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Original Research Article

Formulation and nutritional evaluation of galactagogue-based nutritional health mixes to support lactation

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ABSTRACT

Background: Human breast milk is a rich source of essential nutrients and also contains protective elements such as antibodies and immune factors, along with hormones, growth factors, enzymes, and other bioactive compounds, which are designed for easy digestion and optimal absorption, ensuring the best possible growth and development of infants. However, dysgalactia or insufficient milk production, often linked to inadequate intake of calories and essential nutrients necessary for milk production, is a common hindrance to breastfeeding. In this context, the current study was planned to design and develop different variations of finger millet and oats-based galactagogue health mixes with the intent to encourage milk synthesis.
Methods: Four galactagogue health mixes, namely GHM-R1, GHM-R2, GHM-O1 and GHM-O2 based on finger millet (25 and 50%) and oats (25 and 50%) with nuts and seeds, were developed. Foxnut flour-based health mix was used as a control. A descriptive sensory score card was used for sensory analysis. AOAC methods were used to analyse proximate and dietary fibre. Calcium and iron were analysed using standard protocols.
Results: Among the developed galactagogue health mixes, the sensory quality of GHM-R1 (25% popped finger millet) was found to be highly acceptable with a score of 8.45. GHM-R2 (50% popped finger millet) reported the highest calcium content, 328 mg/100 gm.
Conclusions: There lies great scope in scientifically evaluating the traditional knowledge systems based galactagogues for the mechanism, efficacy, dose, and safety.

Keywords: Calcium, Finger millet, Galactagogues, Iron, Lactation, Oats

INTRODUCTION

Human breast milk, the gold standard for infant feeding and nourishment for infants during their initial months of life, is supported from an evolutionary, nutritional, and financial perspective. It serves as a reservoir of essential nutrients, including carbohydrates, proteins, lipids, vitamins, and minerals. It is not only safe and clean but also contains protective elements such as antibodies, immune factors, hormones, growth factors, enzymes, and bioactive compounds that are uniquely tailored for ease of digestion and optimal bioavailability for the growing infant.

Breast milk production is a complex physiological process that starts with mammogenesis, which is the development of mammary gland, followed by lactogenesis, the capability to secrete milk, and the subsequent process of milk production known as lactation.[1]

As per the Indian Pediatrics Association, it's recommended to exclusively breastfeed infants for the first six months, followed by continued breastfeeding for a minimum of two years, alongside introducing semi-solid family foods, to ensure the baby's health and strength. Children who are breastfed tend to have lower chances of being overweight or obese, are less susceptible to diabetes in the future, and do better on intelligence tests.[2]

Additionally, women who breastfeed experience decreased risks of breast and ovarian cancers, a quicker return to their pre-pregnancy weight, and enhanced psychological well-being (WHO).

Despite the critical role of mother's milk in enhancing an infant's health, many women globally face breastfeeding challenges due to a range of issues, including lack of knowledge, restrictive practices, attitudes towards breastfeeding, and both physiological and psychological limitations. These challenges negatively impact the infant's immunity, growth, and overall development. One major factor contributing to suboptimal breastfeeding is insufficient breast milk production, often caused by an inadequate intake of calories and essential micronutrients required for milk production. However, solutions exist in the form of pharmacological interventions in the form of medications and traditional cultural knowledge-based interventions in the form of plant-based ingredients to stimulate milk production that are collectively termed as galactagogues. Worldwide, in different cultures, there exists traditional knowledge about the use of plant-based sources that supposedly help milk production and sustain it.

Galactagogues can be synthetic, i.e., pharmacological, or plant molecules (natural) used to induce, maintain, and increase milk production.[3] Pharmacological galactagogues include metoclopramide, domperidone, chlorpromazine, and sulpiride, which have adverse effects like gastrointestinal disorders, dry mouth, lethargy, etc.[4] Natural galactagogues are typically derived from botanical sources or other food agents that possess galactagogic properties, i.e., milk production enhancing property or potential. Fenugreek (*Trigonella foenum-graecum*), milk thistle (*silymarin; Silybum marianum*), shatavari (*A. racemosus*), alfalfa (*M. sativa*), blessed thistle (*O. benedictus*), goat's rue (*G. officinalis*), fennel (*F. vulgare*), and brewer's yeast are commonly suggested and used herbal galactagogues. However, there is limited data available on the effectiveness of these herbal products, and their reliability is often subjective evidence. Asparagus, fenugreek, and milk thistle are among the few plant-based galactagogues that have published clinical data on human use, although these kinds of data are sparse.[3,5]

Therefore, there lies a great scope for scientifically exploring plant-based or herbal galactagogues to determine the safety, efficacy, and mechanism by which this increase and maintain milk production. The current study was a step in the direction of formulating a galactagogue health mix (GHM) based on grains, seeds, and nuts that is nutritionally dense, safe, and allegedly increases milk production and improves overall maternal health.

METHODS

A descriptive and experimental study design was employed to develop a galactagogic food product, which was subjected to sensory and qualitative analysis. The study was conducted in the department of nutrition and dietetics, JSS AHER, Mysuru, Karnataka, India, from January 2023 to July 2023.

Materials

All the ingredients were purchased from a local market in Mysore, stored appropriately till use. The chemicals used were of analytical grade.

Four galactagogue health mixes (GHMs) were developed based on popped ragi flour and rolled oats flour, and foxnut (makhana), based served as a control and was used to compare the other variations. The detailed composition of the GHMs along with the control is given in Table 1.

Table 1: Composition of galactagogue health mixes (GHMs).

Product code*	Ingredients** (%)															
	FNF	PFMF	ROF	TG	PS	MS	CS	PS	SS	WS	PC	RA	CA	DC	AM	DT	CB
GHM-M	23.80	-	-	9.52	4.76	4.76	4.76	4.76	4.76	4.76	4.76	4.76	4.76	9.52	4.76	4.76	4.76
GHM-R1	-	23.80	-	9.52	4.76	4.76	4.76	4.76	4.76	4.76	4.76	4.76	4.76	9.52	4.76	4.76	4.76
GHM-R2	-	47.61	-	9.52	2.38	2.38	2.38	2.38	2.38	2.38	2.38	2.38	2.38	9.52	2.38	4.76	4.76
GHM-O1	-	-	23.80	9.52	4.76	4.76	4.76	4.76	4.76	4.76	4.76	4.76	4.76	9.52	4.76	4.76	4.76
GHM-O2	-	-	47.61	9.52	2.38	2.38	2.38	2.38	2.38	2.38	2.38	2.38	2.38	9.52	2.38	4.76	4.76

Product code*- GHM-M: foxnut/makhana (25%); GHM-R1: popped finger millet 25%; GHM-R2: popped finger millet 50%; GHM-O1: rolled oats 25%; GHM-O2: rolled oats 50%. Ingredients**- FNF: Foxnut/Makhana Flour; PFMF: Popped Finger Millet Flour; ROF: Rolled Oats Flour; TG: Tragacanth/Edible gum; PS: Poppy Seeds; MS: Muskmelon Seeds; CS: Cucumber Seeds; PS: Pumpkin Seeds; SS: Sunflower Seeds; WS: Watermelon Seeds; PC: Pistachios; RA: Raisins; CA: Caraway; DC: Desiccated Coconut; AM: Almonds; DT: Dates; CB: Clarified Butter/Ghee.

Preparation of GHMs

The detailed procedure adopted to develop the galactagogue health mixes is presented in Figure 1.

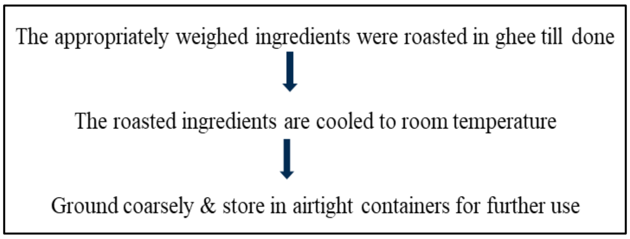

Figure 1: Steps followed in preparing GHMs.

Sensory evaluation

The developed products were subjected to descriptive sensory analysis by a semi-trained panel (n=50) and the results recorded. The descriptives used were colour, texture, taste, flavour, appearance, and overall acceptability was recorded.

Nutrient analysis

Proximate and dietary minerals analysis was carried out for all the GHMs. AOAC methods were used to analyse carbohydrate, protein, fat, dietary fiber, iron, and calcium.[6] Energy value was mathematically derived from the macronutrients.

Statistical methods

Standard deviation and percentages were used to describe the data. Standard deviation helped measure the amount of variation in values of nutrients observed, whereas percentage was used to express the fraction of nutrients as a proportion out of a 100-gm sample.

RESULTS

Dysgalactia, i.e., insufficient milk production during breastfeeding, is a serious concern affecting exclusive breastfeeding. To improve milk production use of galactagogues is a common practice in many cultures across the world. In this context, the current research is directed towards developing galactagogue health mixes (GHMs) with purported galactagogic properties. The developed products were coded GHM-M, which was foxnut flour locally known as makhana based (25%), GHM-R1, containing 25% popped finger millet, GHM-R2, containing 50% popped finger millet, GHM-O1 containing 25% oats, and GHM-O2 containing 50% oats. Refer to Table 1 for the composition of GHMs.

Organoleptic experience

A desirable sensory experience is crucial for its acceptability, usage, and commercial success; therefore, to ascertain the sensory acceptability of the developed GHMs, they were subjected to sensory analysis, and the result obtained is depicted through a radar chart (Figure 2).

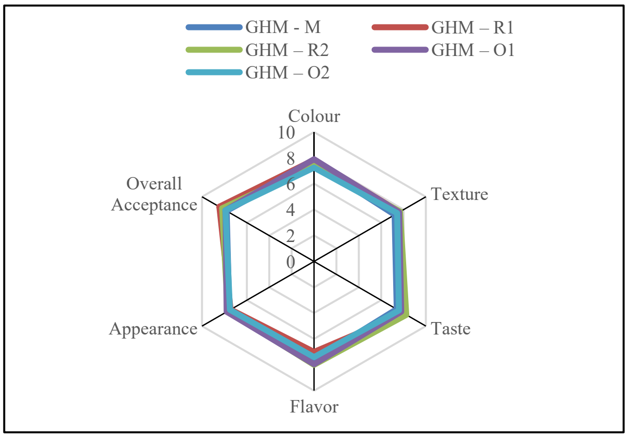

Figure 2: Sensory profile of galactagogue health mixes.
GHM-M: foxnut/makhana; GHM-R1: popped finger millet 25%; GHM-R2: popped finger millet 50%; GHM-O1: rolled oats 25% GHM-O2: rolled oats 50%.

The sensory attributes tested were color, texture, taste, flavor, appearance, and overall acceptability. It was found that the overall acceptability of GHM-R1 made with 25% popped finger millet was most acceptable with a score of 8.45, followed by GHM-R2 made with 50% popped finger millet, 8.2. Sensory scores of the other two GHMs, GHM-O1 and GHM-O2 made with 25% and 50% oats, respectively, were on par with the control mix, GHM-M made with 25% foxnut flour.

Nutritional value

Calculating the nutritional value of food products is crucial for educating consumers and helping them make informed purchasing decisions. The proximate energy value of the developed products is given in Table 2, and Figure 3 depicts the iron and calcium content of the developed galactagogue health mix. Control product (GHM-M) made with 25% foxnut flour against which other variations were compared was most energy dense with 472 kcal/100 gm, followed by 50% oats-based GHM giving 408 kcal/100 gm. Whereas popped finger millet-based products had the highest amount of carbohydrates, i.e., 25% and 50%, popped finger millet-based GHM had 63.8±0.22 and 69.90±0.01 gm/100 gm, respectively. Among the variations, 25% and 50% oats-based GHM had the highest protein content with 15.2±0.14 and 17±0.28 gm/100 gm, respectively. GHM-R2 with 50% popped finger millet had 23.4 mg/100 gm iron and 328 mg/100 gm calcium, whereas GHM made with 50% oats, i.e., GHM-O2, had 7.9 mg/100 gm iron and 92 mg/100 gm calcium. GHM-O2, made with 50% incorporation of oats, had 17±0.28 gm/100 gm protein and was on par with the control mix. The inclusion of ingredients like sunflower, pumpkin, and seeds contributed to the additional protein content of GHM-O2.

Table 2: The proximate (gm/100 gm) and energy (kcal) value of GHM.

Sample code	Carbohydrates	Protein	Total fat	Dietary fiber	Energy (Kcal)
GHM-M	68.00±0.3	18.4±0.1	2.40±0.0	8.40±0.1	472±1.0
GHM-R1	63.8±0.22	10.6±0.14	1.1±0.07	14.2±0.14	358±2.75
GHM-R2	69.90±0.01	11.80±0.07	01.00±0.00	16.00±0.28	376±2.83
GHM-O1	54.0±0.11	15.2±0.14	13.9±0.02	9.8±0.14	391±0.0
GHM-O2	56.1±0.73	17±0.28	12.5±0.14	10.6±0.28	408±1.4

*GHM-M: foxnut/makhana flour; GHM-R1: popped finger millet 25%; GHM-R2: popped finger millet 50%; GHM-O1: rolled oats 25%; GHM-O2: rolled oats 50%

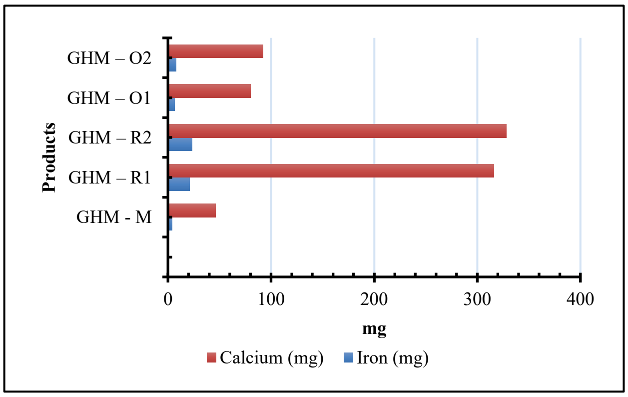

Figure 3: Iron and calcium content of GHMs.
GHM-M: foxnut/makhana; GHM-R1: popped finger millet 25%; GHM-R2: popped finger millet 50%; GHM-O1: rolled oats 25% GHM-O2: rolled oats 50%.

DISCUSSION

Breast milk is a uniquely tailored food for babies that serves as a natural source of various macronutrients, micronutrients that meet the baby's specific needs of growth and development. In addition to providing nutrients, breast milk also contains non-nutrients like the immunoglobulins that are essential for the baby's immunity. Human milk contains carbohydrates, lipids, proteins, vitamins, minerals, fatty acids, amino acids, and trace elements. In addition, numerous cells, macrophages, bacteria, chemokines, cytokines, immunoglobulins, hormones, growth factors, and mucin are present.[7-9] Exclusive breast feeding that is advocated in the initial six months of the infant is impacted by various factors; health condition, personal belief, knowledge, the attitudes of immediate and extended family, cultural and traditional practices, the availability of peer or community health worker support, and workplace policies such as the time and privacy to feed or pump breastmilk, all influence a woman's ability to initiate and maintain exclusive breast feeding.[10] In this context, the sensory scores were highest for finger millet-based galactagogue (Figure 2). Finger millet comprises functional components like the slowly digestible starch and resistant starch and has become a popular choice for making malted, extruded, ready-to-eat products and has been used in India from ancient times.[11] Malted products made with finger millet are also used as complementary/weaning food for infants.

A study aimed at developing value-added products from finger millet (*Eleusine coracana*) viz., biscuits, muffins, crackers, laddoos, and chikkis, along with estimating their nutritive values and organoleptic evaluation, showed that finger millet based products exhibited higher acceptability scores which was done using a standard 9-point hedonic scale compared to control, for e.g., biscuits made 60% refined wheat flour and 40% finger millet flour was the most acceptable with a score of 7.95.[12] The preference of finger millet based GHMs could also be attributed to the popping process being used which enhances the taste and textural properties and enhances digestibility of the starch through gelatinization and degradation of dietary fiber.[13-15] There is enough research available on the effect of different processing techniques on reducing anti-nutrient content and improving nutritional value with respect to millets.[16]

Calculating the nutritional value of food products is crucial for educating consumers and helping them make informed purchasing decisions. Nutrient density, which assesses the quantity of essential nutrients per calorie, plays a key role in determining the quality of a food product. This data informs the development of nutrition policies and standards and aids in spreading consumer-oriented knowledge. By understanding nutrient density, consumers can choose healthier options, and policymakers can create standards that enhance public health. The proximate energy value of the developed products is given in Table 2, and Figure 3 depicts the iron and calcium content of the developed galactagogue health mix. Finger millet-based product showed the highest calcium content; thus, the results are congruent with the fact that finger millet is the richest source of calcium (300 mg/100 gm), which is a vital component of human milk. A study conducted to develop and evaluate the nutritional profile of moringa leaves, ginger, and mint-based galactagogue concoction showed similar results, with calcium being present in higher concentration.[17] Also, if a mother's calcium intake is not adequate, her bone health gets compromised as calcium gets leached from her bones as a compensatory mechanism. The vitamin and mineral composition of breast milk, like vitamin A, D, B_6, and B_{12}, calcium, iron, zinc, and iodine, is reflective of the mother's dietary intake; therefore, it is vital for the lactating mother to have enough through her diet.

The product made with oats had highest percentage of protein, whose recommendation increases by 1.5 gm during lactation, as it is important for milk protein synthesis, essential brain developing fats like DHA (docosahexaenoic acid) and ARA (arachidonic acid) are crucial and should be provided through diet as they are important for infant's brain development. Oats (*Avena sativa L.*) are a popular breakfast cereal, which contains soluble dietary fiber, β-glucans, protein 12.5%, fat 5.9%, fiber 2.2%, ash 6.2%, and total CHO 69.4%. The main storage proteins in oats are globulins.[18] Furthermore, the inclusion of ingredients like sunflower, pumpkin, and seeds contributed to the additional protein content of the oats-based product. Pistachios have a lower fat and energy content and the highest levels of, γ-tocopherol, vitamin K, phytosterols, xanthophyll, carotenoids, certain minerals (Cu, Fe, and Mg), vitamin B6, and thiamine.[19] In general, other ingredients used, like raisins, which are energy dense, caraway that contains calcium, desiccated coconut that has saturated and monounsaturated fatty acids, almonds being protein rich, and dates, which are energy dense, all contributed to increasing the calorie, nutrient, and phytochemical density of the GHMs.

The combination of these ingredients makes the product macro, micronutrient, and phytochemical dense, making it ideal for the increased energy needs of lactation and overall well-being of the lactating mother. As the ingredients used in GHM are used regularly and are considered GRAS, the product can be deemed safe for consumption. A study focusing on the relationship between traditional galactagogue consumption and milk volume, using self-reported surveys from 36 exclusively breastfeeding mothers with infants aged 1 to 3 months found significant correlations between milk volume and the consumption of specific traditional galactagogues (such as banana flower, lemon basil, Thai basil, bottle gourd, and pumpkin) as well as protein sources (such as egg tofu, chicken, fish, and seafood). Maternal energy and carbohydrate intake were also related to milk volume, whereas protein intake was not.[20]

The effects of herbal galactagogues can be attributed to their phytoestrogenic action i.e., they may have similar activity as 17β-estradiol (E2), a natural estrogen, that promotes the proliferation of mammary epithelial cells (MEC).[21,22] During pregnancy, estrogen promotes the development of the mammary gland by increasing the number of alveolar units where milk is produced. It also supports the differentiation of mammary epithelial cells into milk-producing cells (lactocytes).[23] Along with progesterone, prolactin, and human placental lactogen (hPL), estrogen prepares the mammary glands for lactation.[24]

The need of the hour is to conduct extensive studies on the mechanism of these traditionally used plant-based ingredients possessing lactogenic properties so that, by applying principles of food technology, these ingredients can be commercialized for the greater good.

This study presents a novel approach to supporting lactation through the development of nutritionally enhanced health mixes incorporating traditional galactagogues. The use of nutrient-dense ingredients such as cereals, pulses, nuts, and spices not only supports lactation but also contributes to overall maternal nutrition. Sensory evaluation provided important insights into the acceptability of the formulations, which is critical for consumer compliance. Furthermore, the detailed nutritional profiling, including proximate and mineral analysis, validates the health-promoting potential of the mixes. The cultural relevance of the selected ingredients enhances the likelihood of integration into the dietary habits of the target population.

Despite these strengths, the study has certain limitations. Clinical validation to confirm the efficacy of the formulations in enhancing breast milk production was not performed. Sensory evaluation was limited to a small panel (n=50), which may not be representative of the broader target demographic. The study also did not include a shelf-life assessment or long-term stability testing of the health mixes. Additionally, there was no comparative analysis with existing commercial galactagogue products. Socioeconomic feasibility, dietary restrictions, and scalability of the formulations were not explored, which may impact the practical applicability of the products in diverse population settings.

CONCLUSION

Breastfeeding stands as the paramount intervention for child survival and development. It shields infants from infectious illnesses, enhances their immune systems, and furnishes the essential nutrients required for their optimal growth and development. Understanding these multifaceted influences and challenges is essential for developing effective strategies to support breastfeeding mothers, ensuring that they and their infants can reap the full benefits of this natural and valuable practice. Given the deep-rooted cultural significance and scientific interest in galactagogues, there is a growing need to develop effective and convenient solutions to support lactating mothers. Traditional and herbal galactagogues have been used across various cultures to enhance milk production, but there is a lack of standardized, evidence-based products in the market. Therefore, studies like these become critical in establishing scientific validity of the products, formulating usage guidelines, safety and efficacy.

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