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Fenugreek

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Drug Levels and Effects

Summary of Use during Lactation

Fenugreek (*Trigonella foenum-graecum*) seeds contain mucilage, quercetin, luteolin, genistein, vitexintrigonelline, 4-hydroxyisoleucine, sotolon, diosgenin, luteolin, protodioscin and several other pharmacologically active saponins and isoflavones. Fenugreek has been used in a number of geographical regions worldwide as a galactogogue to increase milk supply and is included in numerous proprietary mixtures promoted to increase milk supply.[1-13] The galactogogue effect of fenugreek may be primarily psychological in humans;[14] however, animal studies indicate that fenugreek might work primarily by increasing insulin, prolactin and oxytocin secretion.[12,15] Evidence for a galactogogue effect is mostly anecdotal. A limited number of published studies of low to moderate quality have found mixed results for a galactogogue effect for fenugreek.[16-19] A meta-analysis of controlled studies found fenugreek to have a mild galactogogue effect and unknown safety profile.[13] In a US survey, of 122 mothers who used fenugreek as a galactogogue 43% thought it increased milk supply and 5% thought it decreased their milk supply.[20] Some evidence indicates that fenugreek might be more effective in the first few days postpartum than after 2 weeks postpartum.[21] Some of these studies used a multi-ingredient combination products in which fenugreek was only one component, so the results might be different from studies in which fenugreek was used alone. Galactogogues should never replace evaluation and counseling on modifiable factors that affect milk production.[22,23]

Fenugreek is "generally recognized as safe" (GRAS) as a flavoring by the U.S. Food and Drug Administration. Limited scientific data exist on the safety of fenugreek in nursing mothers or infants, although it has a long history of use as a food and medicine in India and China. When used as a medicinal, it is generally well tolerated in adults, but gastrointestinal side effects such as nausea, vomiting, diarrhea and flatulence may occur. Liver toxicity has been reported, both taken alone and in herbal combinations that included fenugreek.[24-27] Diarrhea and hepatomegaly occurred in a woman taking fennel, fenugreek, and goat's rue as galactogogues.[17] Another mother reported increased heart rate and breast congestion.[28] Allergic reactions, exacerbation of asthma, and a 14% decrease in serum potassium have been reported. One nursing mother developed toxic epidermal necrolysis thought to be caused by her intake of fenugreek as a galactogogue. Cross-reaction with chickpeas, peanuts, and other legumes is possible. Dosages typically used to increase milk supply are 1 to 6

grams daily; in dosages of about 25 grams or more daily, fenugreek may cause lowering of cholesterol and blood sugar. It can also interact with warfarin to cause bleeding. Caution should be used in giving high dosages to women with diabetes mellitus or those taking warfarin. In a survey of nursing mothers in the United States, 85 had used fenugreek as a galactogogue and 45% reported having experienced an adverse reaction from the supplement.[29] Perhaps its most unusual side effect is the imparting an odor of maple syrup to the urine, sweat, feces, and possibly breastmilk by the sotolon in fenugreek.[3,30-32]

Dietary supplements do not require extensive pre-marketing approval from the U.S. Food and Drug Administration. Manufacturers are responsible to ensure the safety, but do not need to *prove* the safety and effectiveness of dietary supplements before they are marketed. Dietary supplements may contain multiple ingredients, and differences are often found between labeled and actual ingredients or their amounts. A manufacturer may contract with an independent organization to verify the quality of a product or its ingredients, but that does *not* certify the safety or effectiveness of a product. Because of the above issues, clinical testing results on one product may not be applicable to other products. More detailed information about dietary supplements is available elsewhere on the LactMed Web site.

Drug Levels

Maternal Levels. Relevant published information was not found as of the revision date.

Infant Levels. Relevant published information was not found as of the revision date.

Effects in Breastfed Infants

A study in mothers of preterm infants less than 31 weeks gestation compared the use of fenugreek 1725 mg 3 times daily for 21 days to placebo. No adverse effects were noted in the infants given the breastmilk.[33]

A small manufacturer-sponsored, double-blind, randomized study compared Mother's Milk tea (Traditional Medicinals, Sebastopol, CA) to lemon verbena tea in exclusively breastfeeding mothers with milk insufficiency. Each Mother's Milk tea bag contained 35 mg of fenugreek seeds as well as several other herbs. Mothers were instructed to drink 3 to 5 cups of tea daily. No differences were seen between groups in infant digestive, respiratory, dermatological, and other maternal-reported adverse events. No differences were seen in the growth parameters of the breastfed infants between the two groups.[34]

In a study of exclusively nursing mothers receiving fenugreek seed 200 mg, turmeric 100 mg and ginger 120 mg (Fenucaps; Herbal Acharn's Home Co. Ltd., Thailand) 3 times daily for 4 weeks, no adverse events were reported in their infants, although the method used to determine this finding were not reported.[35]

In a survey of nursing mothers in Australia, 421 mothers were taking fenugreek as a galactogogue. Seventeen percent of mothers taking fenugreek reported experiencing adverse reactions, most commonly weight gain and various gastrointestinal effects.[36]

Effects on Lactation and Breastmilk

Forty women who complained of an insufficient milk supply at 5 days postpartum were given a combination herbal supplement as 2 capsules of Lactare (Pharma Private Ltd., Madras, India) 3 times daily. Each capsule contained wild asparagus 200 mg, ashwagandha (*Withania somnifera*) 100 mg, fenugreek 50 mg, licorice 50 mg, and garlic 20 mg. By day 4 of therapy, no infants required supplementary feeding. Infants were weighed before and after each feeding on the fifth day of maternal therapy to determine the amount of milk ingested. On the day of the test weighing, infants' milk intake averaged 388 mL, and the fluid and caloric intake was considered adequate.[37] This study cannot be considered as valid evidence of a galactogogue effect of these herbs because it lacks randomization, blinding, a placebo control, and maternal instruction in breastfeeding technique. Additionally, infants were breastfed only 6 to 8 times daily, which is insufficient to maximize milk supply.

A study of healthy women who delivered a full-term infant and desired to breastfeed for at least 4 months compared fenugreek, torbangun (*Coleus amboinicus*) and a product containing placental extract and vitamin B12 (Molocco+B12) for their effects on breastmilk volume. No mention was made of any breastfeeding support provided to the women. Participants were randomly assigned to receive one of the products for 30 days and followed for another 30 days. Capsules containing powdered fenugreek seeds 600 mg (Bullivants Natural Health, Auckland, New Zealand) were given 3 times daily. Infants were weighed before and after each nursing at 2-week intervals during the study to measure 24-hour milk volume. At no time point during the study was milk volume in the fenugreek group (n = 22) statistically different from the reference group (n = 22) who received Molocco+B12, although the torbangun group did have a statistically significant increase. The daily volume of milk actually decreased in the fenugreek group over time, although the change was not statistically significant.[38] The dosage of fenugreek used in this study was lower than that typically recommended by most sources.[2,39]

A randomized, double-blind study in 26 mothers of preterm infants less than 31 weeks gestation compared pharmacist-prepared capsules of fenugreek 1725 mg (n=14) or placebo (n=12), each given 3 times daily for 21 days, starting on day 5 postpartum. Mothers used an electric breast pump 5 to 7 times daily for 21 days starting 12 hours postpartum and recorded pumping frequency and milk volume. Maternal serum prolactin was also measured once weekly during the 21 days. No statistical differences were found in milk volumes or serum prolactin values between the two groups on day 5, 10 or 15 of the study.[33] Although this was a well-designed study, over half of the originally randomized mothers (n=58) did not complete the study and an intention-to-treat analysis was not performed.

Sixty-six postpartum mothers (22 in each of 3 groups) with no concurrent illnesses were randomly assigned to receive an herbal tea, placebo, or nothing after delivering healthy, full-term infants. Mothers in the herbal tea group received at least 3 cups daily of 200 mL of Still Tea (Humana-Istanbul, Turkey; containing hibiscus 2.6 grams, fennel extract 200 mg, fennel oil 20 mg, rooibos 200 mg, verbena [vervain] 200 mg, raspberry leaves 200 mg, fenugreek 100 mg, goat's rue 100 mg, and vitamin C 500 mg per 100 grams, per manufacturer's web site November 2011). A similar-looking apple tea was used as the placebo. All women were followed by the same nurse and pediatrician who were blinded to what treatment the mothers received. Mothers who received the Still Tea produced more breastmilk with an electric breast pump on the third day postpartum than mothers in the other groups. The infants in the Still Tea group had a lower maximum weight loss, and they regained their birth weights sooner than those in the placebo or no treatment arms. No long-term outcome data were collected. Because many of the ingredients in Still Tea are purported galactogogues, no single ingredient can be considered solely responsible for the tea's effects, although the authors attributed the action to fenugreek.[40]

An herbal tea containing fenugreek, hibiscus, fennel, rooibos, vervain, raspberry, goat's rue, and vitamin C (Humana Still-Tee, Humana GmbH, Herford, Germany) or water was randomly given to nursing mothers in a dosage of 3 cups daily beginning on the day of delivery. Several markers of antioxidant capacity were measured in breastmilk on day 1 and again after 7 to 10 days. No difference was found in the markers between mothers who received the tea and the water.[41]

A nonblinded study randomized mother to receive 2 grams of fenugreek as a tea three times a day, 100 grams of palm date flesh three times a day, or nothing beginning on the first day postpartum. The duration of therapy was not stated. Their full-term, healthy infants were weighed on days 3, 7 and 14 of age, and mothers measured the morning (only) milk volume from both breasts on the third day postpartum. The infants of the fenugreek and date flesh groups lost less weight on days 3 and 7 than the control mothers, but there was no difference in weight among the groups on day 14. On day 3, morning milk volumes were greater in the two treated groups than in the untreated group.[42] The lack of blinding and incomplete milk collection call the results into question.

A nonblinded study compared several infant growth parameters after their mothers were randomized to receive either black tea or black tea plus 7.5 grams of fenugreek three times daily. Infants were healthy girls and ranged

from 0 to 4 months old (mean about 2 months). At baseline, control mothers were breastfeeding two times more per day than the fenugreek group (11.2 vs 9.2 times daily). At the end of the 4 week study, several parameters were greater in the fenugreek group than in the control group: frequency of feeding infant weight, head circumference, and daily numbers of wet diapers and defecation. No difference was seen in infant height.[43]

In a survey of 188 nursing women from 27 states (52% from Louisiana), 85 (46%) had used fenugreek as a galactogogue. Of those who used it, 54% felt that it increased their milk supply and 45% reported side effects, including a maple syrup smell emitted from the mother's body, gassiness in the baby, or breastmilk oversupply.[29]

A nonrandomized, nonblinded case-control study compared healthy age-matched postpartum mothers of preterm newborns admitted to the NICU who either received (n = 30) or did not receive 200 mL of fenugreek tea (n = 30) containing 50 grams of fenugreek seed 3 times daily. The allocation method was not stated, but the groups were well matched. Each group pumped milk with a breast pump 8 times daily. Milk volume was measured on days 3, 8 and 15 of the study; maternal serum prolactin was measured on days 3 and 15. Milk volumes were significantly different only on day 3 postpartum, favoring the fenugreek group (275 vs 246 mL). The fenugreek group also had higher serum prolactin values only on day 3 (153 vs 135 mcg/L). The authors concluded that fenugreek affects only the early stage of lactogenesis, and not production of mature milk.[21]

Fifty women in Thailand who were 1 month postpartum and exclusively breastfeeding were randomized to receive either a placebo or capsules containing fenugreek seed 200 mg, turmeric 100 mg and ginger 120 mg (Fenucaps; Herbal Acharn's Home Co. Ltd., Thailand) 3 times daily for 4 weeks. Participants pumped milk on 2 days at 0, 2 and 4 weeks of the study. The average milk volumes increased by 49% at 2 weeks and 103% at 4 weeks among participants receiving the active product. The macronutrient composition of the milk did not change in either group over the 4-week period. Growth of infants was not reported.[35]

A study compared standard care (n = 30) to standard care plus fenugreek 7.5 grams daily for 7 days (n = 30) in mothers of full-term infants who appeared to have low milk supply in the first week postpartum. Infants in the treatment group had more frequent urination than those in the control group over the 7 days of the study. On day 7, the average weights of the infants in the treatment group were slightly greater.[44] The study was unblinded and had no true placebo control, so its results are questionable.

In a survey of nursing mothers in Australia, 421 mothers were taking fenugreek as a galactogogue. On average, mothers rated fenugreek between “slightly effective” and “moderately effective” on a Likert scale. Seventeen percent of mothers taking fenugreek reported experiencing adverse reactions, most commonly stomach cramps, nausea, dry mouth, body odor, weight gain and headache.[36]

A blinded, randomized trial compared fenugreek drops to fenugreek and honey drops in nursing mothers who were 1 to 5 months postpartum. A 21-question questionnaire assessing breastfeeding success was completed by mothers at the beginning of the study and 4 weeks later. The mothers who received the honey-containing product (n = 36) had a higher score and a greater increase in score than those who received fenugreek alone (n = 39).[45]

A randomized, blinded trial compared lactation cookies containing oatmeal, brewer’s yeast, flax seeds, and fenugreek (Oatmeal Raisin Milkmakers Lactation Cookie Bites, Munchkin Inc.) were compared to similar cookies with no purported galactogogues (Famous Amos Chocolate Chip Cookies). Subjects were women nursing full-term 2-month-old infants (n = 176) and instructed to eat one bag of cookies daily for 30 days. They pumped their breasts completely with an electric pump at the start and end of the study. The milk production rate was 5.8 mL/hour in control participants and 5.5 mL/hour in the lactation cookie participants, which was not statistically significant difference.[46]

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Substance Identification

Substance Name

Fenugreek

Scientific Name

Trigonella foenum-graecum

CAS Registry Number

68990-15-8

Drug Class

Breast Feeding

Lactation

Milk, Human

Complementary Therapies

Galactogogues

Phytotherapy

Plants, Medicinal