.93±376.82	3,086.67±295.86	0.901 <sup>a</sup>
Infant sex; n (%)			0.190 <sup>b</sup>
Male	26 (61.9)	21 (50.0)	
Female	16 (38.1)	21 (50.0)	

SD=standard deviation; BMI=body mass index; MCV=mean corpuscular volume; Hct=hematocrit

<sup>a</sup> p-value calculated by independent samples t-test

<sup>b</sup> p-value calculated by chi-square test

### Breastmilk volume and breastmilk nutrient contents

Table 2 shows a significant increase in breastmilk volume in both groups on day 4 and day 10. The mean breastmilk volumes on day 4 after delivery in intervention group was 62.86±44.90 milliliters while the control group was 47.38±32.18 milliliters without statistically significant difference between both groups (p=0.073). It was found that five of the 42 participants (11.9%) in the control group could not give sufficient breastmilk supply after using the breast pump on day 4 possibly because the breast milk started to secrete later in an early stage compared to the intervention group. Nutrient composition of human milk including fat content increased significantly in both groups from day 4 and day 10 and the mean carbohydrate on day 4 decreased statistically significantly compared with the intervention group on day 10. The mean protein decreased significantly in both groups.

### Infant weight

Table 3 shows that the mean infant weight at baseline, on day 4 and day 10 were statistically significant different within groups (p<0.001).

### Maternal total energy, nutrient intake, and mental health in maternal state

The mean energy intake in maternal on day 4

**Table 2.** Breast milk volume and breast milk nutrient contents on day 4 and day 10 after the consumption of LS tea or warm water

Items/group	Day 4; mean±SD	Day 10; mean±SD	p-value <sup>a</sup>
Breast milk volume (mL/time)			
Intervention (n=42)	62.86±44.90	75.83±45.64	0.031*
Control (n=42)	47.38±32.18	80.71±46.18	<0.001*
p-value <sup>b</sup>	0.073	0.627	
Energy (g/100 mL)			
Intervention (n=42)	52.56±9.09	62.54±12.16	<0.001*
Control (n=42)	60.13±8.73	65.86±9.93	0.003*
p-value <sup>b</sup>	<0.001*	0.160	
Protein (g/100 mL)			
Intervention (n=42)	2.06±0.51	1.76±0.27	<0.001*
Control (n=42)	2.15±0.44	1.72±0.24	<0.001*
p-value <sup>b</sup>	0.373	0.440	
Carbohydrate (g/100 mL)			
Intervention (n=42)	8.10±0.99	8.69±1.40	0.006*
Control (n=42)	7.77±0.79	7.89±0.79	0.430
p-value <sup>b</sup>	0.115	0.002*	
Fat (g/100 mL)			
Intervention (n=42)	1.33±1.07	2.30±1.62	<0.001*
Control (n=42)	2.27±0.93	3.05±1.02	<0.001*
p-value <sup>b</sup>	<0.001*	0.013*	

SD=standard deviation

<sup>a</sup> p-value calculated by paired t-test or Wilcoxon signed ranks test for within group comparison

<sup>b</sup> p-value calculated by independent samples t-test for between group comparison

\* p<0.05 is considered statistically significant

**Table 3.** Infant weight on day 0, 4, and day 10 of the intervention and control groups

Time	Infant weight (g); mean±SD		p-value <sup>b</sup>
	Intervention group (n=42)	Control group (n=42)	
Baseline	3,095.93±376.82	3,086.67±295.86	0.901
Day 4	3,082.50±384.21	3,008.64±329.13	0.347
Day 10	3,296.67±396.30	3,216.86±344.58	0.329
p-value <sup>a</sup>	<0.001*	<0.001*	

SD=standard deviation

<sup>a</sup> p-value calculated by repeated measure ANOVA test for within group comparison

<sup>b</sup> p-value calculated by independent samples t-test for between group comparison

\* p<0.05 considered statistically significant

and day 10 after the delivery in intervention group were 1,787.32±403.61 kcal/day and 1,792.59±483.81 kcal/day, and the control group were 1,888.95±434.18 kcal/day and 1,834.54±506.31 kcal/day. The present study found the mean energy intake on day 4 and

**Table 4.** Mental health in maternal state (ST-5) of the intervention group and the control group on day 0 and day 10

Items	Day 0; n (mean±SD)		Day 10; n (mean±SD)	
	Intervention (n=42)	Control (n=42)	Intervention (n=42)	Control (n=42)
ST5 (total=15)				
Mild (score 0 to 4)	42 (0.52±0.71)	42 (0.81±0.74)	42 (0.24±0.48)	42 (0.21±0.47)

SD=standard deviation

day 10 after the delivery in the intervention group were 78.93% and 78.62% and the control group were 82.85% and 80.46% dietary reference intake for lactating women. The total energy and nutrient intake on day 4 and day 10 after delivery did not differ between groups. The findings on a mental health and depressive disorder analysis revealed that no participants in both groups were stressed on day 0 and day 10 after delivery (Table 4.).

### Adverse effect

Adverse effects were not found between the mothers and their infants. Adverse effects included maternal symptoms including dry throat, frequent urination, headache, muscle weakness, diarrhea, insomnia, stomach pain, rash, nausea, swelling and bloating as well as symptoms among infants such as diarrhea, flatulence, and constipation.

### Discussion

The present study found that both groups had a significant increase in breast milk volume as in the standard criteria compared between day 4 and day 10 but there were no significant differences between the groups. In addition, on day 4, the LS group have higher breast milk volume compared to the control group. Regarding the results of the nutrient composition of human milk, the researchers found that the mean protein on day 4 was higher than that on day 10 in both groups. These results were consistent with the report of Ballard and Morrow, whose results showed that the mean macronutrient composition of mature, term milk is estimated to be approximately 0.9 to 1.2 g/dL for protein<sup>(19)</sup>. The mean fat on day 4 was lower than that on day 10 in both groups and the mean fat in the control group were significantly different compared to LS group. Besides, the mean fat content in the milk samples of mothers with female infants was higher than that in mothers with male infants<sup>(20)</sup>. The present study also found that female infants in the intervention group were 16 (38.1%) while those in the control group were 21 (50%), which may result in differences in fat content. The researchers assumed that the overall nutritional status of the mothers and

the stage of lactation might be important factors that deserve attention while studying human milk macronutrient concentrations as a previous study described<sup>(21)</sup>. For protein level, the mean protein decreased significantly in both groups from day 4 to day 10. Recent studies evaluated the change in protein content of breast milk during infancy and concluded that the reduction in protein over the first year of lactation exhibited a linear pattern. However, the data was limited<sup>(22)</sup>.

The mean differences of infant weight at baseline, on day 4 and day 10 were statistically significant different between both groups ( $p < 0.001$ ). In addition, the infant weight increased slightly in the LS group. According to the results of the present study, on day 4 compared with baseline, the percentage of weight loss in both groups were less than 7%. The American Academy of Pediatrics advises that it is necessary to weigh each infant within three to five days after birth. If an infant lose more than 7% of its birth weight, it signifies problems of breastfeeding<sup>(23)</sup>.

The recommended Thai dietary reference intake for lactating women requires 2,280 kcal/day of energy for the first six months<sup>(24)</sup>. The present study reported the mean energy intake on day 4 and day 10 after the delivery in intervention group were 78.93% and 78.62%, and the control group were 82.85% and 80.46% of dietary reference intake for lactating women. The energy received was similar to the study by Buntuchai et al that studied the traditional galactagogue foods in Thai breastfeeding mothers. The results found that the median energy intake was 72.8% dietary reference intake for lactating women<sup>(25)</sup>. Lactation, known as nursing or breastfeeding, means the period when breast milk is formed and secreted after giving birth. The milk formation mode called lactogenesis is classified into two stages. Lactogenesis-II starts right after the females give birth. It is the next stage of high milk secretion<sup>(26)</sup>. Previous studies revealed that if the first-time lactation started later, this could make mothers decided to stop breastfeeding exclusively and to start feeding with other alternative feeds including infant formula<sup>(27,28)</sup>. Interestingly, the results

found that all participants in the intervention group started secreting breastmilk while five participants (11.9%) in the control group could not give sufficient breastmilk supply. Several studies could support these findings, for instance, mothers who used an herbal tea blend had higher increased in milk production from the first to the seventh day. The rate of increased milk production was 80% in the treatment group, 34.3% in the placebo group, and 30% in the control group. In addition, there was no statistically significant difference in baby weight increase between the two groups. Based on mechanism of action, studies have found LS compounds that might behave as phytoestrogens. Quercetin, one of LS compound, specifically promoted primary mammary epithelial cell proliferation and stimulated prolactin receptor (PRLR)<sup>(16)</sup>. Taken together, LS herbal tea supplementation seems to be useful for enhancing breastmilk production without ADR among mothers.

### Limitation

The present study did have limitations. First, because the researchers have been unable to be available with the participants during the breast pump, there could have been errors in the milk volume measurements. Second, the researchers asked the participants to recall the food they for the entire day on days 4 and 10 following the delivery. It was possible that data were missing because it was too difficult for them. In both groups, confounders such as rest period, the food containing estrogen, and the food that stimulated breast milk could not be controlled.

### Conclusion

LS tea is a promising natural galactagogue for increasing breastmilk volume in the immediate postpartum period, and the percentage increase in infant weight on day 10 compared to baseline in the intervention group was greater than that in the control group, with no significant side effects. LS tea tends to stimulate breast milk to be secreted earlier.

### What is already known on this topic?

LS has been used as traditional medicine in Northeast Thailand to stimulate breast milk in postpartum mothers. In a hospital at Yasothon Province, LS was used as a decoction or herbal tea to stimulate breast milk production without any side effects.

### What this study adds?

Since LS has been used for years in Kut Chum

and Loengnoktha Crown Prince Hospitals. This current study using scientific methodology supports and proves that LS has efficacy and safety to promote breastmilk production during the initiation period of lactation. The present study reported markers, including breastmilk volume, nutrition in the milk content, and infant weight, which support the LS use in mothers.

### Acknowledgement

This study was supported by Thammasat University Fund, Contract No. TUGR 2/60/2562.

### Conflicts of interest

The authors declare no conflict of interests.

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