

A Randomized Controlled Trial on the Use of Malunggay (*Moringa oleifera*) for Augmentation of the Volume of Breastmilk Among Mothers of Term Infants

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Objective: To compare the volume of breastmilk among mothers who delivered via NSD of term infants who were given *malunggay* (*Moringa oleifera*) leaves capsules compared to those who were given placebo. **Design:** Single-blind Randomized Controlled Trial. **Setting:** Quezon City General Hospital. **Study Subjects:** Mothers aged 18-38 who delivered term infants via NSD. **Method:** A total of 82 out of 93 mothers aged 18-38 from the Ob-Gyne, Outpatient Department of the Quezon City General Hospital were recruited using questionnaires for possible inclusion in the study. Those assigned to the treatment group were given *malunggay* (Prolacta) leaves in a commercial capsule preparation of 350 mg. two capsules once daily while those who belonged to the placebo group were given flour contained in identical containers. There were 41 subjects for Treatment Group (*malunggay*) and 41 subjects for Control Group (placebo). All data were entered using Epistat. T-test was used to determine differences in numeric baseline variables. One-way ANOVA was used to determine if there were significant differences in the collected volume of breastmilk among mothers on the study medication compared to placebo. A p-value of < 0.05 was considered significant. **Results:** Eighty two (82) subjects were enrolled in the study. Majority of the patients were between ages 21-23, high school graduates, median gravidity of 2, and chest circumference of 36 inches. The subjects in the treatment group had a mean age of 24, typically weighed 60 kg, stood at 158 cm. and gave birth to babies that weigh 3105 g. Those in the control group had a mean of age of 20, weighed 58 kg and stood at 157 cm. Their babies' mean birth weight was 2992 g. The volume of breastmilk among the mothers taking *malunggay* (*Moringa oleifera*) leaves capsules was greatly increased compared to those given placebo. The amount of breastmilk increased progressively from 18 ml (23%) on day 3 postpartum to 245 ml (162%) on day 10 postpartum in favor of treatment group. No adverse reactions were noted after taking the *malunggay* (*Moringa oleifera*) leaves capsules for the treatment group nor for those taking placebo in the control group during the course of the study. **Conclusion:** This study has shown the *malunggay* (*Moringa oleifera*) leaves capsule is effective and safe for augmentation of breastmilk among mothers.

Key words: *Moringa oleifera*, breastmilk

INTRODUCTION

"Breastmilk is still best for babies"

The campaign for breastfeeding is being pursued by the Department of Health, World Health

Organization (WHO), United Nations International Children's Educational Fund (UNICEF) and other organizations involved in the improvement of the health of the mother and the infant.¹

There is an alarming decline in both prevalence and duration of breastfeeding especially in the urban areas. In the Philippines alone, 85 percent of mothers initiated breastfeeding soon after delivery but only 22

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percent of these mothers exclusively breastfeed up to one month old. The most common reason for this was not having enough milk.²

Feeding breast milk is of interest because of its potential nutritional and immunologic benefits. To implement this consensus, mothers of these infants must produce sufficient milk to meet the nutritional needs imposed by the accelerated growth rates of their infants. Most mothers after initiating expression of breastmilk on the first few days after birth often complain of insufficient volume of breastmilk. This complaint prompted most mothers to use milk formula, shift to bottle-feeding and discontinue breastfeeding.

Lactagogues or galactagogues are special foods, drinks or herbs which people believe can increase a mother's milk supply. In most parts of the Philippines, women take *malunggay* (*Moringa oleifera*) leaves mixed in chicken or shellfish soup to enhance milk production. The mechanism of action has not been explained but it was effective as a galactagogue and has been used by generations of nursing mothers especially those with inadequate lactation.

Significance of the Study

Breastmilk is still superior when it comes to providing nutritional and immunologic benefits as compared to milk formula. The role of *malunggay* in the augmentation of breastmilk has been scientifically backed by limited number of studies. Moreover, the exact mechanism of how it effect breastmilk augmentation is still unclear. Due to insufficient amount of expressed milk, some mothers are discouraged to continue breastfeeding and give in to the more convenient use of bottle-feeding.

This study was undertaken to show if the intake of *malunggay* (*Moringa oleifera*) leaves capsules (Prolacta) indeed will augment the volume of milk production for those healthy mothers who will breastfeed their infants. The Quezon City General Hospital supports the Department of Health's program in promoting breastfeeding. As a baby friendly institution, it will further encourage the new mothers to use their own milk to provide for their babies.

Furthermore, *malunggay* is planted throughout the Philippines and is easily available for consumption. Most of the mothers will greatly benefit from *malunggay* as it is a cheap and good source of calcium, iron and phosphorus.

Objectives

General Objective

To compare the volume of breastmilk of mothers who delivered via NSD to term infants who were given *malunggay* (*Moringa oleifera*) leaves capsules (Prolacta) with those who were given placebo.

Specific Objectives

1. To describe the maternal demographic and clinical as well as infant clinical characteristics of the subject population given *malunggay* (*Moringa oleifera*) leaves capsules (Prolacta) and those given placebo.
2. To compare the volume of breastmilk that is expressed 3 to 10 days postpartum among mothers who delivered to term infants who were given *malunggay* (*Moringa oleifera*) leaves capsules (Prolacta) to those who were given placebo.
3. To determine any adverse affects for those mothers taking *malunggay* (*Moringa oleifera*) leaves capsules (Prolacta).

Review of Literature

In 1978, Quisumbing in his study of the medicinal plants of the Philippines attested that the young leaves of *malunggay* is particularly popular as a galactagogue among mothers breastfeeding their infants.

In 1979, Howie, et al. found out that the eventual success of lactation is improved greatly if a satisfactory flow of milk is established during the first week of puerperium. A continuous stimulation of nipple through suckling thereby prolactin response is seen and lactogenesis is initiated.

In 1996 a study done by Almirante and Lim has proven that by giving *malunggay* capsules, enhanced

lactation among breastfeeding mothers yielded an increased volume of breastmilk. There were no reported adverse effects for those given the *malunggay* (*Moringa oleifera*) leaves capsule (Natalac).

Another study by Almirante and Lim on the enhancement of breastfeeding among hypertensive mothers showed a higher prolactin levels after 48 hours among breastfeeding mothers and significant weight gain among their babies.

In the Physician's Guide to Philippine Nutraceuticals, *malunggay* (*Moringa oleifera*) leaves are said to be very rich in calcium and iron. It is also a good source of phosphorus. *Malunggay* leaves also contain 17% protein and conform favorably with the WHO standard.

Another local study done published in the Philippine Journal of Pediatrics last March 2000 on the use of *malunggay* (*Moringa oleifera*) leaves capsules to augment the volume of breast milk among mothers of preterm infants confirmed the earlier findings of increased milk production.

A recent study (June 2002) by a group of pediatricians compared different galactagogues, namely metoclopramide, domperidone and *malunggay* leaves capsules. All three showed promising roles for mothers with lactational insufficiency. Among the three treatment groups, domperidone was the most efficacious, followed by metoclopramide and lastly by *malunggay*.

Definition of Terms

- Term infants - those born at 37 - 42 weeks age of gestation by LMP
- Follow-up period - an 8-hour period where assessment was carried out, from day 3 to day 10 postpartum
- Observation times - two designated visits within the follow-up period; the second visit made 4 hours after the initial visit
- Adverse reaction - signs and symptoms potentially associated with taking pharmacologic galactagogues such as metoclopramide and domperidone which are routinely sought from both study groups - e.g. drowsiness, etc.

- Compliance Criteria
 - a. drug compliance - submission of the empty paper container during the initial visit on each follow-up period
 - b. procedure compliance - use of breast pump during the observation time, assessed as follows:
 - i. direct observation
 - ii. record verification
- Non-compliance
 - a. drug compliance - failure to submit the paper container even on one occasion
 - b. procedure compliance - no account on volume of milk was found by the intern for at least 50% of the expected number of times entry has to be made in the record book.

MATERIALS AND METHODS

Study Design

Single-Blind Randomized Controlled Trial

Study Subjects

Mothers aged 18-38 years who delivered via NSD to term infants at the Quezon City General Hospital and who lived within a five kilometer radius from the said institution.

Inclusion Criteria

- Pregnant mothers between 18-38 years of age who are about to deliver via NSD term infants and who will breastfeed their babies.

Exclusion Criteria

- Mothers with hypertension, diabetes mellitus, chorioamnionitis and chronic illness
- Mothers with acute illnesses such as acute upper respiratory tract infection, urinary tract infection
- Mothers taking any medication on a regular basis except multivitamins and iron supplement
- Mothers with breast anomalies
- Mothers of infants with neonatal illness and congenital anomalies

Study Period

January to October, 2003

Study Procedure

The study was conducted from January to October 2003 at the Quezon City General Hospital. A written permission from the Head of the Department of Obstetrics and Gynecology to conduct the said study was obtained. The sample population recruited at the Prenatal Clinic was composed of all mothers between 18-38 years of age who were about to deliver via NSD to term infants between 37-42 weeks age of gestation, and who were willing to breastfeed their infants. Attempts were made to encourage the mothers who were unwilling to breastfeed their infants thereby promoting breastfeeding as well. The subjects should be residing within a five kilometer radius from the hospital for easy accessibility by the researcher. A written consent signed by the subjects expressing their willingness to undergo the study was obtained. A data collection form was filled up for each subject.

The following baseline clinical characteristics of all the subjects were gathered: maternal age, maternal weight, maternal height, gravidity, mother's educational attainment, mother's chest circumference after delivery, age of gestation, and infant's weight at birth.

All subjects who met the inclusion criteria were enrolled in the study through single-blind randomized sampling method. The researcher randomly assigned subject to the treatment and placebo groups. Those assigned to the treatment group were given *malunggay* (Prolacta) leaves in a commercial capsule preparation of 350 mg/cap, two capsules once daily while those who belonged to the placebo group were given flour-containing capsules in identical containers prepared by a pharmaceutical company in the Quezon City area. Both groups were asked to take the medications starting on the third postpartum day for 8 days.

Manual breast pump with calibrated container was provided to all the enrolled subjects by the researcher. A demonstration by the researcher or a female medical intern on the proper use of breast pump

and collection of breast milk was done at the Prenatal Clinic. After proper orientation, demonstration and training, enrolled mothers were instructed to pump each breast every 4 hours for at least five minutes. The expressed milk was transferred in a standard containers. The amount of milk was recorded immediately.

Study subjects took the first dose on the third to the tenth postpartum day. The senior interns assigned to the community were tasked to follow-up the subjects daily at their houses, twice (observation times) on an 8-hour period (follow-up period from day 3 to day 10). During the initial visits done in the morning, subjects were directly observed by the assigned intern in taking the capsules. In cases when that observation was not carried out, they were obliged to submit the used paper containers. A second visit on the same day, 4 hours after the initial visit was made to ensure the regularity of breastmilk extraction. If the baby had already been fed prior to the arrival of the observer, a corresponding entry in the data book was made and verified as soon as the intern was informed of this occurrence. When available, the volume of milk collected was measured and tabulated by the interns. Senior interns assigned at the community were instructed to follow-up daily the progress of all enrolled subjects.

Subjects were asked to record the amount of milk collected per day in their respective notebooks.

Adverse reactions during the intake of medications were noted. Subjects were advised to discontinue taking the said medications in the presence of these adverse reactions. A list of possible signs and symptoms was provided in their said notebooks.

All subjects who failed to comply with instructions given by the researcher were considered drop-outs. Those who failed to show the used paper container during the time of follow-up were dropped from the study. During the observation period, if pumping was less than five minutes for each breast, the subject was dropped and considered a failure. Mothers who, after taking either the *malunggay* leaves capsules or placebo from postpartum days 3 to 10 manifested signs and symptoms were asked to discontinue and were dropped from the study.

All data were entered using Epistat. T-test was used to determine differences in numeric baseline

variables. One-way Anova was used to determine if there were significant differences in the collected volume of breastmilk among mothers on the study medication compared to placebo. A p-value of <0.05 was considered significant.

RESULTS

Recruitment of subjects was conducted over a 10 month period from January to October, 2003. A total of 94 patients were recruited at the Prenatal Clinic and were asked to join the study.

Of these, 12 (12.7%) were not included in the study, 3 (25%) of whom had 1 or more exclusion criteria while 9 (75%) declined to take part in the study leaving a total of 82 (87.2%) subjects.

In the Treatment Group, out of a total of 41 subjects, only 35 (37.6%) participants completed the required 3-day course of *malunggay* capsules with proper documentation (by writing down in the provided notebook and proper use of breast pump). A 6.45 percent (6) dropout rate was registered due to failure to take *malunggay* capsules even on just one occasion during treatment course or failure to comply with procedures such as completing data entry in the notebook provided or the failure and improper use of breast pump. The Control Group on the other hand had 3 dropouts (3.2%), who did not take *malunggay* capsules on schedule.

Subjects enrolled in the study (82) were then randomly assigned to either the Treatment Group or Control Group. Forty one subjects were placed in the Treatment Group and 41 subjects were in the Control Group.

The mean age of patients in the Treatment Group was 24.4 ± 4.81 compared to Control Group (placebo) whose mean age was 25.65 ± 4.819 . Twenty eight percent in Treatment Group were in the 21-23 year age group. The difference in age between Treatment and Control Groups however, has no statistically significant difference. (Table 1)

Patients in the Treatment Group had a mean weight of 60 kg. Patients in the Control Group had a mean weights of 58 kg. The difference between the mean weights of the two groups was not statistically significant.

The patients in the Treatment Group had a mean height of 158 cm. The Control Group patients had a mean height of 157 cm. However, the difference was not statistically significant.

Chest measurement of the patients revealed a mean of 36 for both the Treatment and Control Groups.

Majority of the study subjects, both in the Treatment and Control Groups were high school graduates, (46.3%) and (58%), respectively.

Table 1. Frequency distribution of baseline demographic and clinical characteristics of the study population.

Baseline Characteristics	Treatment Group (Prolacta capsule) N = 41	Control Group N = 41
Maternal Age (years)	n (%)	n (%)
18 - 20	10 (25)	7 (17)
21 - 23	12 (27.5)	10 (24)
24 - 26	7 (17.5)	8 (19.5)
27 - 29	3 (7.5)	6 (14.6)
30 - 32	5 (12.5)	6 (14.6)
33 - 35	4 (10)	3 (7.3)
36 - 38		1 (2.4)
Mean Age p = .282	24.4 ± 4.814	25.65 ± 4.819
Maternal Weight (kg) p = .2008	59.6 ± 6.45	57.95 ± 5.449
Maternal Height (cm) p = .299	157.925 ± 7.265	156.902 ± 5.739
Chest Circumference (in) (during pregnancy, nearing term) p = .372	35.95 ± 1.182	35.585 ± 1.870
Educational Attainment:		
Elementary Graduate	13 (31.7)	11 (27)
High School Graduate	19 (46.3)	24 (58)
College Graduate	9 (21.9)	6 (15)
Age of Gestation p = .760	39.375 ± 1.233	39.292 ± 1.188
Median Gravidity	2.1 ± 1.79	2 ± 1.188
Infant's Weight p = 7.588	3105 ± 294.464	2992.171 ± 270.905

With regards to age of gestation, the mean age for both groups was 39 weeks. The mean weight of infants in the Treatment Group was 3105 and for the Control Group, 2992. No statistically significant difference was found in their mean weights.

The mean gravidity for both groups was 2.

Table 2 shows the mean values of milk collected in the Treatment and Control Groups from postpartum days 3 to 10.

Table 2. Volume of breastmilk (in ml) on postpartum days 3 to 10 of treatment and control groups.

Day Post-partum	Treatment Group (Prolacta) (amount in ml.)	Control Group (placebo) (amount in ml.)	p-value
Day 3	96.35 ± 14.3	78.56 ± 9.81	< 0.5598
Day 4	111.85 ± 11.95	89.58 ± 16.75	< 0.5598
Day 5	127.5 ± 10.33	93.70 ± 22.60	< 0.5598
Day 6	140.3 ± 11.97	101.5 ± 9.3	< 0.5598
Day 7	185.525 ± 23.40	116.6 ± 116.6	< 0.5598
Day 8	249.025 ± 46.98	128.0 ± 13.2	< 0.5598
Day 9	330.4 ± 39.5	140.3 ± 10.88	< 0.5598
Day 10	395.9 ± 36.33	150.8 ± 16.5	< 0.5598

For each day from postpartum days 3 to 10, greater amount of breastmilk per day was produced by subjects who took *malunggay* capsules than those who took the placebo. However, this was not statistically significant.

DISCUSSION

The superiority of human milk over any other milk for the nourishment of the human newborn and infant is no longer an issue. Over the years, it has become more and more evident that it is the most ideal, safe and complete food for the young ones.

The protective effect of breastfeeding is attributable to a complex of acquired and innate factors unique to human milk and which have been found to have anti-infective, anti-inflammatory and immunoregulatory

functions. The American Academy of Pediatric recommends exclusive breastfeeding until the infant is approximately 6 months of age with timely introduction of complimentary foods and continued breastfeeding to a year or longer if desired.

Special efforts are being undertaken by the World Health Organization (WHO) and UNICEF to educate women as well as men about the benefits of breastfeeding being promoted to establish broader social acceptance of and support for breastfeeding. Mothers are convinced about the advantages of breastfeeding but most often they complain about the inadequacy of milk supply from their breasts.

Breast stimulation by pump can induce prolactin release comparable with that induced by suckling,³ although the correlation between prolactin concentration and milk production has been questioned by several studies. Some mothers exclusively pump and bottle-feed expressed breastmilk, while some reluctantly resort to pumping full or part time due to problems with breastfeeding. The reasons included premature or ill baby, anatomic problems in baby, painful breastfeeding, perceived low supply of breastmilk and those mothers who had psychological issue around breastfeeding, i.e. sexual abuse victims.⁴

Malunggay leaves mixed with chicken or shellfish have been used throughout the generation of Filipino mothers to enhance breastmilk production. The study currently conducted will serve either to accept or refute the age old practice in addition to previously conducted local studies. The data presented revealed a markedly increased volume of breastmilk among healthy mothers.

Lactogenesis is initiated in the postpartum period by a fall in plasma progesterone in the presence of maintained prolactin concentrations. Initiation of the process does not depend on suckling of the infants although the rate of milk secretion after the third or fourth day postpartum declines if milk removal is not practiced at regular intervals.⁵

Physiologically speaking, full breastmilk supply occurs on the third to the fourth day after delivery.⁶ Optimal milk production was associated with five or more milk expressions per day. In the current study, the volume of breastmilk was collected on the third day by

using breast pump to ensure uniformity and make it easier to measure the amount of milk collected at a regular 4-hour interval.

Ages of majority of subjects in both treatment and control range from 21-23. The median gravidity was 2 for both study groups. The state of prolactin receptors number and degree of sensitivity to stimulation are said to be the controlling factor in the amount of breastmilk rather than the amount of serum prolactin. After age 35, these receptors become less sensitive to stimulation. Increased number of receptors is found among multiparous women.³

In the current study, the mean chest circumference which roughly correlates with breast size is 36 inches. Although most Asian women are less endowed than their Caucasian counterparts, during pregnancy the ductal system of the breasts grow and branch. The stroma of the breasts increases in quantity and large amount of fat are laid down in the stroma making the breast bigger during pregnancy.⁷

The size of the breast does not determine how much milk it can make. Much of the breast is made up of fatty and connective tissue rather than milk-producing glands, breastmilk production is mainly dependent on how well the breasts are emptied completely and regularly.⁶

Among the baseline characteristics considered in this study, age of the mother and gravidity surfaced as factors that influence milk production. The subjects in both the treatment and control groups were shown to be comparable with regards to these characteristics. Both produce a good amount of breastmilk, such that any difference in the volume of milk produced between the two groups was attributed mainly to the effect of *malunggay*.

The mean age of gestation was 39 weeks. It was considered term if the age of gestation was between 37 to 42 weeks of gestation. Both study groups were comparable in their baseline characteristics.

The mean pediatric weight for the treatment group was 3105 grams while for the control group, 2992 grams. The results noted were at par with the average weight of newborn infant in the country. In the Philippines, the average weight of a newborn is 3000 grams.⁶

The treatment group taking *malunggay* leaves capsules had marked increase in the volume of breastmilk compared to the control or placebo group. From postpartum days 3 to 10, mothers in the treatment group consistently showed greater production of breastmilk than those who were assigned in the placebo group.

Estrella, et al. in their study on the use of *malunggay* for augmentation of the volume of breastmilk among non-nursing mothers of preterm infants found a trend towards increased milk production among those on *Moringa oleifera* leaves from postpartum days 3 to 5.⁸

The progressive daily increase in the volume per day shown in the current study is substantial by several studies whether using placebo or different galactagogues. Immediately after the baby is born, the lactogenic effect of prolactin from the pituitary gland to assume its natural milk-promoting and over the next 1 to 7 days, the breasts progressively begin to secrete copious quantities of milk.⁷

For each day from day 3 to day 10, greater amount of milk per day was produced by the subjects who took *malunggay* capsules than those who took the placebo. This finding further demonstrates the observations of Almirante and Lim on the effectiveness of Natalac which is another commercial preparation of *malunggay* leaves, as a galactagogue, among normal parturients.¹⁰ However, the parameters used here were serum prolactin levels and infant weight gain. Augmentation of the volume of breastmilk was similarly documented by Estrella, et al. and Co, et al. but among mothers of preterm infants

Breastmilk secretion is facilitated by the early onset of breastfeeding, preferably within 12 hours after delivery or at the latest, 24 hours postpartum. Physiologically speaking, full breast milk supply occurs on the third to fourth day of life. The reflexes governing milk secretion have two mechanisms. The prolactin reflex and let-down or milk ejection reflex. When the baby is put to the breast, the tactile stimulation at the nipple during sucking stimulates the afferent nerve endings sending impulses carried to the hypothalamus. The hypothalamus in turn activates the pituitary gland causing the release of hormones. Prolactin is secreted

from the anterior lobe and its secretion is proportional to the stimulation of the nipple and areola. Simultaneously, oxytocin causes contraction of the myoepithelial cells in the mammary gland propelling milk along the duct and the milk drips from the nipple pores through the mechanism called "let-down" or "milk ejection" reflex.⁶

For the mothers who have difficulty producing adequate volume of milk, *malunggay* leaves offer a solution. Locally, it has other names like *arunggani*, *balungai*, *dool*, *kalamungai*, *kalungai*, *kamalongan*, *malongai* and in English, horse radish tree. *Malunggay* is popularly known by them to be of use particularly, the young leaves, as a galactagogue. Several studies support the use of *malunggay* to enhance volume of breastmilk. However, the mechanism of action remains unknown.¹¹

No adverse reaction was noted during the course of the study for those given *malunggay* leaves capsules. Several studies done by Co, et al.; Yabes-Almirante and Lim and Estrella, et al. made use of *malunggay* leaves capsules as galactagogue. All came up with the same results. No adverse effect was noted for its use.

CONCLUSION

This study has shown that the use of *malunggay* leaves capsule is effective and safe for the augmentation of breastmilk among mothers.

RECOMMENDATIONS

In the light of the findings of this research, the following are recommended:

1. To substantiate the current study, clinical trial using the same drug, *malunggay* leaves capsules, a larger sample size and longer period of use are recommended. The latter will help determine whether the prolonged use will yield a higher volume of breastmilk mothers nursing their infants.

2. *Malunggay* which grows almost throughout the Philippines, should be promoted as an effective galactagogue and a good source of calcium, iron and phosphorus for mothers breastfeeding their infants. The local health center must be tasked to spread and emphasize the use of *malunggay* leaves to augment the yield of breastmilk.
3. Primary care physicians and obstetricians should also remind mothers of the importance of breastfeeding immediately after birth.

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