

The Effect of Herbal Tea Containing Fennel Seed on Breast Milk Sufficiency Signs and Growth Parameters of Iranian Infants

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Background: Breastfeeding is an economic and valuable method to protect infant's health during the life and provides unique biological and emotional effects for mothers and infants.

Objectives: This study aimed to determine the effect of herbal tea containing Fennel seed on breast milk sufficiency signs and growth parameters of Iranian infants in medical health centers of Tehran University of Medical Sciences, Tehran, Iran.

Patients and Methods: This study was a randomized clinical trial performed on 78 girl infants aged 0-4 months who were exclusively breastfed. After getting informed consent infants were randomly assigned into the intervention group (received herbal tea containing 7.5 g Fennel seed powder in addition to 3 grams black tea three times a day) and the control group (received herbal tea containing 3 grams black tea powder three times a day). Before and during four weeks of study, signs of breast milk sufficiency were evaluated through measuring the growth parameters and the number of wet diapers in a day, frequency of defecation and infant breastfeeding times.

Results: Before intervention, there was no significant difference between weight, height, head circumference, the number of wet diapers and frequency of defecation times between the two groups ($P > 0.05$), but the number of breastfeeding times of control group was more than the Fennel group. After fourth weeks, Fennel significantly increased weight from (5261.0256 ± 1167.65801) to (6393.3333 ± 1083.42132), head circumference from (38.6103 ± 2.20033) to (40.1538 ± 2.00510), the number of wet diapers from (5.5000 ± 1.05131) to (8.5421 ± 1.21182), the frequency of defecation times from (1.7692 ± 1.03139) to (2.6410 ± 1.14655) and the number of breastfeeding times from (9.9359 ± 1.85380) to (16.7399 ± 1.63766) ($P < 0.001$), but it had no effect on height ($P = 0.066$).

Conclusions: Herbal tea containing fennel seed improved breast milk sufficiency signs.

Keywords: Breastfeeding; Herbal Tea; Foeniculum Vulgare; Fennel; Growth

1. Background

World Health Organization recommended exclusive breastfeeding as an economic and valuable method for protecting infant's health during the life. It provides unique biologic and emotional effects for both mother and infant (1, 2). Exclusive breastfeeding means that infant is fed only with breast milk without any other liquids or solid food and this definition does not include vitamins, minerals and medicines (1). Malnutrition in the first year of life is the reason of two-third of deaths in fewer than five years old children in the world. Exclusive breastfeeding in first six months of life and continuing with complementary nourishment, decreases malnutrition and as a result decreases mortality of fewer than five years old children (3, 4). Breastfeeding immediately after birth empowers infant's immune system and reduces the risk of mortality up to 20%. The risk of mortality in infants who are not exclusively breastfed is 14 times more than those exclusively breastfed (5). Maternal advantages of breastfeeding include more rapid return to pre-pregnancy weight, decreased risk of type 2 diabetes, osteopo-

rosis, post-delivery depression and breast and ovarian cancer (6). According to the UNICEF reports in 2013, only 39% of infants younger than six months were exclusively breastfed in the world (5). In Iran, 27.7% of infants aged six months were exclusively breastfed, while in those aged four months it was 56.8% (7). The average age of weaning infants in Iran has been reported to be 3.2 months, which is different from 2.4 to 3.7 months in various places. Physicians recommendation is the most common reason for discontinuing exclusive breastfeeding (54%), which has been reported similar in urban and rural areas. Breast milk insufficiency, family and relatives recommendation, infant's cry, and without any special purpose are other reasons (8). Breast milk insufficiency is one of mothers' main reasons to stop breastfeeding in the first six to eight weeks after birth (9). Using Galactogogues is recommended to resolve this problem. Galactogogues are some substances or medicines that initiate, enhance and maintain milk production (10, 11). About 43% of Norwegian women and 15% of American women use herbal galacto-

gogues (12). Fennel is a herb with galactogogues property. Scientific name of Fennel is *Foeniculum vulgare*, which belongs to the Umbelliferae family. The root, leaf, fruit and seed of Fennel are used (13, 14). This plant contains comphen, Fencho and Anethol essences. About 60% of oil seed essence is consisted of Anethol. It seems that Fennel galactogogues mechanism results from Estrogenic and Phyto-estrogenic properties of Anethol and its polymers such as Di-Anethol and Photo-Anethol. Phyto-estrogens due to their structural similarity to estrogens can attach to α and β Estrogens' receptors to exert estrogenic properties (15-17).

Performed studies related to Fennel's galactogogues property are limited and have contradictory results. Since now no study has been performed to evaluate the effect of fennel on infant growth parameters, number of wet diapers in a day, frequency of defecation and infant breastfeeding times. Regarding the fact that this plant is local, cheap and available in Iran, this study was performed for the first time to evaluate the effect of fennel on breast milk sufficiency signs and infant growth parameters.

2. Objectives

This study was conducted to determine the effect of herbal tea containing Fennel seed on breast milk sufficiency signs and growth parameters of Iranian infants in medical health centers of Tehran University of Medical Sciences, Tehran, Iran.

3. Patients and Methods

This study was a double-blind randomized clinical trial with control group. The research sample included 78 mothers and 0-4 month old girl infants referred to medical health centers affiliated to Tehran University of Medical Sciences, Tehran, Iran. Regarding the ethics committee view about the possibility of infertility in boy infants after using fennel, it was decided only to include girl infants in the study. This research was approved by the Ethics Committee of Tehran University of Medical Sciences with the code of 92/D/130/1913 in 23 November 2013. This trial was registered in the Iranian Registry of Clinical Trials with ID number of IRCT201312102751N10. After explaining the aims of the research, mothers filled informed consent forms. Inclusion criteria were girl infants aged 0-4 months, term, birth weight between 2500-4000 grams, normal ability of sucking, not consuming infant formula, herbal and chemical galactogogues, not initiation of complementary feeding, mother and infant without infection with Human Immunity Deficiency Virus (HIV), not addiction to narcotic substances and alcohol, untreated active tuberculosis, using special medicines such as Phenobarbital and Ergotamine and so on, women receiving breast cancer treatment, breast problems such as breast nipple indentation, abscess, mastitis, and mother's underlying diseases such as asthma, cardiac diseases, blood clotting

diseases and diabetic. Exclusion criteria were mother's unwillingness to continue participation in the study and using any galactogogues or infant formula during the study. The sample size was calculated using the formula of difference between the mean and based on a similar study (18). Power = 80%, $\alpha = 0.05$, level of confidence = 95%, Case: $\mu_1 = 365.55$, $s = 69.40$, Control: $\mu_2 = 315.50$, $s = 58.66$ and ($n = 39$) was determined in each group.

$$n = \frac{2\sigma^2(z_{1-\alpha/2} + z_{1-\beta})^2}{(\mu_1 - \mu_2)^2}$$

After filling informed consent, samples were randomly assigned into intervention group (received herbal tea containing 7.5 grams Fennel seed powder in addition to 3 grams black tea three times a day) and control group (received herbal tea containing 3 grams black tea powder three times a day) using lottery method. Simple randomization was used. For sampling by using cards that were numbered with 1, 2 and the lottery in every time mothers were assigned in one of the groups. Herbal tea was produced by Iranian Institute of Medicinal Plants (ACECR) in Iran with registration number of 771188. For validity, content validity and reliability, test-retest method was used ($r = 0.88$). In the beginning, demographic questionnaires including 12 questions about demographic conditions and six questions about breastfeeding conditions were filled by samples. Before the intervention, growth parameters including weight, height and head circumference of infant were recorded. A follow-up form was given to mothers for two days to measure pre-intervention conditions regarding the number of daily wet diapers, frequency of defecation and infant breastfeeding times. Mothers were asked to eat herbal tea three times a day and two hours after eating a meal. Mothers recorded the number of wet diapers in a day, frequency of defecation and infant breastfeeding times during a week. Before each visit, mothers were reminded by phone contact for the next reference and reminded how to consume herbal tea. In each visit, infant's weight was measured (Seca made in Germany). Besides, height by tall-meter table and head circumference by exact meter were recorded. After four weeks, breast milk sufficiency signs and infant's growth parameters were compared in the intervention and control groups.

3.1. Statistical Analysis

Data normal distribution was checked by Kolmogorov-Simonov test and normal distribution of data was verified. Collected data was analyzed using SPSS version 20 (Armonk, New York: IBM corp). Independent sample t-test and repeated measure analyze were used. P value below 0.05 was considered statistically significant.

4. Results

Mothers in Fennel and control groups had an average

age of 27.15 ± 4.777 and 29.49 ± 4.855 , respectively and body mass index of mothers in Fennel and control groups were respectively 25.65 ± 4.153 and 24.87 ± 3.254 . Economically, in fennel group 82.1% of mothers were in good and relatively good conditions. The average of weight, height and head circumference at birth time were (3275.51 ± 340.767), (49.97 ± 1.662) and (34.82 ± 1.032) respectively in the Fennel group and (3299.87 ± 395.808), (50.21 ± 1.301) and (35.08 ± 1.124) in the control group respectively.

Before the intervention, there was no significant difference between the two groups regarding weight, height, head circumference, number of wet diapers, and frequency of defecation ($P > 0.05$). Nevertheless, the number of breastfeeding times in the control group was more than the Fennel group ($P = 0.006$) (Table 1). After fourth weeks compared to pre-intervention conditions, Fennel significantly increased weight from (5261.0256 ± 1167.65801) to (6393.3333 ± 1083.42132), head circumference from (38.6103 ± 2.20033) to (40.1538 ± 2.00510), number of wet diapers from (5.5000 ± 1.05131) to (8.5421 ± 1.21182), frequency of defecation from (1.7692 ± 1.03139) to (2.4610 ± 1.14655) and number of breastfeeding times from (9.9359 ± 1.85380) to (16.7399 ± 1.63766) ($P < 0.001$). However, it had no effect on height ($P = 0.066$).

Despite the fact, after fourth weeks in control group in comparison to Fennel group, no significant changes were observed in measured variables as follows: weight from (5334.8718 ± 1318.59948) to (6018.7179 ± 1261.41353), height from (57.0538 ± 4.6841) to (58.9821 ± 6.23591), head circumference from (38.6051 ± 2.11597) to (39.7769 ± 2.00151), number of wet diapers from (5.9231 ± 1.68405)

to (5.5788 ± 1.46163), frequency of defecation from (2.2051 ± 1.52487) to (1.7363 ± 0.87053) and number of breastfeeding times from (11.2051 ± 2.07338) to (11.4176 ± 1.68470) ($P > 0.05$) (Table 2).

Table 1. Comparing Signs of Breast Milk Sufficiency in the Fennel and Control Groups Before the Intervention

Variable Intervention	Value ^a	P Value
Weight		0.794
Fennel	5261.0256 ± 1167.65801	
Control	5334.8718 ± 1318.59948	
Height		0.737
Fennel	57.4436 ± 5.49487	
Control	57.0538 ± 4.68041	
Head		0.992
Fennel	38.6103 ± 2.20033	
Control	38.6051 ± 2.11597	
Number of wet diapers		0.188
Fennel	5.5000 ± 1.05131	
Control	5.9231 ± 1.68405	
Frequency of defecation		0.144
Fennel	1.7692 ± 1.03139	
Control	2.2051 ± 1.52487	
frequency of infant feeding		0.006
Fennel	9.9359 ± 1.85380	
Control	11.2051 ± 2.07338	

^a Data are presented as mean \pm SD.

Table 2. Comparing Signs of Breast Milk Sufficiency in the Fennel and Control Groups After the Intervention^a

Variable/Intervention	Week 1	Week 2	Week 3	Week 4	P Value ^b
Weight					< 0.001
Fennel	5590.5128 ± 1168.06171	5861.0256 ± 1137.69109	6135.6410 ± 1118.20767	6393.3333 ± 1083.42132	
Control	5510.0000 ± 1301.10479	5682.5641 ± 1288.31125	5724.6154 ± 1527.82929	6018.7179 ± 1261.41353	
Height					0.066
Fennel	58.5487 ± 4.28663	59.0205 ± 4.32582	59.6744 ± 4.13558	60.1154 ± 4.00707	
Control	57.3000 ± 4.62089	57.6231 ± 4.60552	57.8205 ± 4.52096	58.9821 ± 6.23951	
Head					< 0.001
Fennel	39.0026 ± 2.17576	39.3436 ± 2.16780	39.7949 ± 2.13861	40.1538 ± 2.00510	
Control	38.8487 ± 2.03688	39.1282 ± 2.02822	39.3923 ± 2.02788	39.7769 ± 2.00151	
Number of wet diapers					< 0.001
Fennel	6.5165 ± 1.30216	7.6630 ± 1.24129	8.2491 ± 1.16691	8.5421 ± 1.21182	
Control	5.7985 ± 1.64676	5.7143 ± 1.50367	5.5275 ± 1.53448	5.5788 ± 1.46163	
Frequency of defecation					< 0.001
Fennel	2.6081 ± 1.11513	2.7033 ± 1.19630	2.7143 ± 1.12055	2.6410 ± 1.14655	
Control	2.0440 ± 1.22635	1.8974 ± 1.01331	1.8059 ± 0.95859	1.7363 ± 0.87053	
Frequency of infant feeding					< 0.001
Fennel	12.3883 ± 3.14951	14.2637 ± 1.72040	15.7729 ± 1.44937	16.7399 ± 1.63766	
Control	10.9048 ± 1.86215	11.2381 ± 1.85290	11.5861 ± 3.26370	11.4176 ± 1.68470	

^a Data are presented as mean \pm SD.

^b P value < 0.05 was considered statistically significant.

5. Discussion

In this study, the effect of herbal tea containing Fennel seed on infant's growth parameters such as height, weight and head circumference, number of wet diapers in a day, frequency of defecation and infant breastfeeding times were evaluated in girl infants aged 0-4 months during four weeks of study and compared with the control group. Regarding the ethics committee view about the possibility of infertility in boy infants by using fennel, only girl infants were included. Our study showed that herbal tea containing fennel seed improved signs of breast milk sufficiency and infant's growth parameters compared to the control group. However, it had no effect on infant's height growth. Since height growth is slower than weight and other parameters, it seems reasonable that height growth did not change in the control group so much. The results of our study supported many studies that evaluated Fennel's galactogogues property. In Westfall's study entitled "Galactogogues Herbs: A Qualitative Study and Review", Fennel was reported as a galactogogue plant with estrogenic properties. In many countries galactogogues tea is a combination of Fennel and Anise. In addition, it has been said that Fennel consumption is not contradicted in breastfeeding (19).

In the study of Agarwal entitled "Oculohypotensive Effects of *Foeniculum Vulgare* Experimental models of glaucoma" mentioned that Fennel has a Phyto-estrogenic property that causes breast growth and milk production (20). Albert-Puleo in his study entitled "Fennel and Anise as Estrogen Agents" stated that Fennel was used for its estrogenic properties for centuries and these estrogenic properties are due to Anetol found in Fennel, which exert galactogogues property, delivery facilitation and menstruation (21).

Honarvar *et al.* study was performed on 46 breastfeeding mothers to evaluate Fennel effect on prolactin level of blood serum. Mothers took 3 grams Fennel powder in six 500 mg capsules daily. Serum prolactin was evaluated before the intervention and 15 days after it. The average level of serum prolactin before the intervention was 64.55 ± 32.06 ng/mL and 95.55 ± 65.90 ng/mL after it (22). In this study, fennel increased prolactin in blood serum, which confirms the present study regarding the key role of prolactin in milk production.

Results of Dehkhoda's study conducted to evaluate "The Effect of an Educational and Supportive Relation Program on Weight Gain of Preterm Infants" confirm our study regarding breastfeeding times and weight gain. Mothers received galactogogues pill containing Fennel (50%), Fenugreek, Cumin seed and Dill and 10 mg Metoclopramide pill. On the 14th day of study, infant breastfeeding in the intervention group was reported 5-12 times compared to 1-7 in the control group and infants' weight of intervention group as 1765.86 ± 156.96 grams compared to 16730 ± 131.280 in the control group (18). The results of abovementioned study are in agreement with ours regarding milk production, increase in breastfeeding times and weight gain.

In the study of Siahi *et al.* the effect of liquid extract of Fennel plant was assessed on the level of prolactin excretion and breastfeeding of female rats. This study was performed on 75 adult Wistar female rats, aged 2-30 months, and weighting 200-1800 grams. Rats were divided into four experimental groups and one control group with 15 rats in each group. Four experimental group received 35, 70, 140 and 280 micro liter dosages of Fennel extract for 5, 10 and 15 days, respectively. At the same time physiologic serum was injected to the control group as peritoneal. During the experiment and after the end of intervention, blood prolactin level was measured. The effect of the extract was measured regarding two variables of mothers' prolactin variation and infants' weight change. According to normal prolactin level of 13.7-23.3 in rats, prescription of extract did not change the prolactin level. However, at doses of 140 and 280, prolactin levels increased significantly, but this increase was not effective to increase milk production and subsequently infant's weight gain (23). Observed increase in prolactin level of rats' serum was not significant, and the difference in the results of this study and the recent study can be due to differences in samples.

Another research performed by Shariati *et al.* entitled "The survey of effect of using Shirafza Drop by nursing mothers on weight gain (WG) of 0-6 months exclusively breastfed", 158 mothers with 0-6 months exclusively breastfed infants were studied. These mothers were unsatisfied of milk adequacy and the growth chart of their infants' was descending, constant or non-ascending. The galactogogues drop contained six galactogogues plants including Fennel, Anisa, Crarawat seed, Dill, Green cumin and Black Cumin. Mothers used galactogogues 30 drops in three times in half of cup water. In this study, infants' weight increase in the two groups did not show significant difference after four weeks follow-up ($P = 0.5$). However, comparison of infants weight gain in the two groups with minimum weight gain of infants in the first trimester (26 grams daily) and in the second trimester (17 g daily) showed that infants with more than three months old in the intervention group achieved a normal weight (24). In this study feeling of mothers associated with increased milk in the two groups was the same, while in our study two-third of mothers in the Fennel group mentioned an increase in their milk production, but in the control group it was not observed. Regarding frequency of urine ($P > 0.05$) and defecation, there was no significant difference between the two groups. In our study, number of wet diapers and frequency of defecation were higher in the Fenugreek group. Following elimination of a large number of samples, sample size was not completed, which can have negative impact on the results. This contradiction with our results can be due to difference in medicine type, infant's age and incompleteness of studied samples.

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Authors' Contributions

Vida Ghasemi, Masoomeh Kheirhah and Leila Neisani Samani participated in design and writing the manuscript. Vida Ghasemi participated in data collection, design, statistical analysis and writing the manuscript. Mohsen Vahedi analyzed the data. All authors read and approved the final version for publication.

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