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Original Research Article

A study to evaluate the effect of Lactobites bar as a galactagogue to increase the production of milk in lactating women and promote overall healthy recovery of lactating mothers

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ABSTRACT

Background: Breastfeeding is widely acknowledged as the preferred and recommended mode of infant nutrition. However, women who have undergone cesarean deliveries may face an increased risk of inadequate breast milk production, which can be addressed through various techniques, including the use of galactagogues, which stimulate breast milk production. Galactagogues are synthetic or plant molecules that induce, maintain, and increase milk production.

Materials and Methods: In this current real-world evidence study, 53 lactating women were enrolled. During the study, they received lactobites bar for 28 days. The intestinal health of the baby, incidences of formula feeding, the volume of breast milk, baby's anthropometric measures: such as changes in height, changes in the quality of hair and skin of the mother were evaluated. The feeling of wellness in the mother and haemoglobin levels were also assessed during the study.

Results: The haemoglobin levels were significantly increased in mothers who were given lactobites bar. A significant increase was observed in hours of night and day sleep, stool frequency per day, vol. of breast milk [baseline vs 28th day: 30.19 ± 34.4 vs 448.06 ± 651.11 ; $p < 0.05$], no. of diapers per day, height [baseline vs 28th day: 47.39 ± 1.72 vs 50.1 ± 1.62 ; $p < 0.05$], changes in quality of hair and skin of mother, and the feeling of wellness in mother [baseline vs 28th day: 0.04 ± 0.19 vs 1.88 ± 0.32 ; $p < 0.05$]. A significant reduction was observed in formula feeding incidence ($p < 0.001$). No side effects were reported.

Conclusion: Lactobites bar can be used as a galactagogue to increase the human milk volume in lactating women.

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1. Introduction

Difficulty in lactation or breastfeeding may be due to cesarean delivery, poor nutrition have been linked to lactation difficulties.¹ Breastmilk production can be increased through galactagogues, kangaroo mothering and relaxation techniques.^{2,3} Domeperidone is not approved by the US FDA due to suspected higher risk

of ventricular arrhythmia and sudden adult cardiac death.⁴ Instead of pharmaceutical products, various complementary and alternative techniques can be employed as galactagogue. The Galactagogues are synthetic or plant molecules of milk production-inducing, -maintaining, and -increasing molecules that operate as mediators of intricate physiological and physical processes.⁵ These include herbal medicines and techniques such as herbal compression, herbal supplements, herbal bars, and herbal teas that contain ginger, stinging nettle, fenugreek, or

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turmeric that promote breast milk production without causing adverse effects.^{6,7}

Lactobite bar is a natural lactation supplement containing Fennel, Moringa Leaves, Shatavari, Halim Seeds, and Berries that are rich in antioxidants and are known to naturally assist lactation. The objective of this study was to evaluate the effect of Lactobites bar as a galactagogue to increase the production of milk in lactating women and the metabolism-boosting effect, which can contribute to weight loss and fat burn.

2. Aim

To evaluate the effect of Lactobites bar as a galactagogue to increase the production of milk in lactating women.

3. Objective

The objective of this study was to evaluate the effect of Lactobites bar as a galactagogue to increase the production of milk in lactating women. The intestinal health of the baby, incidences of formula feeding, the volume of breast milk, baby's anthropometric measures: such as changes in height, changes in the quality of hair and skin of the mother were evaluated. The feeling of wellness in the mother and hemoglobin levels were also assessed during the study.

4. Materials and Methods

4.1. Study design

This study was a Real World Evidence study. The study protocol was approved by Suraksha Institutional Ethics Committee (Reg No.ECR/644/Inst/MH/2014/RR-20) and related materials in compliance with ICMR (Indian Council of Medical Research),⁸ New Drugs and Clinical Trials Rules, 2019, ICH GCP, and the declaration of Helsinki.

4.2. Patient criteria

Study included lactating women between 23 and 45 years old who have given birth to a healthy baby at term (born between 37 and 42 weeks) and those who have the perception of having a little volume of milk or nutritional composition of milk that is not adequate for their baby, women with 2 weeks of breastfeeding, and that at the time of beginning the study, they are not supplementing with formula milk for feeding their baby, they have the firm intention of breastfeeding for 28 more days.

The study excluded participants suffering from any disease that may hinder or prevent breastfeeding, being currently consuming or having consumed in the two weeks prior to the study a probiotic or a supplement with plant extracts, being consuming any drug that can alter the volume or composition of breast milk, have an allergy to any antibiotics or peanuts, have an allergy to any of the components of the products under study.

4.3. Study product

Mothers were instructed to consume Lactobite bar (manufactured by Nutrizoe Nutriifoods), 1 - 2 bars daily for 28 days. Lactobite bar is composed of energy-boosting ingredients like Dates, Berries (8% of Cranberry and 8% of Blueberry), Pea Protein, Seeds (Sesame, Pumpkin, Halim (Aaliv)), Fructooligosaccharide (FOS), Oats, Almonds, Amarnath flour, Goond, Ghee, Honey, Coconut, Fennel powder, Spinach powder, Moringa leaves powder, Shatavari & Cinnamon Extract, Antioxidant (Vitamin E), and Dates.

4.4. Outcome measures

The primary outcome measures involved were levels of haemoglobin of the mother.

The secondary outcome measure involved sleep parameters of the baby: hours of the night sleeping per day and hours of total sleeping during the day, intestinal health of the baby, incidences of formula feeding, the volume of the breast milk, baby's anthropometric measures: such as changes in weight, height & BMI, changes in quality of hair and skin of the mother, and feeling of wellness in mother.

4.5. Statistical analysis

The data were analyzed for demographics, effectiveness and tolerability. The data are presented as mean \pm standard deviation (SD) or number (percentage). Since observations are quantitative, a paired t-test was carried out to test the significance of parameters pre and post-study. All statistical analyses were performed using the Statistical Package for Social Sciences (SPSS) version 26.0 statistical software (IBM SPSS Statistics, Armonk, NY). The software that is used is Statistical Software: Microsoft Excel 2023, SPSS 22.0.

5. Results

A total of 53 lactating women were recruited during the study. The average age of the subject was 30.72 years.

A significant increase was observed in haemoglobin levels ($p < 0.001$) (Figure 1, Table 1); hours of night and day sleep ($p < 0.001$) (Figure 2); stool frequency per day ($p < 0.001$) and number of diapers per day ($p = 0.002$) (Figure 3); baby's height ($p < 0.001$) (Figure 4); Formula feeding Incidence ($p < 0.001$) and volume of breast milk ($p < 0.001$) (Figure 5); changes in quality of hair and skin of mother ($p < 0.001$) and the feeling of wellness in mother ($p < 0.001$) (Figure 6). A significant reduction was observed in formula feeding incidence ($p < 0.001$) (Figure 5 a Table 2).

All the patients completing the study and reported no major side effects during the study period. Allergic contact dermatitis, antibiotic resistance, and anaphylaxis was not observed in any patient. The lactobite was overall well tolerated by the mothers.

Table 1: Evaluation parameters for mother

Parameters	Mean	SD	P Value	% change	Result
Haemoglobin (Hb) levels (g/dl)					
Baseline	11.06	1.12	<0.001	8.17	Sig
Day 28	11.96	0.98			
Volume of Breast Milk (ml)					
Baseline	30.19	34.4	<0.001	1384.27	Sig
Day 28	448.06	651.11			
Changes in the Quality of hair and skin of the mother					
Baseline	0.1	0.41	<0.001	93.33	Sig
Day 28	1.47	0.73			
Feeling of Wellness in Mother					
Baseline	0.04	0.19	<0.001	97.96	Sig
Day 28	1.88	0.32			

Table 2: Evaluation parameters for infant

Parameters	Mean	SD	P Value	% change	Result
Hours of Night Sleep					
Baseline	2.27	1.3	<0.001	42.74	Sig
Day 28	3.25	1.66			
Hours of Day Sleep					
Baseline	2.37	1.4	<0.001	51	Sig
Day 28	3.58	1.46			
Stool Frequency Per Day					
Baseline	2.08	1.3	<0.001	45.45	Sig
Day 28	3.02	1.45			
Formula Feeding					
Baseline	6	1.92	<0.001	81.88	Sig
Day 28	1.09	1.26			
Baby Height (cm)					
Baseline	47.39	1.72	<0.001	5.71	Sig
Day 28	50.1	1.62			
Number of Diapers per day					
Baseline	5.51	3.57	0.002	18.86	Sig
Day 28	6.55	2.16			

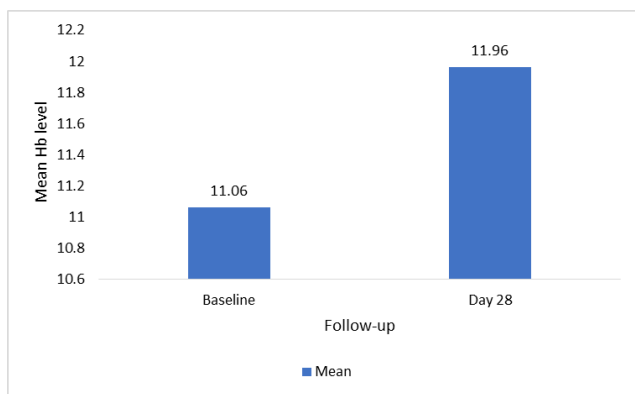


Figure 1: Haemoglobin levels

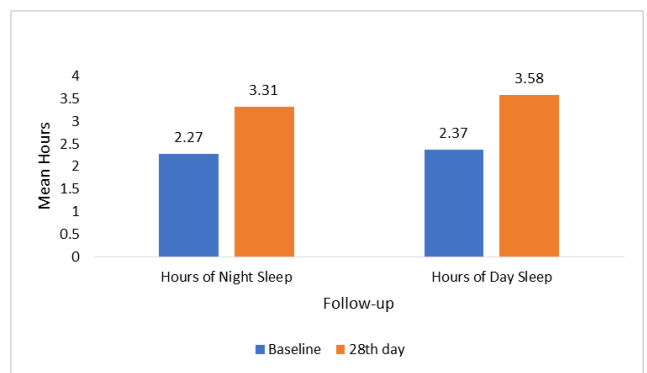


Figure 2: Hours of sleep in the night and day

6. Discussion

The current Real World Evidence study showed that consumption of Lactobites bar as a natural galactagogue

supplement increased the breastmilk production in lactating women. There was a significant increase in hours of the night and day sleep, stool frequency per day, number of diapers per day, baby’s height. In the mothers, lactobite bar

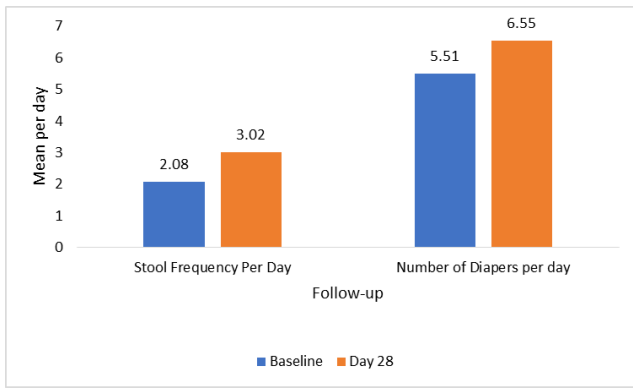


Figure 3: a): Stool frequency per day; b): Number of Diapers per day

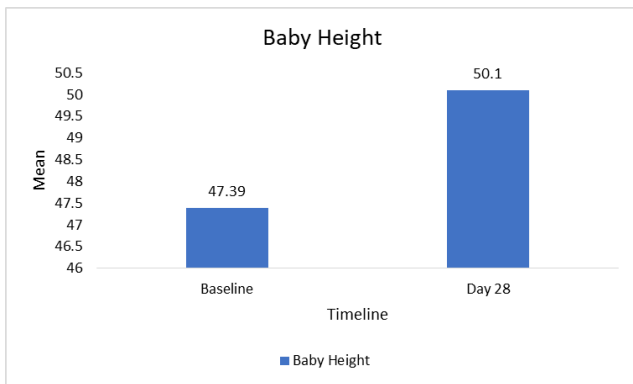


Figure 4: Baby height

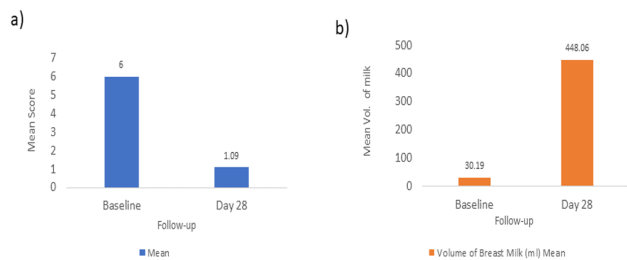


Figure 5: a): Formula feeding incidence; b): Volume of breast milk

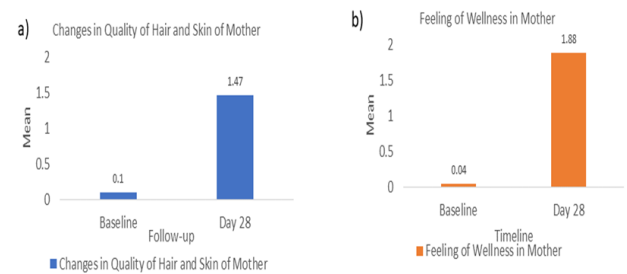


Figure 6: a): Changes in quality of hair and skin of mother; b): Feeling of wellness in mother

improved hair and skin health, increased feeling of wellness, volume of breast milk and increased haemoglobin levels. There was a significant reduction observed in formula feeding incidence. There were no serious side effects observed, and it is safe for both the mother and the baby.

Nutrition and composition of dietary intake plays a crucial function in controlling the amount and quality of milk supply during lactation.⁹ Fennel seeds contain volatile oil mainly composed of anethole, a phytoestrogen that mimics the effects of estrogen in the body. Fennel galactagogues improved breast milk volume, fat content, and infant weight gain. Fennel has been used in humans as a galactagogue, and no side effects have yet been recorded. Furthermore, fennel enhanced reproductive cyclicality, facilitate birth, and increased libido.^{9,10}

Asparagus racemosus Wild. (Shatavari) is an anti-inflammatory, boosts immunity.¹¹ Additionally, it has elements that have antidepressant properties. As a result, it can avoid postpartum depression or blues, which frequently affect nursing mothers.¹² For postpartum women and even mothers of preterm newborns, moringa can work as a galactagogue, a natural ingredient to support lactation.¹³ Moringa (*Moringa oleifera*) leaves have been shown to lengthen a baby’s naps, boost weight gain in infants, and enhance breast milk production. Edible gum (gondh) improves health, endurance, and immunity. The most common use is to cure weakness. Women who are pregnant or nursing require an additional nutritional boost. Garden cress seeds (halim seeds) are very high in Iron and Folic acid content. In a preclinical study, garden cress seeds exhibited a strong mammatrophic and lactogenic effect.^{14,15}

The antioxidant power of blueberries is greater than that of any other fruit. It has been established through previous articles that antioxidants get through to the baby, which may aid in illness prevention in infancy. Cranberry (*Vaccinium macrocarpon*) fruit contains phenolics, flavonoids, anthocyanidins, and ellagitannins. It is most often used to prevent urinary tract infection.¹⁶ Mother’s milk flow is increased with the aid of cinnamon. Additionally, it will aid in extending the postpartum period. Dates have also been shown to contain antioxidant and antimutagenic properties. It also acts as a tonic to strengthen uterine muscles, and it may also promote brain health.¹⁷

Fresh spinach has a higher iron content than other vegetables, with 2.7 milligrams of this crucial element present in a serving of 100 grams of fresh spinach. Spinach powder is a rich source of fiber and its whole dietary fiber content is preserved by dehydration.^{18,19} Essential elements like Vitamin E, Vitamin B2, Vitamin B3, and Vitamin B1 are abundant in almonds. Additionally, it is a good source of minerals like calcium, iron, magnesium, copper, phosphorus, and zinc.²⁰ Oats help stay calm by releasing oxytocin and relaxin, which stimulates milk production and helps with flow. Oats have the presence of nutrients such

as beta-glucans, protein, fiber, and healthy carbohydrates, that are responsible for a healthier, lusher milk supply.²¹ In honey, there is an excessive amount of fructose and glucose, and it provides energy and endurance. It has anti-bacterial, anti-fungal and antioxidant properties that boost the immune system.^{22,23} Pumpkin seeds, or pepitas, are a rich source of iron, protein and fiber. Iron is essential for proper nerve cell development and the specialisation of specific brain cells. Pumpkin seeds provide omega 3 fatty acids those are important for baby's nerves and brain development. It is also a natural source of DHA and alpha linolenic acid which help nursing moms in breastfeeding supply.²⁴

Based on the above results, we can infer that the lactobites bar are safe for mothers as they don't cause any serious side effects and also, they are safe for baby as it can be observed from the stool frequency. The lactobites bar are also filling for the baby as the change in number of diapers is quite frequent compared to baseline.

7. Limitation

The study has a few limitations, like a relatively small sample size and self-reported outcomes. The study does not provide comparative data with other existing formulations since this is a novel nutraceutical product. The results obtained so far encourage additional research to establish a more extensive database.

8. Conclusion

In conclusion, this real-world evidence study demonstrated a significant increase in the volume of breast milk, baby's weight and height, babies hours of night and day sleep, stool frequency per day, and no. of diapers per day. It showed a significant reduction in formula feeding incidence. It showed the overall wellness of mothers by supporting increase in haemoglobin and overall recovery during the postpartum period.

9. Abbreviations

ICMR - Indian Council of Medical Research, ICH - International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, GCP - Guideline for Good Clinical Practice, BMI - Body Mass Index, SD - Standard Deviation.

10. Source of Funding

The study was sponsored by Nutrizoe Nutriifoods Pvt. Ltd.

11. Conflict of Interest

None.

12. Acknowledgement

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