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Evaluation of early postpartum fenugreek supplementation on expressed breast milk volume and prolactin levels variation

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A B S T R A C T

Background: The most common reason for the interruption of exclusive breastfeeding is the assumption of insufficient breast milk. Egyptian women have traditionally used fenugreek to increase milk flow and supplementation. However, this practice has not been scientifically evaluated or proved yet.
Objectives: The study aimed to evaluate the effect of the consumption of one of the herbal galactagogues (fenugreek) on expressed breastmilk volume and postpartum prolactin level change.
Methods: The study included 60 healthy mothers whom baby was admitted to Pediatric Ain shams University NICU for more than two weeks and used to express breast milk using manual breast pump. Mothers were divided into two equal groups as following: group 1 included 30 mothers who consumed three times 200 ml of fenugreek tea (50 gm of fenugreek seeds) with eight times breast pump and group 2 included 30 mothers who used breast pump 8 times per day without fenugreek consumption. Total daily volume of pumped breast milk was assessed at day 3, day 8 and day 15. Serum prolactin was withdrawn at day 3 and day 15 at 9 am.
Results: The results showed that the mean breastmilk volume increased earlier (at day 3) in the fenugreek group more than the control group (274.60 ± 46.97 ml, 246.37 ± 46.62 ml respectively $p < 0.005$). Yet at day 8 & 15 the net daily volume showed no significant difference between both groups. Prolactin level was significantly higher on day 3 in group of fenugreek than other group (152.77 ± 18.46 ng/ml versus 134.53 ± 17.35 ng/ml) with no significant difference later on.
Conclusion: Fenugreek consumption affects the early stage of lactogenesis and prolactin level but did not affect the established breastmilk volume or change in prolactin level at later stages so it can be used for mother satisfaction and reassurance in the early stages of lactation.

Introduction

Nutrients play an important role in the functioning and the development of the human body.[1] Breast milk has been accepted as the gold standard of infant nutrition. Although the World Health Organization recommends exclusively breastfeeding for the first six months of life, the adoption of exclusive breastfeeding as the primary mode of providing nutrition to young infants is challenging.[2] The perception of insufficient milk production is the most common worldwide maternal factor of the early cessation of breastfeeding.[3]

Many cultures believe that certain foods increase human milk production during breastfeeding. These foods are believed to have galactagogue properties.[4] Galactogogues are substances thought to assist in the initiation, continuation, or augmentation of breast milk production. They include pharmaceutical agents and herbal supplements. Special food items containing galactagogues are one option for improving human milk and supporting breastfeeding. Many galactagogues, including shatavari, fenugreek, fennel, milk thistle, chaste berry, and goat's rue, are used as herbal medicines and food supplements to improve human milk.[5] Fenugreek (Trigonella foenum-graecum), have been used since ancient times as a herbal galactagogue. Fenugreek is a Greek hayseed originating in the Mediterranean, Southern Europe, and Western Asia. Its seeds contain 50% fiber (30% soluble fiber and 20% insoluble fiber), One hundred grams of fenugreek contains 26.2 g of protein, 5.8 g of fat, 44.1 g of carbohydrate, and 333 kcal. Fenugreek is a natural source of iron, silicon, sodium, and thiamine.[6] Women around the world consume fenugreek seeds to facilitate lactation during the postpartum period. Although the exact mechanism for how fenugreek may work is not fully understood, it was thought that the seed contains hormone precursors that may increase milk production.[7] It is also believed that fenugreek stimulates sweat production and because breasts are modified sweat glands, one hypothesis is that this is how fenugreek may increase milk production.[8] Egyptian traditional galactagogue consumption is still observed today. However few scientific studies describe this practice. This study aimed to evaluate the efficacy of fenugreek as a traditional Egyptian galactagogue in increasing milk volume of expressed breast milk and prolactin level in preterm newborn mothers.

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Methods

Study design

This study was a case-control study performed, on 60 healthy mothers whom newborn infants were admitted to Ain Shams University Pediatric hospital Neonatal Intensive Care Unit (NICU) in Egypt for more than two weeks and used to express breast milk using manual breast pump from June 2017 to December 2017. The study was explained to the mother by an expert neonatologist, and lactation consultant before recruitment in the study and they are included after verbal consent was taken.

Enrolled mothers were divided according to fenugreek consumption into cases and control. The case group (fenugreek group) included 30 mothers who consumed three times 200 ml of fenugreek tea (50 gm of fenugreek seeds) with eight times of breast pumping per day while the control group included 30 age-matched mothers who used breast pump eight times per day without fenugreek consumption.

Study participants

Eligibility requirements at screening included: mothers to newborn infants (32 weeks or less gestational age) who were older than 18 years, started pumping within 24 h from birth and were able to follow up daily with the lactation consultant and report the amount and follow instructions accurately.

Exclusion criteria included: a known contraindication to fenugreek, a history of infertility or induction pregnancy, any abnormalities in the breast growth or surgery, a chronic disease as hypertension, diabetes or thyroid dysfunction or any endocrinal disease, a severe nutrition deficiencies or anemia, or a history of allergy from the fenugreek or other food allergies were excluded from the study. Enrolled mothers were discontinued from the study if they withdrew their consent or if they were lost to follow up at any time during the study period.

Study procedures

All mothers were educated on the correct usage of the manual breast pump (medella®) by a lactation consultant, eight times a day during the study period. Enrolled mothers underwent a screening process at baseline that included medical history taking, a clinical examination, regular blood sugar assessment, and answered a diet questionnaire[9] (Appendix 1). Enrolled mothers were then observed for a period of 15 days that included three evaluation time points for breast milk volume; day 3, day 8 and day 15. Mothers were provided with a log book to record the time and volume of pumped milk.

Two mL peripheral blood (PB) samples were obtained from all enrolled mothers at 9 am on day 3 and day 15 of birth. PB samples were processed on the same day of sample collection. A 96-well plate has been pre-coated with anti-Prolactin IgG antibodies. Samples and standards and are added to the wells, where Prolactin in the sample and standards binds to the pre-coated antibody. Added Anti-Prolactin-HRP conjugate binds to the antibody-Prolactin complex. After incubation, the wells are washed to remove unbound material, and TMB substrate was then added which is catalyzed by HRP to produce blue coloration. The reaction was terminated by the addition of a “Stop Solution” which stops the color development and produces a color change from blue to yellow. The intensity of the signal was directly proportional to the amount of Prolactin in the sample, and the intensity was measured at 450 nm.

Statistical analysis

Data were analyzed using statistical package for social science (SPSS) for Windows (version 15.0.1). Means with standard deviations and counts with percentages were used to describe continuous and categorical variables, respectively. Comparisons of continuous variables among groups were made using paired *t*-test. Comparisons between categorical variables were performed using chi-square test. A *p*-value ≤ 0.05 was considered to be significant.

Results

Demographic and baseline characteristics are elaborated in Table 1 below.

The volume of expressed breast milk was significantly higher in the

Table 1
Demographic data of the studied groups.

		Control Group No. = 30	Fenugreek Group No. = 3	Test value	P-value	Sig.
Age of the mother	Mean ± SD Range	24.77 ± 3.59 19–34	23.30 ± 4.09 18–33	1.477·	0.145	NS
Previous location	0 1 2 3	13 (43.3%) 14 (46.7%) 2 (6.7%) 1 (3.3%)	20 (66.7%) 9 (30.0%) 1 (3.3%) 0 (0.0%)	3.905*	0.272	NS
Number of pregnancy	1.00 2.00 3.00	8 (26.7%) 16 (53.3%) 6 (20.0%)	14 (46.7%) 12 (40.0%) 4 (13.3%)	2.608*	0.271	NS
Type of delivery	CS Vaginal	14 (46.7%) 16 (53.3%)	19 (63.3%) 11 (36.7%)	1.684*	0.194	NS
Infant gender	Male Female	15 (50.0%) 15 (50.0%)	12 (40.0%) 18 (60.0%)	0.606*	0.436	NS
Mean age	Mean ± SD Range	22.70 ± 2.88 18–28	22.70 ± 2.88 18–28	0.000·	1.000	NS
Contraindication of location	Respiratory Surgical GIT	14 (46.7%) 9 (30.0%) 7 (23.3%)	12 (40.0%) 8 (26.7%) 10 (33.3%)	0.742*	0.690	NS
Nutritional score	Mean ± SD Range	4.33 ± 1.83 2–8	5.03 ± 1.87 2–8	−1.469P	0.147	NS

* Chi-square test.
· Independent *t*-test.

Table 2
Comparison between the volume of expressed milk and prolactin level between both group on day 3, 7 and 15 of birth.

		Control Group No. = 3	Fenugreek Group No. = 3	Test value	P-value	Sig.
Total milk volume expression in ml						
Day 3	Mean ± SD	246.37 ± 46.62	274.60 ± 46.97	−2.337	0.023	S
	Range	170–340	204–370			
Day 8	Mean ± SD	474.83 ± 59.11	485.27 ± 58.84	-0.685	0.496	NS
	Range	340–580	350–590			
Day 15	Mean ± SD	772.50 ± 89.58	771.33 ± 90.43	0.050	0.960	NS
	Range	580–910	580–920			
Prolactin ng/ml						
Day 3	Mean ± SD	134.53 ± 17.35	152.77 ± 18.46	-3.943	0.000	HS
	Range	100 – 173	120 – 180			
Day 15	Mean ± SD	76.10 ± 8.56	73.53 ± 8.29	1.180	0.243	NS
	Range	63 – 93	60 – 90			

* Chi-square test; •: Independent *t*-test.

fenugreek group than the control group on day three only; 274.60 ± 46.97 and 246.37 ± 46.62 ml respectively ($p = 0.023$). Furthermore, a significant difference in prolactin level observed between both groups on day three only as well with 134.53 ± 17.35 in the fenugreek group and 152.77 ± 18.46 in the case group ($p < 0.001$) (Table 2).

Discussion

Galactagogues consumption is still observed traditional postpartum practices. However, few scientific studies describe it. We sought to evaluate the efficacy of consumption one of the herbal galactagogues (fenugreek) in increasing breast milk production and post-partum prolactin level change. The present study found a significant effect of fenugreek consumption on human milk volume in the early stage of lactogenesis but did not affect the established breastmilk volume or the level of prolactin at later stages. Therefore, fenugreek can be used for mother satisfaction and reassurance in the early stages of lactation.

Fenugreek (Trigonella foenumgraecum) is the most commonly used herbal galactagogue in published literature, however little is known about its efficacy.[6] Mohanty et al. reported that phytochemicals including alkaloids, isoflavones, polyphenols, tannins, and saponins affect milk production; they were found to stimulate milk ejection, improve milk protein levels, and enhance lactation by increasing prolactin levels.[10] Previously (Gupta & Shaw) and (Turkyılmaz et al.) hypothesized that galactagogue might increase milk volume by an estrogenic effect.[11,12] It is thought that fenugreek stimulates sweat production, and since the breast is a modified sweat gland, fenugreek may affect breast milk production in this manner. It has also been suggested that fenugreek may have an estrogenic activity.[13]

Studies showed that there are two feasible ways to increase milk production through galactagogues. First, galactagogue phytoestrogens bind with receptors in the mammary glands to induce alveolar cell proliferation. Then, the anterior pituitary lactotrophic cells and phytoestrogens bind with a β-estradiol receptor through α-isoform of the membrane-associated estrogen, and this may induce prolactin gene expression. Also, phytoestrogens act as dopamine antagonists by inhibiting the pathway activated by a dopamine receptor and increasing prolactin secretion to induce milk production.[6] One study using in vitro assays found that fenugreek seeds contain estrogen-like compounds and that they stimulate pS2 expression in MCF-7 cell lines. The pS2 is frequently used as a marker for assessing the estrogenicity of a compound.[14] The phytoestrogens and diosgenin content (a type of steroidal sapogenin) of fenugreek appear to account for the increase in milk flow observed from its use, but the exact mechanism of action is as yet undefined. Phytoestrogens are similar in chemical structure to endogenous estrogen and can bind to both α and β estrogen receptors. Thus they have the potential to act as estrogen agonists or antagonists, which could alter the structure or functioning of the endocrine system.[15] In agreement with our results, Turkyilmaz et al.[12] found that the fenugreek group had almost twice the expressed breast milk volume as placebo.

In contrast to our results, Damanik et al.[16] reported an increase in breast milk volume using torbangun, but not fenugreek; lactating women, received Coles amboinicus (CA) supplementation for one month and had a 65% increase in milk volume during the last two weeks of supplementation (from Day 14 to Day 28). This increase was higher than that of lactating women receiving Molocco + B12 tablets (10%) or Fenugreek seeds (20%). The conflicting results may be due to the difference in dosages and formulations of fenugreek used as it is unclear how much was used and the different study populations; Di Pierro et al.[17] reported an increase in breast milk volume from the administration of silymarin. In agreement with our finding that fenugreek affected early lactogenesis.

In our study, we tried to decrease the bias of other nutritive factors on the milk productivity and limit the confounding factors, so we assessed the diet score of both groups, and we found no significant difference.

Because most industrial herbal galactagogues products in randomized trials contained other substances that may affect the concurrent actions the validity of the results is affected. Therefore we used the purified compound same as the trial conducted by Di Pierro et al.[17] and Gupta & Shaw.[11] The Turkyilmaz et al.[12] study used a commercially prepared herbal tea containing fenugreek.

Prolactin (PRL) levels rise during pregnancy, from about ten ng/ml in the nonpregnant state to approximately 200–400 ng/ml at term. Baseline levels do not drop back to prepregnancy levels in lactating women but average about 100 ng/ml at three months and 50 ng/ml at six months. Because when the time between breastfeeding is the longest caused the highest concentration of prolactin at night and early morning, we chose to have the PRL levels drawn after a morning pumping.[18]

The effect of herbal galactagogues on prolactin level was studied by Gupta and Shaw[11] who observed that shatavari increased serum prolactin level by 3.5 times that of placebo. However, that contradicted the results done by Sharma et al.[19] who found no galactagogue effect of shatavari. Ushiroyama et al.[20] reported increases in breast milk volume and serum prolactin level in their study of Xiong-gui-tiao-xue-yin. Studies on galactagogues varied in eligibility criteria, such as whether infants were term or preterm, which may have affected milk production by local feedback mechanisms or if the mothers have different breastfeeding practices, these differences may confound or modify the association observed. Therefore in our study, we fixed the age and excluded the local suckling effect; eliminating any bias in the results of hormone level or milk volume production. Three trials used serum prolactin level as the primary outcome. In the trial assessing the prolactin response to

mechanical breast pumping at two, four and six weeks postpartum in 18 women with prematurely delivered, non-nursing (< 1500 g) infants, significant increases in plasma prolactin occurred in response to pumping at 2 and four weeks, but not at six weeks.[21] Another study on Japanese herbs named Xiong-gui-tiao-xue-yin[20] on 82 women who had a normal delivery in Osaka Medical College Hospital, demonstrated an increase in prolactin level without an increase in oxytocin level in the postpartum period. A randomized, double-blind clinical trial in 60 lactating mothers measured changes in their prolactin hormone level during the study; the oral administration of the research drug led to more than three-fold increase in the prolactin hormone level of the subjects in the research group as compared to the control group.[11]

Given the paucity and lack of standardization of experimental studies on herbal galactagogues, it is recommended that future studies addressing the limitations are needed to generate evidence for recommendations regarding the use of herbs as galactagogues.

Conclusion

Fenugreek consumption affects the early stage of lactogenesis and prolactin level but did not affect the established breastmilk volume or change in prolactin level at later stages so it can be used for mother satisfaction and reassurance in the early stages of lactation.

Conflict of interest

None.

Appendix 1

Appendix 1

Maternal Diet evaluation	If Yes, score 1	If No, score 0
Vegetables	Two or more cups of vegetables a day	
Fruit	Two or more pieces of fruit a day	
Whole grains	2 or more whole grains a day	
water	More than 1 ½ liter/day	
Fish	Fish 2 or more times a week	
Legumes/beans	2 or more servings a week	
Nuts/Seeds	A handful of nuts most days	
Fat	Lots of olive oil and few other fats	
Red or Processed Meat	Two servings or fewer a week	
Score evaluation		
score 8–9	Excellent	
6–7	Very well	
4–5	well	
0–3	Bad	

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