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A randomized trial of peppermint gel, lanolin ointment, and placebo gel to prevent nipple crack in primiparous breastfeeding women

Authors' Contribution:
A Study Design
B Data Collection
C Statistical Analysis
D Data Interpretation
E Manuscript Preparation
F Literature Search
G Funds Collection

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Summary

Background: Sore nipples are common during lactation and remain the major reason for failing to establish successful breastfeeding. To formulate a peppermint gel and to evaluate its effect on the prevention of nipple crack associated with breast-feeding, a randomized double-blinded clinical trial comparing the above formulation with modified lanolin and a neutral ointment was carried out.

Material/Methods: Two hundred and sixteen primiparous participants were assigned randomly to three groups. Each group applied only one of the above three preparations on both breasts for 14 days. Each group consisted of 72 primiparous mothers and was seen for a maximum of four follow-up visits within 14 days and a final visit at week 6. The rate of nipple and areola crack and pain was evaluated.

Results: The study groups were comparable in mean age and route of delivery. Nipple crack were less in mothers who received peppermint gel than in those who received lanolin ointment or placebo (χ^2=16.8, *df*=6, *P*=0.01). Relative risk of nipple crack in the lanolin group (RR: 2.41, 95% *CI*: 1.20–3.01) was higher than in the peppermint group (RR: 1.85, 95% *CI*: 1.64–3.10).

Conclusions: Prophylactic peppermint gel in breastfeeding lactating women is associated with fewer nipple cracks and is more effective than lanolin and placebo. It could be recommended for preventing of nipple crack along with teaching better breastfeeding technique at the initiation of breastfeeding.

key words: **breastfeeding • nipple crack • peppermint gel**

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Background

It is a dream for most mothers to have comfort in breastfeeding, but sore nipples are still a common problem, and pain or cracks frequently occur after breastfeeding [1]. When the nipples are hurt, breastfeeding is in jeopardy. It is estimated that 80 to 90 percent of breastfeeding women experience some nipple soreness, with 26 percent progressing to cracking and extreme nipple pain [2,3]. Up to one third of the mothers who experience these symptoms may change to alternate methods of infant nutrition within the first six postnatal weeks [4,5]. However, very sore, cracked, blistered, or bleeding nipples are not normal [1]. Many risk factors may traumatize the nipples [6,7]. Several methods have been suggested to prevent nipple crack [8–13]. One of the agents used for the prevention of nipple crack and pain is lanolin. Tanchev et al. used purified lanolin and found it suitable for the prophylaxis and treatment of sore nipples [14]. In none of the published studies however, was any method completely efficacious, and the effectiveness of the many interventions used to prevent nipple pain or trauma in breastfeeding women was inadequate [15,16]. Unfortunately, many women delay seeking treatment until substantial damage has already occurred and sore nipples remain a frustrating clinical dilemma [17].

With the resurgence of interest in breastfeeding, there is increasing demand for natural remedies for the minor problems that accompany nursing. The efficacy of these remedies is insufficiently documented. Despite the large number of preparations found to be effective, there is still a continuous search for finding additional preparations with increasing specificity [17]. It is important to do something about nipple soreness before it gets worse and the nipples develop painful cracks. In a previous study, we found that simple, self-administered, natural remedies such as peppermint water are effective in the prevention of sore nipples [18]. Peppermint is a household remedy in Azarbayejan Province of Iran and is a method among the people to prevent nipple crack. This prompted us to design a trial to formulate a topical preparation of peppermint gel and to investigate its preventive effect on nipple crack in lactating primiparous women. In this study, a peppermint gel was formulated and its effects on the prevention of nipple crack associated with breast-feeding were compared with those of modified lanolin and placebo.

Material and Methods

A double-blinded, randomized study was carried out in a population of postpartum women who delivered from Sept. 2005 to Jan. 2006 at Talegani teaching hospital in Tabriz, East Azarbayejan Province, northwestern Iran, to compare the effect of three agents to prevent nipple crack. Only mothers with healthy term infants were included in the study. An initial interview was conducted during the postpartum stay. All candidates received comprehensive hospital breastfeeding education before the infant was at the breast. After taking the mother's history, the researcher carried out physical examination of the infant and of the mother's breasts and assessed the breast-feeding technique of all candidates. Mothers who were discharged before the interview or who had preterm delivery, postpartum fever, breast infection, nipple abnormalities, or were less than 18 years of age, had twins, took medications at night, did not have a telephone, or who were illiterate were excluded. In addition, infants who were fed infant formula or used a pacifier or who had mouth infection or an abnormally short frenulum were excluded. Equal numbers of women who had given birth vaginally and by cesarean section were included.

The participants were randomly divided into three groups to receive one of three preparations, i.e. purified lanolin, peppermint gel, and placebo gel, using a table of random numbers. The preparations were named as A, B, and C, as they were unknown to the researchers and the patients during the experimental process and the analysis of the results. The peppermint gel was formulated based on standard formulation methods. A brief description of the preparation of peppermint gel is outlined in the appendix. The same formulation without peppermint oil was prepared as the placebo. The new mother was instructed to rub the preparation on the nipples and areola after feeding the baby and wash it before the next feeding. Any refusals or loss to follow-up after recruitment were documented. A chart was produced to track the flow of participants through the trial. Demographic and peripartum information was abstracted from the labor and delivery records and filled into a form. Mothers were instructed not to wash nipples with soap.

Follow-up telephone interviews were conducted at days 4, 7, 10, 14, and 42 after delivery assessing the patients' perceptions regarding the use of the preparation and any nipple damage. All mothers were asked about the frequency and duration of breastfeeding over 24 hours. In the case of nipple or areola crack and pain, both examination of the breasts and the scoring were carried out by one researcher as described elsewhere [7,19]. A follow-up visit was arranged 8 and 15 days after recruitment or every time the mother showed sore nipples. All mothers were asked at week 6 about nipple crack and pain. A questionnaire was used for gathering the data. Each mother scored her own pain during breastfeeding. Rating scales were used to determine the levels of pain [19]. The physical examination was carried out based on the presence or absence of cracks within and beyond the areola. Cracks was expressed in millimeters using criteria as described by Amir et al. [7]. According to these criteria, nipple damage was defined based on the width of the damage as follows: 1–2 mm, mild; 3–9 mm, moderate; >10 mm, severe, with or without a visible yellow color in the crack. Areola damage was also assessed according to the same criteria. The severity of cracks and the presence or absence of pain at day 14 were used as the major outcomes for the evaluation of the mother's breast condition following the intervention.

The study was approved by the Tabriz University of Medical Sciences Research Committee. Permission was obtained from the university ethics committee and all participants were given adequate information and consent was obtained from each volunteer.

Sample size

The sample size of the study was determined according to references by the formula of

$$N = \frac{4\sigma^2 \left(Z_{1-\frac{\alpha}{2}} + Z_{1-\beta}\right)^2}{D^2}$$

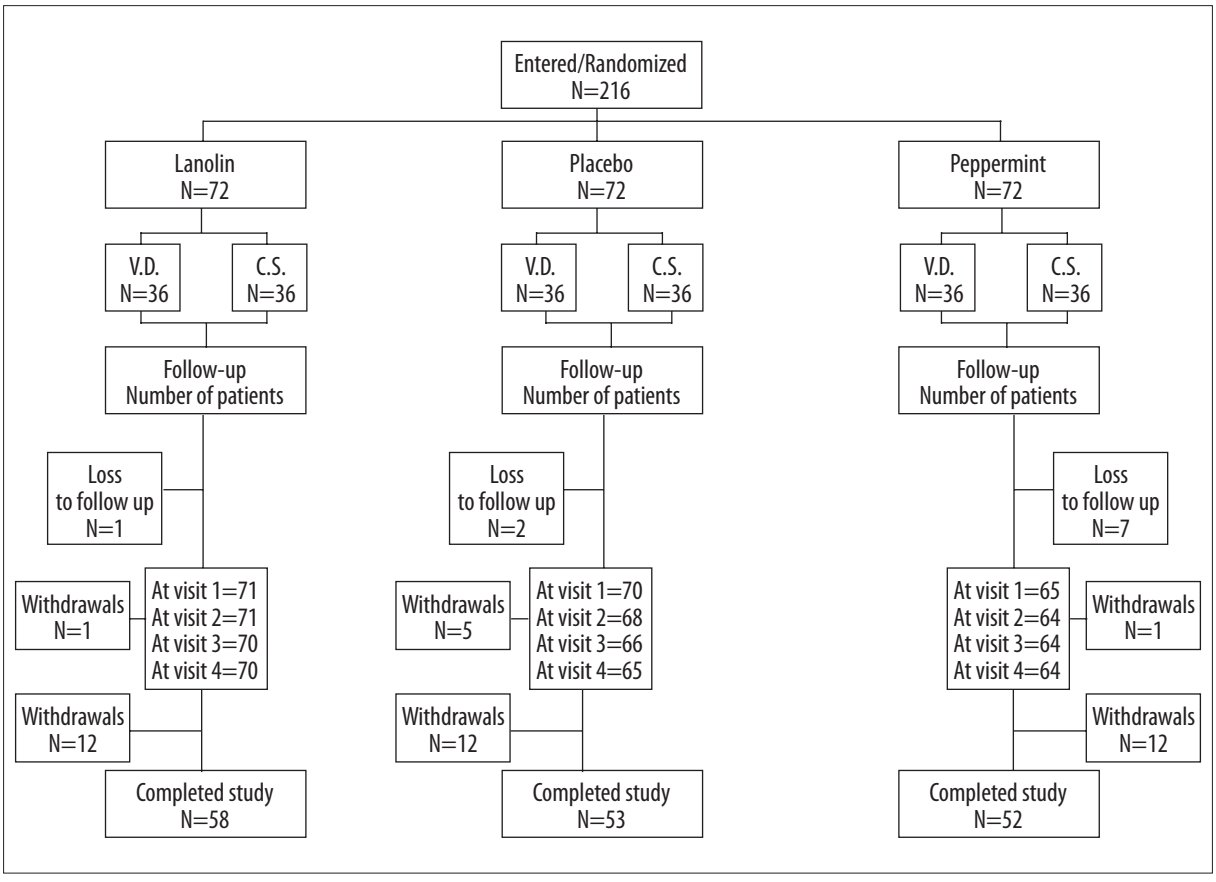

Figure 1. Flow of the patients in the study.

Table 1. Some characteristics of the breastfeeding mothers using lanoline ointment, peppermint gel, and placebo gel.

Variables	Lanolin (n=58)	Peppermint (n=52)	Placebo (n=53)	Statistic	*df*	*p* value**
Age (y)	25.05±51	24.33±4.15	25.15±5.7	F=0.46	(2.160)	0.63
Infants sex (%)						
Female	24 (41.4)	26 (50.0)	28 (52.8)	χ^2=1.59	2	0.45
Male	34 (58.6)	26 (50.0)	25 (47.2)			
Infant weight (kg)	3.20±0.33	3.18±0.35	3.21±0.30	F=0.07	(2.160)	0.92
Number of breastfeeding/24 hrs	9.08±0.79	9.21±0.93	9.12±0.94	F=0.28	(2.160)	0.75
Duration of breastfeeding (min/24 hrs)	16.09±2.72	16.62±2.43	16.66±2.63	F=0.84	(2.160)	0.43

* Differences were considered statistically significant at $p<0.05$;
** Data are given as the mean ±*SD*.

[20, 21]. This was used to estimate the sample size required for detecting significant differences in the different treatment groups using the nonparametric Kruskal-Wallis test. For estimating the total sample size, there was needed to perform an ANOVA test in the three different groups. Hence, the sample size was calculated and adjusted using the appropriate ARE (Asymptomatic Relative Efficacy) and then divided into three equal groups. The parameters used to calculate the sample size were: α=0.05, power=0.8, D=2.44, and ARE=0.864. Therefore, the total number of patients needed to conduct the study was calculated to be 216.

Staistical analysis

Statistical analysis was carried out using SPSS 14.0 for Windows statistical software. Values were given as the median (range) or means (*SD*). Kruskal-Wallis and one-way ANOVA tests were used to compare variables in the three groups. The difference between means and the chi-squared test (χ^2) were used for the assessment of association when appropriate. For all statistical analyses, differences were considered statistically significant at $p<0.05$.

Table 2. Comparison of the occurrence of cracked nipples from days 1-7 in women using lanolin ointment, peppermint gel, and placebo gel.

Day of nipple crack*	Group					
	Lanolin n=58	Peppermint n=52	Placebo n=53	χ^2	*df*	*p* value**
2	1 (1.7)	0 (0.0)	1 (1.9)			
3	2 (3.4)	0 (0.0)	4 (7.5)			
4	1 (1.7)	1 (1.9)	4 (7.5)			
5	0 (0.0)	0 (0.0)	2 (3.8)	14.68	10	0.14
6	0 (0.0)	1 (1.9)	1 (1.9)			
No crack	54 (93.1)	50 (96.2)	41 (77.4)			
Total	**58 (100.0)**	**52 (100.0)**	**53 (100.0)**			

* The results are expressed as the number of women followed by the percentage in parenthesis within groups;
** Differences were considered statistically significant at $p<0.05$.

Table 3. Comparison of nipple crack in the mothers using lanolin ointment, peppermint gel, and placebo gel.

Nipple crack*	Lanolin ointment	Peppermint	Placebo	Total number	χ^2	*df*	*p* value**
No crack	54 (93.1)	50 (96.2)	41 (77.4)	145 (89.0)			
Mild	2 (3.4)	2 (3.8)	3 (5.7)	7 (4.3)			
Moderate	2 (3.4)	0 (0.0)	3 (5.7)	5 (3.1)	16.80	6	0.01
Sever	0 (0.0)	0 (0.0)	6 (11.3)	6 (3.7)			
Total	**58 (100.0)**	**52 (100.0)**	**53 (100.0)**	**163 (100.0)**			

* The results are expressed as the number of women followed by the percentage in parenthesis;
** Differences were considered statistically significant at $p<0.05$

Table 4. Reports of nipple pain in women who received lanolin ointment, peppermint gel, and placebo gel at day 14.

Pain	Group					
	Lanolin	Peppermint	Placebo	χ^2	*df*	*p* value
(No pain)	20 (34.5)	22 (42.3)	23 (43.4)	1.10	2	0.57
(Mild)	38 (65.6)	30 (57.7)	30 (56.6)			

Results

Of the 216 participants, 163 were followed throughout the study. The CONSORT flow chart is illustrated in Figure 1. Ten women were unavailable for follow-up (one from the lanolin group, group A, seven from the peppermint group, group B, and two from the placebo group, group C). Seven women were withdrawn because of breast infection, one from group A, one from group B, and five women from group C. Thirty-six infants used a bottle and pacifier and were therefore withdrawn from the study, leaving 58 women in group A, 52 women in group B, and 53 in group C. Demographic characteristics were found to be similar in the three groups (Table 1). There were no significant differences in the reports of cracked nipples on

Table 5. Assessment of outcomes for the 163 women using lanolin ointment (n=58), peppermint gel (n=52), and placebo (n=53) and objective evidence of nipple cracks in the first two weeks as well as reported pain and breastfeeding at six weeks postpartum.

Clinical outcome	Lanolin (n)	Peppermint (n)	Placebo (n)
Intact nipples	54	50	41
Painless feeding	51	49	42
Full breastfeeding	52	49	41
Partial breastfeeding	6	3	12

Table 6. Composition in the formulations.

Formulation code	Carbopol 934 (%w/v)	Methyl paraben (%)	Propyl paraben (%)	Triethanolamine (%w/v)	Glycerine (ml)	Viscosity
F1	0.1	0.1	0.2	0.07	15	Very low
F2	0.5	0.1	0.2	0.34	15	Low
F3	1.0	0.1	0.2	0.67	15	Moderate
F4	1.5	0.1	0.2	1.32	15	High
F5	2.0	0.1	0.2	1.90	15	Very high

different days of using the three interventions at the first week (χ^2=14.68, *df*=10, *p*=0.144) (Table 2). The overall nipple crack rate in the three groups was 11% (6.9% in lanolin group, 3.8% in peppermint group, and 22.6% in placebo group), which was found to be significant (χ^2=16.80, *df*=6, *p*=0.01) (Table 3). There was no areola crack in the study groups. The results of the Kruskal-Wallis test showed that the mean differences between the groups with regard to the severity of nipple crack were significant (χ^2=10.99, *df*=2, *p*=0.004), with the peppermint and placebo groups having the lowest and highest rates of crack, respectively. There was a significant association with the use of peppermint gel. Relative risk of nipple crack in the lanolin group (RR: 2.41, 95% *CI*: 1.20–3.01) was higher than in the peppermint group (RR: 1.85, 95% *CI*: 1.64–3.10).

Some of the mothers reported mild degrees of pain during breastfeeding at follow-up (Table 4). No statistical difference was found between the groups (*p*=0.79). Mastitis developed in 2 of the 53 mothers treated with placebo compared with none of the mothers treated with modified lanolin or peppermint gel.

Assessment of the outcomes for the 163 women using lanolin ointment, peppermint gel, and placebo are presented at Table 5. At week six, most of the participants in all the groups continued to breastfeed, whereas 13% (n=6) of the mothers in the lanolin group, 5.6% (n=3) in the peppermint group, and 27% (n=12) in placebo group used infant formula in addition to breast milk.

Discussion

The health benefits of breastfeeding for mothers and infant are well-documented [8,11,17]. One of the major problems in lactating women at the beginning of breastfeeding is nipple crack, and this may represent an obstacle to successful breastfeeding, leading to a decrease in milk production [9]. Bearing in mind the health hazards associated with not breast feeding and the fact that sore nipples are not inevitable during the early days of breastfeeding [1,5], it is logical to create a healthy, flexible tissue very resistant to cracks. A number of reviews have examined the effect of various protocols for this issue [16,22,23], including the application of various oils [13,16], drugs [1,19,24], education [3,8,10,25], sprays [24], warm water [11], breast milk [26], and combinations of different methods [1,12,27]. However, there are some other reports with different and sometimes controversial results [9,13,18,28,29].

In the present study, the application of peppermint gel was found to be an effective method to prevent nipple crack. In addition, no areola crack was observed in the studied group. In our pervious study [18], the use of peppermint water was found to be three times more effective than expressed breast milk (EBM; 27% vs. 9%). The rate of nipple crack in the present study in mothers who used peppermint gel was 3.8%, which is relatively less than the value of 9% obtained in our pervious study for the rate of nipple crack in peppermint water users [18]. This may indicate that the use of peppermint water in combination with an oily base could have some beneficial effects in reducing nipple crack. Furthermore, no moderate or severe pain or areola crack were observed in the three groups in the present study, which may show the therapeutic effects of the formulations' ingredients on nipple pain and areola crack. Modified lanolin ointment, which has been used in several studies and has shown different results [1,24,26,27], was also used in this study and was less effective than the peppermint gel. In addition, placebo gel with only the basic formulation was less effective than both.

Peppermint (*Mentha piperita*), which is used as a popular flavoring for gum, toothpaste, and tea, has a calming and numbing effect and has been used to relieve skin irritations [30]. It also has an antiseptic effect and increases tissue flexibility, making it resistant to cracks [31].

Conclusions

The results showed that the formulated peppermint gel as a natural remedy is effective in the prevention of nipple crack. To our knowledge, this is the first study reporting the effect of the peppermint oil-containing dosage form on nipple and areola crack and pain. Based on the present findings, peppermint gel application could be suggested as a prophylaxis of nipple crack alongside proper instruction at the initiation of breastfeeding.

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APPENDIX

Preparation of peppermint oil gel

The composition of the peppermint oil gel formulations used in this study is shown in Table 6. The gels were prepared by dispersing various concentrations of carbopol 934 in water containing 0.2% propyl paraben and 0.1% methyl paraben as preservatives and 15 ml glycerine (as a humectant) for a period of 2 h. Peppermint oil (0.2 ml) was added gently to the carbopol dispersion under continuous stirring (200 rpm) to produce a concentration of 0.2% v/w. As carbopol 934 is a free acid and soluble in water up to 5% and forms a solution of fairly low viscosity with a pH of around 3, carbopol polymers must be neutralized in order to achieve maximum viscosity and a transparent gel. Upon neutralization with a base (this is easily achieved by neutralizing the carbopol polymer with a common base, such as sodium hydroxide or triethanolamine) a highly viscous gel is formed. Optimum neutralization is achieved at a pH of 6.5–7.0. To obtain acceptable viscosity (neither too runny nor very viscose) for a topical gel formulation, different concentrations of carbopol 934 were used. The results showed that the concentration of 1% carbopol 934 produced acceptable viscosity (medium viscosity). The same formulation without peppermint oil was prepared as the placebo.

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