# A double-blind, randomized controlled trial on the use of *malunggay (Moringa oleifera)* for augmentation of the volume of breastmilk among non-nursing mothers of preterm infants

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## ABSTRACT

*OBJECTIVES:* To determine if there is a significant difference in the volume of breastmilk on postpartum days 3 to 5 among mothers with preterm infants who take *malunggay (Moringa oleifera)* leaves compared to those who were given placebo.

*SETTING:* Tertiary government hospital

*STUDY DESIGN:* Double-blind, randomized controlled trial

*PATIENTS AND METHODS:* A total of 68 postpartum mothers admitted at a tertiary government hospital and whose infants had pediatric ages of less than 37 weeks and admitted to the NICU for tube feedings were included in the study. The mothers were randomized to receive *Moringa oleifera* (encapsulated in a commercial preparation containing 250 mg of leaves) or an identical capsule containing flour as placebo. They were asked to pump their breasts using a standardized breastpump from day 1 to day 5 postpartum. The mothers were given capsules on postpartum days 3 to 5 . The contents of the capsules were unknown to both Investigator and subjects. T-test was used to determine differences in baseline variables. Chi-square was used to determine difference in baseline proportions between groups. One-way ANOVA was used to determine if there were significant differences in the volume of breastmilk between treatment and control groups. A p-value of <0.05 was considered significant.

*RESULTS:* There was a trend towards increased milk production among those on *Moringa oleifera* leaves (Day 3: 114.1 ml $\pm$ 62.9 vs. 87.2 $\pm$ 49.1; Day 4: 190 ml $\pm$ 103.5 vs. 128.8 $\pm$ 84.9; Day 5: 319.7 ml $\pm$ 154.10 vs. 120.2 $\pm$ 54.7). This was statistically significant on Day 4 ($p = 0.007$) and on Day 5 ($p = 0.000$).

*CONCLUSION: Moringa oleifera* leaves increase milk production on postpartum days 4 to 5 among mothers who delivered preterm infants.


*KEYWORDS:* breastmilk, *malunggay*

Feeding breastmilk to premature infants is of interest because of its potential nutritional and immunologic benefits. The prevailing consensus is that early milk produced by women who deliver prematurely is more appropriate for VLBW infants than is donor milk from later stages of lactation, and that is to feed each infant milk produced by his/her mother minimizes potential risks from contaminants. To implement this consensus, mothers of VLBW infants must produce sufficient milk to meet the nutritional needs imposed by the accelerated growth rates of their infants. More often than not, however, the biggest obstacle to the initiation of feeding breast milk is collection. Most mothers after initiating expression of breastmilk on the first few days after birth complain of insufficient volume of breastmilk. This complaint has prompted most mothers to use milk formula, shift to bottle feeding, and discontinue breastfeeding.

Little quantitative data are available with which to evaluate protocols for the initiation and maintenance of successful lactation during the long periods of infant-mother separation that commonly follow premature delivery. De Carvalho, et al (1985)[1] reported that the frequency of milk expression was associated positively with milk production in mothers of premature infants, but the mean volumes of milk produced by women in that study did not meet the nutrient needs of VLBW infants and declined production are common problems associated with premature delivery.

A pilot study was done by the authors among 10 mothers who delivered neonates whose pediatric ages were less than 37 weeks in a tertiary government hospital. The total amount of volume of breastmilk expressed for 24 hours was plotted from Day 1 to Day 7. Results showed that there was a steady increase in milk volume from days 1 to 3 after which a constant or lower volume was recovered from days 3 to 5. The authors determined that 3 to 5 days postpartum is critical for the success of implementing a breastfeeding program among mothers who deliver preterm

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infants.[2]

## OBJECTIVES

This investigation is being undertaken with the following objectives: to determine the volume of breast milk that is expressed on postpartum days 3 to 5 among mothers who delivered prematurely who were given *malunggay* leaves compared to those who were given placebo and to determine if there is a significant difference in the volume of breast milk on postpartum days 3 to 5 between the two groups.

## PATIENTS & METHODS

This is a double-blind randomized controlled trial.

All mothers who delivered live infants less than 37 weeks and admitted to the NICU for tube feedings were eligible for inclusion into the study. Excluded were mothers with hypertension post-delivery, diabetes mellitus, chorioamnionitis, chronic illness or taking any medication on a regular basis, breast anomalies, and those with infants with congenital anomalies. After informed consent, mothers were randomized using a table of random numbers. Randomization was done by a person not involved in the study. Assignments were concealed using sealed opaque envelopes. Those assigned to the treatment group were given *Moringa oleifera* leaves in a commercial capsule preparation 250 mg every 12 hours starting on the 3rd postpartum day. Those who were assigned to the placebo group were given flour contained in identical capsules. Capsules were prepared by a research assistant who was not directly involved in the study. Treatment assignments were unknown to both the investigators and study subjects.

After proper orientation, demonstration and training, mothers were then instructed to pump their breasts every 4 hours using a standardized breast pump. Volume was measured using standardized containers and recorded in standard notebooks provided by the study personnel. When available, the volume of milk collected was also measured by the study personnel. Total milk volumes were tabulated from post-partum days 3 to 5.

All data were entered using Microsoft Excel 97. Statistical analysis was done using SPSS version 9.0 software.

T-test was used to determine differences in numeric baseline variables. Chi-square was used to determine difference in baseline proportions between groups.

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

A total of 82 mothers were recruited. There were 14 subjects who did not submit their notebooks and who were considered drop-outs, 9 from the treatment group and 5 from the control group. There were 11 mothers whose data were not complete because their infants expired before the 6th postpartum day. Thus, a total of 68 mothers were analyzed. Thirty-one (31) mothers were in the Treatment Group and 37 mothers were in the Control Group.

There is no significant difference in the gravidity, maternal age, and infants' pediatric ages and infants' birthweights.

The mean volume of milk collected among the treatment groups from postpartum days 3 to 5 are presented in Table 2 and Figures 1.

On day 3, the Treatment Group had a

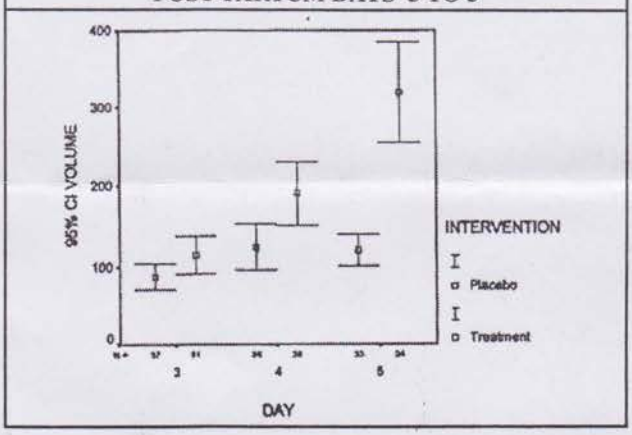
**Table 1**
**BASELINE CHARACTERISTICS OF TREATMENT AND CONTROL GROUP**

| Baseline Characteristic | Treatment Group | Control Group | p - value |
|---|---|---|---|
| Maternal Age (years) | 25.8 ± 5.1 | 30.9 ± 15.7 | 0.09 |
| Pediatric Age (weeks) | 33.7 ± 1.9 | 33.1 ± 2.3 | 0.30 |
| Infant's Weight (grams) | 1,532.7 ± 361.5 | 1,424.6 ± 359.2 | 0.22 |
| Median gravidity | 2 | 3 | 0.32 |

**Table 2**
**VOLUME OF BREASTMILK (in ml) ON PASTPARTUM DAYS 3 TO 5 OF TREATMENT AND CONTROL GROUPS**

| Day Post-partum | Treatment Group | Control Group | p - value |
|---|---|---|---|
| Day 3 | 114.1+1-62.9 | 87.2+1-49.1 | 0.052 |
| Day 4 | 190.0 + - 103.5 | 123.8 + - 84.9 | 0.007 |
| Day 5 | 319.7 + - 154.1 | 120.2+1-54.7 | 0.000 |

**Figure 1**
**VOLUME OF BREAST MILK COLLECTED FROM POST-PARTUM DAYS 3 TO 5**



mean breast milk volume of 114.1 ± 62.9 ml compared to the Control Group with a mean of 87.2 ± 49.1 ml. This showed a mean difference of 20-30 ml or a 28-32% increase in breast milk volume in favor of treatment.

On day 4, the Treatment Group had a higher mean breast milk volume of 190 ± 103.5 ml compared to the Control Group with only 123.8 ± 84.9 ml. This showed a mean difference of 54-77 ml or a 51-58 % increase in favor of treatment.

On day 5, the difference was even bigger with the Treatment Group having a breast milk volume of 319.7 ± 154.1 ml compared to the Control Group who had 120.2 ± 54.7 ml. This had a mean difference of 154 - 245 ml or a 152-176 % increase in breast milk volume in favor of treatment.

There were no reported adverse effects in both groups.

## DISCUSSION

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 infant although the rate of milk secretion after the third or fourth day postpartum declines if milk removal is not practiced at regular intervals.[3] A foreign study[4] on milk volume produced by women aged 20 to 38 years who delivered at 28 to 30 weeks gestation showed that optimal milk production was associated with five or more milk expressions per day and pumping durations that exceeded 100 minutes per day.

After delivery, the basal levels of prolactin fall and, even in women who breastfeed, they approach the normal range by 2 to 3 weeks postpartum.[5] When suckling occurs prolactin is promptly released, the levels rising 5 to 10 fold for about 30 minutes. Tactile sensitivity of the nipple, markedly reduced during pregnancy, increases within a few hours of delivery and is clearly geared to efficient suckling.

In the early puerperium, the amount of milk produced correlates with the amount of prolactin released during suckling, significantly larger amounts of prolactin being released by "good" feeders (over 700 ml of milk a day) than by "poor" feeders, both the yield of milk and the amount of prolactin released increases.[6]

Many physiologic factors influence milk composition and volume. These include premature delivery, age of the mother, within-feed regulation of milk release, and the baby's demand for milk.[7] There is little information on milk volume produced by mothers giving birth prematurely.[1] Anecdotally, premature deliveries have been associated with a decrease in volume of breastrnilk compared to term deliveries because of the relative absence of sucking stimulation among mothers of preterm infants who cannot nurse because of the long infant-mother separation and because their infants may be too small to suckle directly.

Hormonal stimulation of the mammary gland, such as occurs during nursing, is an important regulator of amount of milk produced. In the non-nursing mother, breast stimulation by pump can also induce prolactin release comparable with that induced by suckling.[6] As long as sucking stimulation continues, in this study, the pumping action of a breast pump/reliever, there is production of large volumes of milk. Conversely, if there is a decrease in blood flow, as occurs in response to stress, milk secretion declines because the mammary supply of oxygen, glucose, fatty adds, and amino adds is reduced.[8] Maternal stress was not evaluated during the study, although each family was experiencing strain due to their infants' hospitalization.

Lactagogues or galactogues 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 soups to enhance breast milk production. The mechanism of action has not been explained but it was effective as a galactogogue and has been used by generations of nursing mothers especially those with inadequate lactation. [9]

A local study done in 1996 by Almirante and Lim demonstrated the lactation-enhancing effect of malunggay leaves as evidenced by a greater increase in maternal serum prolactin levels and percentages of gains in the infants' weights among the lactating mothers who took the malunggay leaves.[10] This can probably explain its mechanism of action. A follow-up study done by the same authors among hypertensive mothers showed similar results, with significant increases of tin values in the treatment group *(Moringa oleifera group)* compared to the placebo.[11] The authors in the same study recorded the breastmilk volume of a subgroup of mothers (eight out of 31 mothers) whom they did direct measurements of expressed milk on the first, second, and fourth month postpartum. They recommenced adding more subjects to this subgroup of mothers to increase the level of significance.[11]

So far, no study has demonstrated the clinical effect of malunggay leaves on a more clinically relevant outcome, that of breast milk volume, particularly on mothers of preterm infants.

Our current study demonstrated the lactation-enhancing effect of malunggay (Natalac capsules) leaves as evidenced by the significantly greater increase in the volume of milk expressed by mothers on the 3rd to the 5th postpartum day given *Moringa oleifera* capsules compared to those given placebo. The increase in volume of breastmilk on the third day postpartum only had a tendency to be significant at $p < 0.052$. This may be due to the fact that we only started giving the treatment drug (*Moringa oleifera* capsules) on this day. We recommend either giving the treatment drug earlier, probably on postpartum day 2 or increasing the sample size to increase the level of significance for statistical analysis on day 3 postpartum.

## CONCLUSION

We, conclude that *Moringa oleifera* leaves increase the volume of breastmilk produced by mothers of preterm infants on post-partum days 3 to 5. We therefore

recommend its routine use among mothers of preterm infants to augment lactation, thereby ensuring an adequate supply of breastmilk in the population that needs it the most.

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