



THE EFFECT OF FENUGREEK SEED POWDER IN AUGMENTING EXPRESSED BREAST MILK VOLUME FROM MOTHERS OF PRETERM INFANTS AT TIKUR ANBESSA NEONATAL INTENSIVE CARE UNIT.

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ABSTRACT

The aim of this study is to investigate the effect of fenugreek seed in augmenting expressed breast milk volume of mothers of preterm infants at TASH NICU. A case-control experimental study was carried out in 88 mothers of preterm infants (<34 wks of GA) who were selected randomly and meet the inclusion criteria. The study began by measuring the baseline expressed milk volume in both groups for the first 24hour. For the experimental group water extract of fenugreek seed powder (6gm) was administered 3 times a day for five consecutive days while measuring the expressed milk volume of each participant every 3hr in 24hrs. The average amount of expressed milk volume in all participants before the experiment was 183 ± 16 ml/24hr. There were no statistically significant difference between baseline value of expressed milk volume in experimental and control groups. Following administration of fenugreek seed powder, the expressed milk volume (ml) on 1st, 2nd, 3rd, 4th, and 5th days were 249 ± 15 , 298 ± 19 , 342 ± 19 , 399 ± 20 , and 383 ± 20 respectively, and each of these values were significantly higher as compared to baseline value ($P < 0.05$). Comparison of expressed breast milk volume between experimental and control group showed statistically significant difference (249 ± 15 vs 187 ± 13 , 298 ± 19 vs 216 ± 16 , 342 ± 19 vs 233 ± 16 , 399 ± 20 vs 244 ± 19 , and 383 ± 20 vs 257 ± 18) for each of the experimental days from day 1-5 respectively. Expressed milk volume increase with increased number of babies, and mothers of male neonates express more milk than mothers of female neonates. In conclusion, mothers of preterm infants at TASH NICU expressed low breast milk volume. Administration of water extract of fenugreek seed powder to mothers of preterm infants for five consecutive days showed significant increase in breast milk volume.

KEYWORDS : Fenugreek seed, breast milk volume, galactagogue

INTRODUCTION

The process of producing an adequate milk volume begins during pregnancy when the breast undergoes a number of anatomical and physiological changes in preparation for breastfeeding (Meier *et al.*, 2010). There is a physiological variation in milk production over the course of lactation. It has been shown that milk production increases rapidly in the first weeks of life, and it is constant from the first month of life until 6 months of age then steadily declines (Stam *et al.*, 2013). The average milk volume of 100ml/24hr on the first day postpartum begins to increase until 36 h after birth and levels off at an average of 500 ml at the fourth day. Milk composition also changes dramatically during this period (Neville and Morton, 2001). The average baseline milk production on the days 6–7 is highly predictive. According to Jones and Spencer (2007), adequate milk volume is defined as greater than 500 ml/ day.

Due to the incomplete breast stimulation of the shortened pregnancy duration, and stress created by preterm delivery, mothers of preterm (born before 37 weeks of gestational age) infants have diminished milk production (Underwood, 2013). Therefore, human milk should be quantitatively measured for each day of the NICU stay. Mothers who are not breastfeeding but are expressing milk by hand or with a pump often experience a decline in milk production after several weeks so the use of galactagogue has been recommended for such mothers (ABM, 2011). Galactagogues stimulate milk secretion, and increase milk flow. There are both medically prescribed (e.g. metoclopramide, domperidone) and traditionally used herbal (e.g. fenugreek seed) galactagogues (Forinash *et al.*, 2012). The medically prescribed galactagogues exert their effects through antagonism of the

dopamine receptor to induce lactation, which results in subsequent increase in prolactin release (Penagos *et al.*, 2014). The release and production of prolactin is dependent on the inhibition of a factor known as prolactin inhibitor factor (PIF), produced by the hypothalamus, and dopamine-releasing neurons. The release of prolactin from the anterior pituitary stimulates the production and secretion of breast milk (Gabay, 2002). Herbal galactagogues are widely used by lactating women. Some of them are fenugreek, goat's rue, milk thistle, oats, dandelion, millet, seaweed, anise, basil, blessed thistle, fennel seeds, and marshmallow (Wills *et al.*, 2000). The mechanism(s) of action for most herbals are unknown. Most of them have not been scientifically evaluated, but traditional use suggests safety and possible efficacy (ABM, 2011).

The significance of this research work lies in the fact that it will contribute a new literature in assessing the volume of expressed breast milk, and effect of fenugreek seed in milk volume from mothers of preterm infants, which has not been done in Ethiopia. The result obtained from this study can be used to compare the milk volume of preterm mothers included in the study with the internationally studied milk volume.

MATERIALS AND METHODS

Study Period and Study Area

The study was conducted from September 2014 – Jun 2015 G.C. This study was carried out in Tikur Anbessa Specialized Hospital Neonatal Intensive Care Unit (TASH NICU). This unit has 2500-3000 neonates' admission annually. The referred cases are heterogeneous socioeconomically as well as demographically representing the diversified population. Moreover, this study site

was selected mainly due to the availability of mothers during every 24 hour starting from the date of their infant's admission. The presence of skilled and cooperative health professionals at TASH NICU play a role because infant's of mothers included in this study depended on tube feeding as their suckling ability were not yet established. Besides, when a baby is referred to TASH NICU for admission the nurses teach the mothers how to express their breast milk and create attachment with their baby. This was helpful to proceed with the study smoothly.

Study Design

This study is a randomized experimental study done on mothers of preterm infants (<34 weeks of gestation) by conventional/convenient sampling method. During recruitment period, the mothers were at 3-5days postpartum with no postpartum bleeding and solely express breast milk (not yet started breastfeeding). All participants entered in to the study willingly and signed the informed consent, which was prepared in language, that each of them can understand. The informed consent as well as the questioner was filled in separate and private place. Questionnaire was used to get personal, family and medical information. Data collectors were around to clarify questions when participants filled the questionnaire.

Eligibility Criteria

The following criteria were used to select eligible participants to be included in the study.

Inclusion Criteria

- Mothers at day 3 to 5 post-delivery with no postpartum bleeding.
- Mothers with live babies between 32- 34weeks of gestational age.
- Non-smokers, non-alcoholics, non-diabetics.
- Healthy with no symptoms of malnutrition or chronic diseases, not taking any medication on regular basis, or have no medical conditions or complications during previous pregnancies or deliveries.
- Mothers who express exclusively with a minimum of eight times in 24 hour.

Exclusion Criteria

- Mothers taking anti-coagulant, anti-hypertensive, and related drugs.
- Mothers with bleeding.
- Mothers with a history of thyroid abnormality (hyper or hypothyroidism).
- Mothers with pea or bean allergic reaction (works only for experimental group).
- Breast-feeding mothers (mothers who feed breast milk directly from breast).
- Mothers with inverted nipple.

Experimental Procedures

Preparation and Administration of Fenugreek Seed Powder Water

Extract

Crude fenugreek seed was bought from market then washed, slightly roasted, and grinded. The powdered fenugreek seed was used as a stock. Pilot study on a total of nine volunteer mothers was performed before the experimental process. These mothers were divided in to three groups and given 6, 8, and 10 gram of fenugreek seed solution. Due to minor gastrointestinal discomfort that was observed in mothers taking 8 and 10 gram of the seed, in our study we selected 6 gram

as a safe dose to augment breast milk volume. For administration of each dose, 6gram (equivalent to one tea spoon) of fenugreek seed powder was soaked in one-liter water for 12 hours to decrease anti-

nutrients and bitterness. After 12 hours the water was discarded and the remaining water extract jelly soup was blended with one teaspoon of sugar. The blended soup was given as a single dose of fenugreek 3 times a day for five consecutive days.

Measuring Expressed Breast Milk Volume

Day one of the experimental study began by collecting 24hr hand expressed milk from all participants as a baseline volume measurement. Then the participants were randomly classified into case and control group to further record their expressed milk for 5days. Those in experimental group planned to receive a dose of 6gm-powdered fenugreek 3 times a day (18 gm/day) for 5 days. Breast milk expression was done using hand every 3hours in 24-hour period for a duration of 20 minutes for both experimental and control group. The Marmet technique of manual milk expression (Marmet, 2000) demonstrated for all study participants to be used in the hand expression of breast milk. Sequential breast expression was used; one breast expressed and emptied then the other breast follows. There was no sequential preference between the left and the right breast. It was possible for a participant mother to start hand expression from the left or right breast but not the two breasts simultaneously. During hand expression all study participants were instructed to empty their breast as much as possible by checking the last drops of hind milk to ensure the breast is emptied for a given expression session. Uniform techniques of measuring and recording the expressed breast milk volume were followed throughout the experimental study period.

Study Variables

Expressed breast milk volume among mothers of preterm infants is the central theme to be investigated in the study. Hence, the following study variables are included in the study:-

- -Dependent variable: Expressed breast milk volume
- Independent Variables: There are a number of factors that affect the / dependent variable/ volume of expressed breast milk volume from literature. Therefore, the following variables are labeled as independent variables that potentially influence volume of expressed breast milk:
 1. Administration of fenugreek seed for five consecutive days.
 2. Sex of the neonate whose mothers are participants of the study.
 3. Number of baby delivered in the current delivery.
- Controlled Variables: Gestational age of the neonates (32-34wks)

Ethical Considerations

This study was conducted after approved for ethical issues by the departmental research committees (DRC) of physiology and pediatrics. Written and verbal informed consent was obtained from mothers, who were willing to participate in the study. Confidentiality and anonymity of the subjects were maintained by coding throughout the experimental procedure.

Data Quality Assurance

Quality of the data was assessed prior to analysis. During data entry to Microsoft Excel, the data was inspected for missing, unrecorded and abnormal data. Frequency for each variable was run to check errors with respect to each identity code for every participant. Finally, whether a measurement is normally distributed or not, was checked to decide the correct test in analysis.

Data Analysis Procedures

Statistical Package for Social Science (SPSS) version 20 was used to analyze data that was arranged and organized by Microsoft Excel 2007. Descriptive statistics was used to describe percentage distribution of study participant mothers by selected personal and obstetric characteristics. Independent sample t-test was used to compare the mean expressed breast milk volume experimental and

control group, in mothers with male and female neonates, and with singleton and multiple deliveries. Paired sample t-test was used to compare expressed milk volume before and after taking fenugreek seed in the case group.

Results

A total of 88 mothers of preterm infants in two groups (44 in experimental group and 44 in controls) who express eight or more times in 24hour period were included in this study. 82 (93%) of the participants were able to complete this experimental study for a period of six days. The remaining six mothers (7%) (3 from experimental and 3 from control groups) did not complete the study for reasons that were not related to the study outcome: two mothers in the experimental group withdrew because of sickness of their baby, two mothers from the control group withdrew because of death of their neonates, one mother from the experimental group and one from the control group were discharged from the hospital in the middle of the study time.

Characteristics of the Study Participants

The age, marital status and obstetrics characteristics of the study participants are shown in Table 1. The average age of the study participants ranges from 20 to 43 years. Their mean age was 30 years. Majority of the study participants 48(59%) aged between 20 and 31 years. Ninety five percent of the participants were married and the rest were separated (4%) and widowed (1%).

Obstetric Characteristics of the Study Participants

As shown in Table 1 among the 82 (93%) study participants; one mother had triplet, 11(13%) had twins, and 70(85%) had singleton neonates, 25 male and 45 female neonates. Among the 82 participants 45 (55%) were first time mothers for the current delivery (Primiparous), 22 (27%) and 9 (11%) mothers had one and two previous deliveries respectively. The remaining 6 mothers were with previous delivery of 3 and above number of children.

Table 1: percentage distribution of study participants by selected personal and obstetrics characteristics

Variables	Number	Percentage
Age (in completed years)		
• 20 – 31	48	59
• 32 – 43	34	41
Marital status		
• Married	78	95
• Widowed	1	4
• Separated	3	1
Parity		
• Primiparous	45	55
• Para one	22	27
• Para two	9	11
• Para three and above	6	7
Sex of the neonate (singleton)		
• Male	25	36
• Female	45	64
Number of babies delivered (With current delivery)		
• Singleton	70	85
• Twin	11	13
• Triplet	1	2

Baseline Expressed Breast Milk Volume

The baseline expressed milk volume was measured in both groups for a period of 24 hour before administering fenugreek seed to the experimental group. Table 2 shows the mean value in the two groups before administration of fenugreek to the case (experimental) group. The value .590 is not statistically significant so the null hypothesis (which states that there is no difference between the volumes of baseline expressed breast milk volume between the two groups) will not be rejected.

Table 2. Baseline Expressed Breast Milk Volume In Experimental and Control Groups Before Fenugreek Seed Administration (Independent Samplest Test).

	Group	N	Mean ±SE	95% confidence Interval		P value
				Lower	Upper	
Expressed breast milk Volume (ml/24hrs)	Experimental group (before fenugreek seed administration)	41	189 ±13	-32.2	56.2	.590
	Control group	41	177 ±18			

Comparison of Expressed Breast Milk Volume between Experimental and Control Group

The mean values of expressed milk volume for each of the five days between the groups are shown in Table 3. As shown in this Table there was statistically significant difference in expressed milk volume between the two groups in each of the five days of follow up. These results proved the alternate hypothesis, which states that there is a difference in mothers, expressed breast milk volume between the case and control groups. The change in milk volume between experimental and control group started from day1 but the greater difference was observed from day 3 to 5.

Table 3. Expressed Breast Milk Volumes For Experimental and Control Groups (Independent Samplest Test).

	Group	N	Mean	Mean Difference (Case Control)	Mean ± SE	P value
Expressed milk volume (ml)at 1st day after grouping	Case	41	249	62	249 ± 15	.002*
	Control	41	187		187 ± 13	
Expressed milk volume (ml) at 2nd day after grouping	case	41	298	82	298 ± 19	.001*
	control	41	216		216 ± 16	
Expressed milk volume (ml)at 3rd day after grouping	Case	41	342	109	342 ± 19	.0001*
	control	41	233		233 ± 16	
Expressed milk volume (ml) at 4th day after grouping	Case	41	399	155	399 ± 20	.0001*
	Control	41	244		244 ± 19	
Expressed milk volume (ml)at 5th day after grouping	Case	41	383	126	383 ± 20	.0001*
	Control	41	257		257 ± 18	
Total		82				

Discussion

Fenugreek is the most widely used herbal galactagogue in the world (ABM, 2011). However, there are no studies done in Ethiopia to evaluate the galactagogue effect of fenugreek seed in any mothers as well as in mothers of preterm infants. The result of the current study provided evidence for the efficacy of fenugreek seed in augmenting expressed breast milk volume in mothers of preterm infants. The results were not biased by the frequency and hours of milk expression because milk expression process was carried out for complete 24-hour periods with every 3hr interval. Other potentially confounding factors such as food and variation due to individual difference were matched by one to one ratio of individuals in both experimental and control group throughout the experimental process. Furthermore, the gestational age of the infant were pre-determined to minimize unintended outcome. Pilot study was done to establish 6 gram of fenugreek seed powder as safe dose to augment breast milk volume. After the participant mothers were got trained for hand milk expression by the data collectors, the mothers expressed their breast milk effectively, and the measured milk (ml) registered on the check list. The baseline milk volume, initial expressed milk volume measured for all study participants 24 hour prior to the seed administration was found to be 183 ±16 ml/24hr. There were no statistically significant difference in

expressed milk volume between the experimental and control group before the five experimental days.

However, comparison of expressed breast milk volume between experimental and control group following administration of the fenugreek seed powder showed statistically significant difference. That is, administration of fenugreek seed powder three times a day for five consecutive days showed a significant increase in milk volume. The difference in milk volume started from day 1 but the greater difference was observed from day 3 to 5. This difference in milk volume may be due to the cumulative effect of the seed. The mechanism of how fenugreek seed augment breast milk is unknown; 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 (Mortel and Mehta, 2013). It has also been suggested that fenugreek may have estrogenic activity. 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. pS2 is frequently used as a marker for assessing the estrogenicity of a compound (Sreeja *et al.*, 2010).

Our study further investigated potential obstetric factors for the difference in breast milk volume by using baseline expressed milk volume before administration of fenugreek seed. In seventy mothers with singleton neonates, sex of the neonate was found to be one of the potential obstetric factors affecting breast milk volume significantly. Expressed breast milk volume in mothers of male neonates (207 ± 20 ml/24hr) was significantly higher than that produced by mothers of female neonates (150 ± 12 ml/24hr). The justification for greater milk production in mothers of male preterm infants could favor fetal survival, and protective outcome adapted from evolution.

Our study also found the average amount of milk produced by the mothers of twins (260 ± 36 ml/24hr) to be significantly higher than that produced by mothers of singletons (170 ± 11 ml/24hr). It has been reported that mothers of twins consistently released twice the volume of milk as compared to mothers of singletons. Thus, both the volume and the content of breast milk can be adequate to feed multiples (Flidel-Rimon and Shinwell, 2006).

Generally, the results of this study showed that mothers of preterm infants (born less than 34 weeks of gestational age) at TASH NICU had very low expressed breast milk volume. Administration of 6gm fenugreek seed powder water extract to mothers of preterm infants for five consecutive days showed a significant increase in breast milk volume. There was no complication observed in association with the administration of 6gm fenugreek seed.

In conclusion, fenugreek seed can be considered as a routine postnatal supplement to mothers of preterm infants, and to other breastfeeding mothers who are fit to take the herb. However, caution should be taken for safe dose while advising mothers to take fenugreek. It should also be noted that assessing and quantifying the milk volume of mothers of preterm infants would help to identify whether the milk is sufficient or low to feed their neonates.

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