



Fennel

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Drug Levels and Effects

Summary of Use during Lactation

Fennel (*Foeniculum vulgare*) seeds contain the volatile oil composed largely of anethole, which is a phytoestrogen, as well as fenchone, estragole, 1,8-cineole (eucalyptol), and other constituents. Anethole is excreted in breastmilk.[1] Fennel is a purported galactagogue that has been used in traditional medicine as well as being included in some proprietary mixtures promoted to increase milk supply.[2-13] Two small studies found an increase in some parameters such as milk volume, fat content and infant weight gain with fennel galactagogue therapy. However, no increase in serum prolactin has been found with fennel use in nursing mothers.[14] Galactagogues should never replace evaluation and counseling on modifiable factors that affect milk production.[15,16] Immersing the breast in a warm infusion of fennel seeds and marshmallow root has been suggested as a treatment for breast inflammation,[17] but no scientific data are available that support this use. Fennel is generally well tolerated in adults, and fennel oil is "generally recognized as safe" (GRAS) for use in food by the U.S. Food and Drug Administration. It has been safely and effectively used alone and with other herbs in infants for the treatment of colic,[18-20] so the smaller amounts in breastmilk are likely not to be harmful with usual maternal doses. Some sources recommend limiting the duration of treatment to 2 weeks. Excessive maternal use of an herbal tea containing fennel, anise and other herbs appeared to cause toxicity in 2 breastfed newborns that was consistent with toxicity caused by anethole, which is found in fennel and anise. Fennel can cause allergic reactions after oral or topical use affecting the respiratory system or skin, including photosensitivity. Diarrhea and hepatomegaly occurred in a woman taking fennel, fenugreek, and goat's rue as galactagogues.[21] Elevated liver enzymes occurred in another woman taking Mother's Milk Tea, which contains fennel.[22] Avoid excessive sunlight or ultraviolet light exposure while using this herbal. Mothers should avoid fennel if they or their infants are allergic to carrots, celery, or other plants in the Apiaceae family because of possible cross-allergenicity.

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

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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. Eighteen lactating women were given 100 mg of trans-anethol in a capsule on 3 test days. Milk samples were collected every 2 hours for 8 hours starting at the time of ingestion. Trans-anethol was detected in milk at all collection times, with the average concentrations of 2 mcg/L at 0 hours, 9.9 mcg/L at 2 hours, 9.2 mcg/L at 4 hours, 7.3 mcg/L at 6 hours and 4.3 mcg/L at 8 hours after the dose. The average peak anethol concentration in milk was 23.2 mcg/L. Only small amounts of anethol glucuronide metabolites were present in the milk samples.[1]

Twelve nursing mothers who were 19 weeks to 19 months postpartum ingested 100 mg of 1,8 cineole (eucalyptol) in the form of delayed-release capsules (Soledum-Klosterfrau Vertriebs GmbH, Germany) that release the drug in the intestine. Then they pumped 1 to 4 milk samples at the time they perceived the smell of eucalyptus on their breath which had been previously shown to be approximately concurrent. A total of 21 milk samples were obtained. Odor was rated by a panel of 3 to 5 experts as either smelling like eucalyptus or not. Fourteen of the samples had a distinct eucalyptus-like odor. Chemical analysis of the positive odor tests found 1,8-cineole in concentrations from 70 to about 2090 mcg/kg of milk, most in the range of 100 to 500 mcg/kg of milk. Samples with negative odor tests contained concentrations in the range of 0.98 to about 20.23 mcg/kg of milk. In one woman who donated 3 samples, the highest concentration of 71 mcg/kg occurred at 1.5 hours after ingestion, with concentrations of 1 mcg/kg before ingestion and 15 mcg/kg at 9.5 hours after ingestion.[23] Eight women had their milk analyzed for 1,8-cineole metabolites. Ten metabolites and several enantiomers of these metabolites were detected.[24,25]

Five women who were nursing infants between 6 and 55 weeks of age drank 950 mL of fennel-anise-caraway tea (Messmer Ostfriesische Tee Gesellschaft Laurens Spethmann GmbH & Co. KG, Seevetal, Germany). The main odorant components of the tea are the following terpenes: limonene, 1,8-cineole, fenchone, estragole, carvone, trans-anethole, p-anisaldehyde and anisketone. Mothers collected milk samples at 30 minutes, 1 and 2 hours after ingesting the tea. Ingestion of the tea did not increase the overall terpene content of the milk, but there was wide variation from mother to mother. Some mothers had high background levels of some terpenes, probably from other foods or person care products. In addition, a sensory panel found no significant change in the odor profile of the breastmilk samples compared to blank samples.[26]

Eighteen nursing mothers who were nursing their infants of 8 to 53 weeks of age were served a curry dish that contained an average of 394 mcg of 1,8-cineole. Baseline 1,8-cineole concentrations in milk averaged 1.44 mcg/L (range 0.07 to 7.57 mcg/L). Milk samples contained 1,8-cineole in concentrations of 0.19 to 7.41 mcg/L at 1 hour after eating, 0.33 to 7.86 mcg/L at 2 hours after eating and 0.22 to 3.33 mcg/L at 3 hours after eating.[27]

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

Effects in Breastfed Infants

Two breastfed infants, aged 15 and 20 days, were admitted to the hospital for a reported lack of weight gain in the previous 7 to 10 days, caused by "difficult feeding". The parents reported restlessness and vomiting during the past day. One of the mothers also reported feeling drowsy and weak. On examination, the infants were afebrile but had hypotonia, lethargy, emesis, weak cry, poor sucking and weak responses to painful stimuli. Infant laboratory values, electrocardiograms and blood pressures were normal, and septic work-ups were negative. Both mothers had both been drinking more than 2 liters daily of an herbal tea mixture reportedly containing licorice, fennel, anise, and goat's rue to stimulate lactation. After the mothers discontinued breastfeeding and the herbal tea, the infants improved within 24 to 36 hours. Symptoms of the affected mother also resolved rapidly

after discontinuing the herbal tea. After 2 days, breastfeeding was reinstituted with no further symptoms in the infants. Both infants were doing well at 6 months of age. The authors attributed the maternal and infant symptoms to anethole, which is found in both fennel and anise; however, the anethole levels were not measured in breastmilk, nor were the teas tested for their content.[28]

Nursing mothers who were participating in an experiment on the excretion of 1,8-cineole (eucalyptol) in breastmilk took a 100 mg capsule of 1,8-cineole orally. Although instructed not to, 12 mothers breastfed their infants during the experiment. Mothers reported that none of their infants refused their milk or breastfed less than usual. Two mothers felt that their infants were more agitated a few hours after breastfeeding. A third mother reported that the infant stopped nursing from time to time and "looked puzzled", but resumed nursing. Upon repeating the experiment 6 weeks later, the infant did not react in an unusual way during breastfeeding. [23]

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 560 mg of bitter fennel fruit 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.[29]

Effects on Lactation and Breastmilk

A group of 5 nursing mothers were given no herb for 5 days, 15 mL of a 5% infusion of fennel seeds 3 times daily for 10 days, followed by another 5-day control period from days 15 to 20. Their diet and environment were kept constant during the study period. Milk volume was measured daily and milk fat percentage was measured on days 5, 10, 15 and 20. Milk volume and fat content increased somewhat during the 10-day treatment period and carried over for 3 to 5 days after discontinuation.[30] Because of the lack of randomization, blinding and controls, and small number of participants, no valid conclusion can be made from this study on the galactagogue effects of fennel.

One hundred fifty-eight mothers in Iran of who reported difficulty in breastfeeding were given either a proprietary mixture of herbs (Shirafza Drop) or a chlorophyll solution as a placebo. The herbal mixture contained the purported galactagogues fennel, anise, cumin, black seed, and parsley. Infant ages ranged between 0 and 6 months and they were exclusively breastfed. Weight gain of the infants was measured over time. No difference in infant weight gain was seen between the two groups of infants.[31] Blinding and randomization in this study is unclear.

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, fullterm 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 galactagogues, including fennel, no single ingredient can be considered solely responsible for the tea's effects, although the authors attributed the action to fenugreek. [32]

An herbal tea containing fennel, fenugreek, hibiscus, 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.[33]

An uncontrolled, nonrandomized, nonblinded study in Iran enrolled 46 healthy nursing mothers between 18 and 35 years of age. At the start of the study, mothers were all nursing their infants and having no difficulty in doing so. The mothers' serum prolactin was measured in the morning before breakfast at least one hour after the previous nursing bout. Prolactin was measured before and after receiving powdered fennel in a dose of 3 grams daily by mouth for 15 days. The average baseline serum prolactin concentration was 64.6 mcg/L. The serum prolactin concentration after fennel therapy was 95.6 mcg/L. The difference was statistically significant. No measurements of milk production were made.[34]

A double-blind study compared the effects of an herbal tea containing 7.5 grams fennel seed powder plus 3 grams of black tea to 3 grams of black tea alone taken three times a day in mothers exclusively nursing their 0- to 4-month old female infants. After 4 weeks, "breastmilk sufficiency" and infant's growth parameters were compared in the two groups. Infants whose mothers received the fennel had greater increases in the frequency of feedings, number of wet diapers, frequency of defecation, weight gain, and a slightly greater increase in head circumference than infants in the control group. No difference was seen in height gain.[35,36]

In a survey of 188 nursing women from 27 states (52% from Louisiana), 29 had used fennel as a galactagogue. Of those who used it, 59% were not sure that it increased their milk supply and 6 reported (unspecified) side effects.[37]

A randomized trial assigned mothers of preterm infants to receive either a purported herbal galactagogue tea twice daily, a fruit tea twice daily or nothing. The galactagogue tea mixture (Natal, Hipp [Turkey]) contained 1% stinging nettle as well as melissa, caraway, anise, fennel, goat's rue, and lemon grass in unspecified amounts. All mothers received similar breastfeeding advice from the same nurse and two groups were told that the tea would increase milk production, but compliance with the study teas was not assessed. Mother used breast pumps to extract and measure their milk and output on day 1 and day 7 of the study were compared. Although the increase in volume of extracted milk was greater in the galactagogue tea group, there was no difference in maternal serum prolactin between the groups at 7 days. No difference in infant weight gain was seen between groups, although the authors stated that additional supplementation was provided to all infants in addition to the pumped milk.[38] The study was not blinded, the randomization method was not stated, intent-to-treat analysis was not performed, and some of the numerical results were internally inconsistent, so the quality of the study was poor.

Women who had just given birth were randomized to either a syrup containing fennel 3 grams, honey, frankincense (n = 35) or a syrup containing honey, frankincense taken once a day before breakfast for 15 days (n = 34). Blood samples were taken at 8 a.m. when fasting and at least 1 hour after breastfeeding on days 1 and 15 postpartum. Prolactin levels were lower on day 15 than on day 1 in both groups, and after adjusting for the serum prolactin level on day 1, no difference was found between the prolactin levels of the two groups on day 15.[14]

In a survey of nursing mothers in Australia, 157 mothers were taking fennel as a galactagogue. On average, mothers rated fennel as being between "slightly effective" and "moderately effective" on a Likert scale. Four percent of mothers taking fennel reported experiencing adverse reactions, most commonly nausea and stomach cramps.[39]

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Substance Identification

Substance Name

Fennel

Scientific Name

Foeniculum vulgare

Drug Class

Breast Feeding

Lactation

Milk, Human

Complementary Therapies

Galactogogues

Phytotherapy

Plants, Medicinal