Influences of Consumption of Herbal Galactagogue Tea on Composition of Human Milk Macronutrients

Galaktatog İçeren Bitki Çayı Tüketiminin Anne Sütü Makro Besin Ögesi Bileşimine Etkisi

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ABSTRACT

Objective: The aim of this study was to determine the influences of herbal galactagogue teas consumption on the composition of human milk energy and macronutrients.

Methods: It was a cross-sectional study conducted between 12 March and 30 June 2018, involving mothers having 1-4 month old infants consuming (n=43) and non-consuming (n=56) herbal tea containing galactagogue. Energy and macronutrients of human milk collected from mothers by hand expression were measured using a human milk analyzer, and retrospective 1-day food consumption records were obtained. The significance level was accepted as p < 0.05.

Results: Herbal tea consumption was significantly higher in highly educated mothers (p = 0,009). No significant difference was found between the energy and macronutrient content of breast milk of the groups who consumed and did not consume herbal galactagogue tea (p > 0.05). Type of herbal galactagogue tea did not affect the content of human milk (p > 0.05). There was no statistically significant difference between the two groups in the average daily energy and macronutrient intakes of the mothers (p > 0.05).

Conclusion: The consumption of herbal galactagogue teas did not change HM energy and macronutrient composition. It has been proposed that the safety, efficacy, and possible side effects of these teas should be assessed in larger sample groups and randomized controlled trials **Keywords:** Human milk, Galactagogue, Herbal tea, Energy, Macronutrient

ÖZ

Amaç: Bu çalışmanın amacı galaktagog içeren bitki çayı tüketiminin anne sütü enerji ve makro besin ögesi bileşimine etkisini belirlemektir.

Yöntem: Çalışma 12 Mart – 30 Haziran 2018 tarihleri arasında, 1-4 aylık bebeği olan, galaktagog içeren bitki çayı tüketen (n=43) ve tüketmeyen (n=56) anneler ile yürütülmüştür. El ile sağılan sütlerin enerji ve makro besin içeriği anne sütü analizi cihazı ile ölçülmüş; annelerden geriye dönük bir günlük besin tüketim kaydı alınmıştır. Anlamlılık düzeyi p < 0,05 kabul edilmiştir.

Bulgular: Galaktagog içeren bitki çayı tüketiminin eğitim düzeyi yüksek olan annelerde anlamlı olarak daha yüksek olduğu tespit edilmiştir (p = 0,009). Anne sütü enerji ve makro besin ögesi içeriği açısından galaktagog içeren bitki çayı tüketen ve tüketmeyen anneler arasında anlamlı bir fark bulunmamıştır (p > 0,05). Galaktagog içeren bitki çayı türünün anne sütü içeriğini etkilemediği saptanmıştır (p > 0,05). Annelerin günlük ortalama enerji ve makro besin ögesi alımları açısından iki grup arasında istatistiksel olarak anlamlı bir fark bulunmamıştır (p > 0.05).

Sonuç: Galaktagog içeren bitki çaylarının anne sütü içeriğini değiştirmediği belirlenmiştir. Bu çayların güvenlik, etkinlik ve olası yan etkilerinin daha büyük örneklem gruplar ve randomize kontrollü çalışmalarda değerlendirilmesi gerektiği düşünülmüştür.

Anahtar Kelimeler: Anne sütü, Galaktagog, Bitki çayı, Enerji, Makro besin ögesi

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1.INTRODUCTION

Human milk is the most suitable and natural food that contains the energy and macro-, micronutrients and bioactive components required for the optimal growth of fetal newborns with sufficient fetal storage (Yin & Yang, 2016). World Health Organization (WHO) and United Nations Children's Fund (UNICEF) recommended that breastfeeding should be started within 1 hour after birth, exclusive breastfeeding for the first 6 months and to continue breastfeeding with appropriate complementary feeding for 2 years of age and onwards (WHO, 2018a).

Human milk production is a complex process that needs physical (maternal and neonatal health, good breast attachment), emotional (stress, maternal rest, maternal confidence), and hormonal regulations (Amir, 2006). Milk volume, sucking time, the time between two breastfeeding, maternal age, ethnic origin, weight gain during pregnancy, birth weight of the baby, and nutrition of mother may affect the mother's milk composition (Andreas, Kampmann & Le-Doare, 2015). Environmental factors such as cultural factors, home social life have a positive effect on successful breastfeeding and milk production can be increased in various ways such as psychological support and relaxation techniques (Zuppa et al., 2010; Shukri, Wells & Fewtrell, 2018; Shukri et al., 2019).

In Greek, the word "galactagogue" means "milk secretionenhancing substance" (galactose-milk, agro-secretion), termed herbal origin, synthetic or endogenous substance that induces and increases the secretion of human milk. Many nutrients, plants, and pharmaceutical agents (e.g. domperidone and metoclopramide) are used as galactagogues from past to present (Gabay, 2002).

Herbal teas are widely used by mothers due to their milk induction and secretion enhancing properties (Abascal & Yarnell, 2008). It is thought that the herbal galactagogues increase estrogenic or oxytocic activity, stimulate the milk glands, increase breast tissue or have a placebo effect (Bryant, 2006; Ağagündüz, 2020). The oxytocin effect is caused by the stimulation of the milk channels in the breast by oxytocin hormone and by the contraction of the cells here (Zuppa et al., 2010). It is also stated that by regulating blood flow in the mammary glands and triggering sweating with the phytoestrogens they contain, it has the potential to increase milk production by stimulating the mammary glands (Tiran, 2003). Although there is not sufficient evidence in the literature regarding the safety and efficacy of galactagogues, they are often used by mothers and can often be recommended by health providers across the world (Ağagündüz, 2020). Fenugreek, milk thistle, and asparagus are herbal galactagogues that are frequently recommended to mothers. Apart from these plants, goat's rue, fennel, verbena, anise, linden, sage, rosehip, and nettle are also used to induce and increase milk production (Zuppa et al., 2010).

The use of galactagogues is not recommended by the Academy of Breastfeeding Medicine (ABM) at present due to the lack of proven efficacy and potential side effects (Mortel & Mehta, 2013; Brodribb, 2018). Although there are researches about breastfeeding practices, consumed foods, and herbal teas for increasing milk production in Turkey (Türkyılmaz et al., 2011; Erkaya, Gürsoy & Güler, 2012; Gökduman & Balkaya, 2013), there is no research on the effect of galactagogue tea consumption on human milk composition in full-term healthy infants. The aim of this study was to determine the effects of herbal galactagogue teas consumption on energy and macronutrient composition.

2. METHODS

The study was conducted using a cross-sectional design at Marmara University Pendik Training and Research Hospital between the 12th of March and the 30th of June 2018. The participants were a convenience sample of mothers of exclusively breastfed babies within an age range of 1-4 months. The mothers who exclusively breastfeeding their babies, did not use drugs or any nutritional supplements, did not smoke and drink alcohol were included in the study. Mothers with chronic conditions such as diabetes, hypertension, allergic disorders, who had preterm deliveries (gestational age <37 weeks), and low birth weight babies (< 2500 g) or those who had inverted nipples, and mastitis at the time of data collection were excluded. Mothers who came to the outpatient clinic for the follow-up of their babies meeting the inclusion criteria were invited to participate in the study by the outpatient clinic nurse. Those who agreed to take part in the study were asked to fill out the questionnaires and to obtain human milk after signing the written informed consent. The study was approved by the Marmara University Faculty of Medicine Clinical Research Ethics Committee in accordance with the standards of the Declaration of Helsinki (Protocol No: 09.2018.057).

The sample size calculation was made using the Sample Size Calculator for two independent study groups with binomial primary endpoints based on the study by Damanik et al (ClinCalc, 2018; Damanik, Wahlqvist & Wattanapenpaiboon, 2006). The number of study and control groups were calculated as 35 mothers with 95% confidence interval, 90% power, and Type I error 0.05. However, considering the exclusion criteria, 60 eligible mothers were included in each of the study and control groups. Mothers who could not express sufficient milk (n=9), those who did not complete the questionnaire (n=2), and those who did not drink herbal tea containing galactagogue regularly (n=6) were excluded from the study group and mothers who did not complete the questionnaire (n=4) were excluded from the control group.

A questionnaire including questions such as demographic characteristics of the mothers, type of delivery, weight gain during pregnancy, breastfeeding, consumption of herbal tea was filled out by face-to-face interviews and 1-day recall was recorded. Herbal tea consumption was defined as "drinking \geq 3 cups/day (1 cup = 240 ml) of herbal tea containing galactagogue" (Türkyılmaz et al., 2011).

Forty-three mothers who consume herbal galactagogue tea \geq 3 cups per day (within the last 24 hours) and who give only human milk to their baby constituted the study group. Fifty-six mothers who do not consume fenugreek or fenugreek extract, fennel extract, fennel oil, milk thistle or any nutrients or beverages which contain galactagogue constituted the control group. After the explanation was made by the researchers, volunteer mothers were invited to the study.

During the comparison of herbal tea type and breast milk content, herbal tea or herbal tea mixture specified by the mothers in the 1-day recall was used (Türkyılmaz et al., 2011). In the questionnaire form, the teas consumed and their content were questioned. Herbal tea mixture consumed by mothers belongs to Humana Still-Tea[®] brand that mothers bought from the market. These tea mixtures include sucrose, maltodextrin, roselle extract (%2.6), L-ascorbic acid (%0.5), raspberry leaf extract (%0.2), fennel extract (%0.2), fenugreek extract (%0.1), goat's rue extract (%0.1), and fennel oil (%0.02) (Humana, 2018). Cumin and fennel herbal tea were bought and consumed by mothers from herbalists.

Four ml of mature human milk was obtained from all mothers and the analysis was repeated 2 times for the reliability of the results. After feeding the babies, the hind milk obtained by hand expression from the right breast was placed in Eppendorf tubes and analyzed with Miris[®] HMA (Human Milk Analyzer) [™] in 2 hours on the 1-day recall day. Protein, fat, carbohydrate and energy values were determined. Miris[®] HMA[™] (Uppsala, Sweden) is approved by International Standards Organization (ISO) 9622: 1999.

The energy and macronutrient intakes of mothers were calculated from the 1-day recall using the BeBis 8.1 (nutrition information system) software. The body weight and height of the mothers were measured according to the standards. Body weight was measured using the InBody 120, and height was measured using the stadiometer. The Body Mass Index (BMI) was calculated by dividing body weight (kg) by the square of height (cm). For the evaluation of the results, WHO's classification was used (Underweight: < 18.5 kg/m²; Normal: 18.5–24.9 kg/m²; Overweight: 25.0–29.9 kg/m²; Obese: \geq 30 kg/m²) (WHO, 2018b).

The data were evaluated statistically in SPSS (version 16.0. Ink) package program. Descriptive statistics include number, percentage, mean, median, 25.-75. quartile, and upper and lower values, as well as the standard deviation. The normal distribution of the variables was checked by using the Kolmogorov Smirnov test. Categorical variables were evaluated with the Chi-Square test. If data within the normal distribution, Independent Samples T-Test was used for comparisons between two independent groups, and

One-Way ANOVA test was used for comparisons between three or more independent groups. If the data was not normally distributed, Mann – Whitney U Test was used to compare two independent groups, and Kruskal-Wallis Test was used to compare three or more groups. Statistical significance of all analyzes was accepted as p < 0.05.

3. RESULTS

A comparison of maternal demographic characteristics according to the herbal galactagogue tea consumption was given in Table 1. It was found that more than half of mothers consuming herbal galactagogue tea were in the \geq 35 age group (56.0%) and the mothers not consuming 68.0% in the 30-34 age group. Also, 65.2% of the mothers consuming herbal galactagogue tea were high school graduates, and 75.0% of the mothers in the control group were primary school graduates (p = 0.009). No statistically significant difference was found in age, working status, and BMI according to herbal tea consumption (p > 0.05).

 Table 1. Comparison of maternal characteristics according to the herbal galactagogue tea consumption

Demographic characteristics	Herbal galactagogue tea consuming		Herbal galactagogue tea non-consuming		X ²	р
	Ν	%	n	%		
Age group (year)						
19-24	7	38.9	11	61.1		0.373
25-29	14	45.2	17	54.8	3.126	
30-34	8	32.0	17	68.0		
≥35	14	56.0	11	44.0		
Education level						
Primary school	7	25.0	21	75.0		0.009*
Middle school	7	30.4	16	69.6	11.503	
High school	15	65.2	8	34.8		
University	14	56.0	11	44.0		
Working Status						
Working	16	61.5	10	38.5	4.704	0.053
Not working	27	37.0	46	63.0		
BMI						
Normal	22	51.2	23	41.1	2.024	0.364
Overweight	15	34.9	19	33.9	2.021	
Obese	6	14.0	14	25.0		

*p <0.05, Chi-square test

In mothers consuming herbal galactagogue tea, human milk energy content for 100 ml was 67.4 ± 17.2 kcal, fat content was 3.7 ± 1.8 g, protein was 1.2 (1.0 - 1.3) g, and lactose content was 7.0 (6.8 - 7.2) g. In the non-consuming group, human milk energy content was 72.5 ± 15.4 kcal, fat content was 4.2 ± 1.7 g, protein content was 1.2 (1.1 - 1.4) g, and lactose content was 7.0 (6.8 - 7.2) g. Herbal galactagogue tea consumption constituted a difference in neither the energy nor the macronutrient composition of human milk (p > 0.05) (Table 2).

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Table 2. Comparison of human milk content according to the herbal galactagogue tea consumpt	ion
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	Herbal galacta	agogue tea consuming	Herbal galactagogue tea non-consuming						
	n	Mean ± SD		n	Mean ± SD			t	p ^a
Milk energy (kcal)	43	67.4 ± 17.2		56	72.5 ± 15.4			-1.378	0.168
Milk fat (g)	43	3.7 ± 1.8		56	4.2 ± 1.7			-1.538	0.122
	n	Median (2575. quartile)	Mean rank	n	Median quartile)	(2575.	Mean rank	Z	p ^b
Milk protein (g)	43	1.2 (1.0-1.3)	46.5	56	1.2 (1.1-1.4)		52.7	-1.067	0.286
Milk lactose (g)	43	7.0 (6.8-7.2)	52.5	56	7.0 (6.8-7.2)		48.1	-0.775	0.438

^aIndependent Samples T-Test, ^bMann – Whitney U Test; The values show the amount of macronutrients in 100 ml of human milk.

Table 3 shows the comparison of the herbal galactagogue tea type and the human milk composition, and it was determined that there were no significant differences in milk composition (p > 0.05) (Table 3).

Table 3.	Comparison	of human i	milk content	according	to the	herbal
galactag	gogue tea typ	e (n=99)				

		Mean ± SD	Minimum	Maximum	f	p ^a
Milk energy (kcal)	Herbal tea mix	62.3 ± 19.3	39.0	99.0		
	Fennel	70.0 ± 16.5	46.0	102.0	0.668	0.577
	Cumin fennel	72.0 ± 1.4	71.0	73.0		
Milk fat (g)	Herbal tea mix	3.2 ± 2.1	0.8	7.2		
	Fennel	3.9 ± 1.8	1.8	7.6	0.631	0.600
	Cumin fennel	4.2 ± 0.0	4.2	4.2		

		n	Median (25. – 75. quartile)	Mean rank	X ²	þ
Milk	Herbal tea mix	15	1.3 (1.0 – 1.4)	22.0		
protein	Fennel	25	1.2 (1.1 – 1.3)	21.3	0.053	0.974
(g)	Cumin fennel	2	1.1 (0.8 – 1.4)	20.3		
Milk	Herbal tea mix	15	7.0 (6.8 –7.2)	20.8		
lactose (g)	Fennel	25	7.0 (6.9 – 7.2)	22.1	0.160	0.923
	Cumin fennel	2	6.9 (6.6 – 7.2)	19.5		

^aOne-Way ANOVA Test, ^bKruskal – Wallis Test; The values show the amount of macronutrients in 100 ml of human milk.

The energy and macronutrient compositions of human milk were compared according to the BMI status of the mothers participating in the study, in Table 4. It was determined that there was no significant difference in human milk energy and macronutrients according to the BMI of the mothers (p > 0.05).

In Table 5, the energy and macronutrient intake of mothers were compared according to the herbal galactagogue tea consumption. There was no statistically significant difference (p > 0.05) (Table 5).

		Me	an ± SD	Minimum	Maximum	f	p ª
N 4111-	BMI						
IVIIIK	Normal	70.3	1 ± 15.0	44.0	113.0		
(kcal)	Overweight	69.9	9±15.6	39.0	102.0	0.066	0.936
(Keal)	Obese	71.5	5 ± 20.5	46.0	107.0		
	BMI						
Milk fat	Normal	3.9	±1.6	1.0	8.8		
(g)	Overweight	3.9	± 1.7	0.8	7.6	0.169	0.844
	Obese	4.2	± 2.3	1.4	8.3		
		n	Mediar	1 (25. – 75. 2)	Mean rank	X ²	₽ ^b
	DMI		quartin	-			
Milk	DIVII	45	1 2 / 1 4	4 4)	52.07		
protein	Normal	45	1.2 (1.1	. – 1.4)	53.07		
(σ)	Overweight	34	1.2 (1.1	. – 1.4)	49.85	1.611	0.447
(6)	Obese	20	1.1 (0.9	9 – 1.4)	43.35		
N 411	BMI						
Milk	Normal	45	7.1 (6.8	8 – 7.2)	53.07		
(a)	Overweight	34	7.1 (6.9	9 – 7.1)	50.38	1.930	0.381
(g)	Obese	20	6.9 (6.8	3 – 7.2)	42.45		

Table 4. Comparison of human milk content according to BMI

^aOne-Way ANOVA Test, ^bKruskal – Wallis Test; The values show the amount of macronutrients in 100 ml of human milk.

Table 5. Comparison of daily energy and macronutrient intake of mothers according to the herbal galactagogue tea consumption (n=99)

Energy and macronutrient	Herbal galactagogue tea consuming	Herbal galactagogue tea non-consuming	t	р	
	Mean ± SD	Mean ± SD			
Energy (kcal)	1925.4 ± 747.4	1892.9 ± 546.0	0.250	0.811	
Protein (g)	65.6 ± 26.2	65.6 ± 21.3	-0.011	0.991	
Fat (g)	86.6 ± 36.5	87.8 ± 29.6	-0.184	0.855	
Carbohydrate (g)	217.7 ± 106.9	206.3 ± 74.2	0.625	0.553	

Independent – Samples T-Test

4. DISCUSSION AND CONCLUSION

In this study conducted with 99 exclusively breastfeeding mothers, no difference was found between mothers who consumed herbal galactagogue tea and those who did not in terms of energy and macronutrients in human milk. In the literature, there are no studies examining the effect of herbal galactagogue teas consumption on the composition of breast milk. It was determined that the studies are generally aimed at determining the effect of the consumption of herbal galactagogue teas on breast milk production and volume

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(Türkyılmaz et al., 2011; Ozalkaya et al., 2018; El Sakka, Salama & Salama,2014). However; in a study evaluating the effect of herbal galactagogue mixture on the composition of human milk, it was found that there was no significant difference in the human milk composition of mothers who consumed and did not consume the mixture (Bumrungpert et al., 2018). For this reason, it was thought that there is a need for studies investigating the effect of herbal galactagogue teas consumption on the composition of breast milk.

In a study investigating mothers' practices during the lactation period, it was found that there was no significant difference between the use of a method to increase human milk according to mother's education level (Erkaya, Gürsoy & Güler, 2012). It was found that the nutrients consumed in order to increase human milk were affected by the education level of the mothers, and as the level of education increased, the consumption of nutrients became more frequent (Gökduman & Balkaya, 2013). In this study, it was found that the consumption of herbal tea containing galactagogue was significantly higher in mothers with university and postgraduate education. It was thought that this result might be due to the fact that mothers with higher education levels had easier access to information.

In the literature, it was reported that the BMI of mothers may affect the energy and macronutrient composition of human milk, but there are controversial results (Quinn et al., 2012; Chang et al., 2015). Quinn et al. (2012) found that the BMI of mothers did not affect the total energy, fat, and protein content of milk, but it was inversely correlated to lactose content. In a study conducted with 2632 mothers in Korea, the mother's BMI was positively correlated with the protein and fat content of milk but lactose content was found negatively correlated (Chang et al., 2015). In our study, it was found that the mother's BMI did not affect the energy and macronutrient content of human milk. It was thought that this result may be due to the fact that BMI affects breast milk hormone composition rather than energy and macronutrient content (Bzikowska-Jura et al., 2018; Sims et al., 2020).

Also, studies on determining the content of human milk were searched in the literature. In a study conducted with 102 mothers the energy of 100 ml human milk was found to be 72.0 \pm 15.0 kcal, fat 3.81 \pm 1.5 g, protein 1.34 \pm 0.48 g, and lactose 7.31 \pm 0.58 g (Quinn et al., 2012). In another study conducted with 2632 lactating mothers, the energy of 100 ml milk was 61.1 \pm 12.1 kcal, fat 3, 0 \pm 1.4 g, protein 1.4 \pm 0.3 g and lactose 7.1 \pm 0.4 g (Quinn et al., 2012). In our study, in line with previous studies, the energy, protein, fat, and lactose contents of 100 ml human milk were similar in both groups.

Limitations of the study include information on the consumption of herbal galactagogue tea was based on maternal self-reports. In addition, the analysis of human milk is performed on one occasion only and the food consumption record is taken for one day retrospectively. The large sample size (n = 99) and the limited number of studies on the possible effects of herbal galactagogue tea consumption on human

milk energy and macronutrient composition were evaluated as strengths of the study. In addition, the method used in the analysis of human milk is valid, and all the analysis is uniformly performed by the principal investigator.

In conclusion, no difference was found between mothers who consumed herbal galactagogue tea and those who did not in terms of energy and macronutrients in human milk. However, the majority of herbal teas were non-manufactured products, so safety concerns should be addressed. Increased consumption of herbal tea in the more educated mothers should be taken into account in planning education and counseling services for pregnant and lactating mothers. Also, it might be proposed that the safety, efficacy, and possible side effects of these teas should be assessed in larger sample groups and randomized controlled trials.

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