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Comparison of the Effects of Lanolin, Peppermint, and Dexpanthenol Creams on Treatment of Traumatic Nipples in Breastfeeding Mothers

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ABSTRACT

Introduction: Traumatic nipple is among the most common problems of the breastfeeding period which leads to early cessation of breastfeeding. The study aimed to compare the effects of the lanolin, peppermint, and dexpanthenol creams on the treatment of traumatic nipples

Methods: This double-blind randomized controlled trial was carried out on 126 breastfeeding mothers. The mothers had visited at the health centers and children's hospitals in Sanandaj City. The selected participants were randomly divided into the following three groups of lanolin, peppermint, and dexpanthenol cream groups. Nipple pain was measured using the Store scale while trauma was measured with the Champion scale. Analyses were carried out through the Kruskal–Wallis test, Chi-square, ANOVA, and repeated measures ANOVA by using SPSS software ver. 13.

Results: The result showed that the mean score of nipple pain and nipple trauma at the prior to intervention stage, third, seventh, and fourteenth days of intervention was not significantly different between three groups. But, repeated measures ANOVA showed a significant difference in comparison of the four time periods of intervention in each group.

Conclusion: Results of this study revealed that the lanolin, peppermint, and dexpanthenol medicines had similar therapeutic effects on traumatic nipple.

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Introduction

Breastfeeding, especially Exclusive Breast-Feeding (EBF), is the ideal method for feeding and growth in the first 6 months of birth.[1] Breast milk not only reduces the risk of incidence of many acute and chronic diseases such as diarrhea and respiratory infections in breast-fed infants, but also it has numerous benefits to mothers (for example, the reduced risk of breast cancer, uterus cancer, ovarian cancer, and osteoporosis).[1,2]

Among all the possible problems arising during the breastfeeding period, breast conditions and those occurring in the early days of breastfeeding are most important.[3] Nipple problems include the development of macroscopic lesions that occurs on the nipples and areola. These lesions may appear as eroded skin, wounds, and fissure as well as clinical signs of erythema, edema,

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white or yellow blisters, dark spots, and ecchymosis.[3,4]

Traumatic nipples pose threats to mothers, infants and societies. The most common consequences of traumatic nipples include infants' deprivation of breast milk benefits and it may lead to stress and dissatisfaction in mothers. Studies indicate that problems occurring in the first days following birth may lead to the cessation of breastfeeding. Moreover, according to the statement issued by the World Health Organization (WHO), less than 40% of infants below 6 months of age are exclusively fed by breast milk.[5,6]

The incident of traumatic nipples varies between 29% and 76%, while nipple pain caused from breastfeeding varies between 34% and 96%.[7-9] Few studies have been carried out to study the treatments of traumatic nipples.[10] It is estimated that 80% to 90% of breastfeeding women experience mild nipple pain. If these pains remain untreated, 26% of nipple pains will develop into nipple fissure and severe pain.[11]

Unfortunately, treatment of traumatic nipple is complicated because of the repeated sucking by the infant, infections caused by the entrance of microorganisms through the nipple fissure, and constant exposure of nipple skin with the infant's oral flora.[12,13]

Treatment of traumatic nipple dates back to the seventeenth century, but there is no explicit statement on the most suitable topical treatment for traumatic nipples.[1] In this regard, complementary medicine, especially herbal medicine, plays a major role in improving the quality of postpartum care. Currently, 40% of common medicines are derived from plants and natural resources.[14]

Among the available treatments, lanolin improves traumatic nipples through giving moisture to the nipples. Lanolin penetrates to the skin and facilitates the absorption of medicines. This composition is capable of absorbing up to 30% of water.[15]

In 2008, Dennis indicated that the application of lanolin is effective for the treatment of sore nipples. He stated that lanolin along with teaching the correct breastfeeding technique is the best solution to the treatment of nipple fissure.[9] In contrast, Gartner showed that recovery of nipple fissure in the lanolin group took longer.[11] In another study, Dodd & Chalmens carried out a comparison between the effects of hydrogen dressing and lanolin on the treatment of traumatic nipples and showed that the hydrogen dressing group experienced a significant decrease in pain as compared to the lanolin group.[16] However, no significant difference was observed in wound healing between two groups.

Dexpanthenol is one of the skin healers which belongs to the family of B complex vitamins. This medicine functions as a moisturizer by reducing water loss through the epidermis and maintaining the softness and elasticity of the skin. Kusch indicated that dexpanthenol is effective in the prevention of nipple pain.[17] Peppermint herb which is a native plant to Iran, is widely used for the treatment of skin numbness, burns, scars, itching and inflammation.[8] In 2003, Ahluwalia made a comparison between the contributions of peppermint, lanolin, and teabag to the treatment of traumatic nipples and reported a significant decrease in pain and a significant increase in the nipple trauma healing of the peppermint group.They concluded that peppermint increases tissue flexibility and prevents fissure.[18]

In another study, Sayyah Melli showed that the administration of peppermint juice was three times more effective than breast milk in the prevention of nipple fissure. However, lanolin was less effective than peppermint.[12] In 2014, Akbari indicated that peppermint essence can improve nipple fissure in primiparous women.[19]

After a vast review of the existing literature, no study was found to have

confirmed the effects of dexpanthenol and peppermint on the treatment of traumatic nipple in Iran, as all of the studies in this country were conducted on the prevention of trauma.

Considering the high prevalence of traumatic nipple and its complications, the lack of any agreed treatment for traumatic nipples, and the necessity of early treatment of traumatic nipples with the lowest side effects, the present study was carried out to compare the effects of lanolin, peppermint, and dexpanthenol creams on the treatment of traumatic nipples

Materials and methods

This randomized controlled trial conducted to compare the effects of lanolin, peppermint, and dexpanthenol on the treatment of traumatic nipples in breastfeeding mothers.

The target population included the breastfeeding mothers who visited at the Abbas Abad and Farabi health centers and Sanandaj children's hospital in 2014. These centers were selected for this study because the number of breastfeeding mothers visiting these centers was high.

Based on the research by Ahluwalia et al.,[18] the sample size was calculated to be 35 for each group by confidence interval of 95% and statistical power of 80% and using the three-group comparison formula. Finally, by considering a sample loss of 20%, 42 women were selected in each group.

The research samples were all of the breastfeeding mothers, who visited at the children's hospital and health centers and who had no drug prohibitions. After obtaining the permission of the Ethics Committee and the research deputy of Tabriz Medical Sciences University, the samples were selected from breastfeeding mothers, who met the inclusion criteria and visited at the Abbas Abad and Farabi health centers and Sanandaj children's hospital.

After explaining the research and its method and objectives to the mothers, the written consent was obtained from all participants. Afterwards, the personal and social information forms were completed and midwifery histories of the subjects were recorded. The forms and records were completed based on the observation of the breastfeeding methods of the mothers using the Store and Champion scales. The samples were finally selected based on the following inclusion criteria: 1) primiparous mothers; 2) exclusive feeding with breast milk; 3) term infant; 4) infant with below two months of age; 5) obtaining the minimum score of 1 from the Store and Champion scales; 6) mothers free of any medical disorders; 7) lack of sensitivity of mothers to lanolin, peppermint, and dexpanthenol; 8) infant weight of 2500 to 4000 grams; and 11) lack of any nipple disorders (flat and depressed nipples). The exclusion criteria included the followings: 1) infants suffering from tongue and tooth disorders; 2) using pacifiers, bottles, and plastic nipples for infants; 3) history of maternal psychological disorders reported by mothers; and 4) mother or infant suffering from any nipple-irrelevant condition that lead to cessation of breastfeeding.

Consort guidelines were followed in this research. The samples were randomly assigned into the lanolin, peppermint and dexpanthenol groups. The allocation sequence was determined by a computer-generated randomization scheme with the block sizes of 3 and 6 and the allocation ratio 1:1:1. Then, the tubes were filled with 50 mL of lanolin, lanolin, or dexpanthenol by the Laboratory of Pharmaceutics of Tabriz School of Pharmacy. They were put in pockets and numbered by the research supervisor.

The lanolin tube contained pure lanolin without additives. The peppermint tube contained carbopol, methylparaben, triethanolamine, and glycerin along with

0.2% of peppermint oil, and the dexpanthenol tube contained 5% B complex analogue. Every woman entering the study received sealed, opaque pockets (of apparently similar sizes). Numbers ranging from 1 to 126 were printed on the pockets with identical uniform tubes. The pockets included three types of cream: lanolin cream, peppermint cream, and dexpanthenol cream. The subjects were randomly assigned into three groups receiving lanolin, peppermint, and dexpanthenol, and neither the researcher nor the subjects were aware of the assignment sequence and the position of each subject. That is to say, this study was a double blind trial.

The breastfeeding mothers were not allowed to use any other treatment method during the study period and they were asked to report any case of sedatives consumption during the study. The participants were asked to apply a thin layer of the cream to the traumatic nipple and its areola three times a day immediately after breastfeeding for two weeks. The participants had recontamination of hand washing with warm water and soap before applying the cream.

The information was collected through four steps (prior to intervention and on the third day, seventh day, and fourteenth day).

The participants, who were trained on completion of the Store and Champion scales in advance, completed the scales on the third, seventh, and fourteenth days and submitted them to the researcher on the fourteenth day (the appointment day). The researcher completed the forms at least once. In addition, a follow-up appointment was set for all of the participants one week after entering the research to record the intake of any sedatives or development of any complication caused by the treatment. The patients were given a cell phone number to be able to call and ask any questions related to the disease during the daytime until 12 AM. The data collection instrument consisted of three parts.

The first part questioned the demographic and social information and the maternal history of subjects. This questionnaire covered information such as the patient age, marriage age, marital status, education, profession, residence location, midwifery information (including the number of pregnancies, number of delivery, number of living children), history of medical surgeries and history of breastfeeding (number of infants, duration of breastfeeding period, sedatives received for breastfeeding pains, treatment effect, breastfeeding status, and breast care during pregnancy, following birth and during breastfeeding). The positive response (Yes) was assigned the 1 score while the negative response (No) was assigned the 0 score. The questionnaire was completed through interviews before the intervention. The second instrument which used to collect data was the Storre scale. This scale was designed to measure nipple pain. The breastfeeding mothers measured their pain using this scale and its numerical scale. Score 0 was assigned to no pain and score 5 (the maximum score) was assigned to the highest level of pain.[20] The third instrument for data collection was the Champion scale. This scale was designed to identify and rank nipple trauma. It is also used to assess the recovery of wound depth and the extent of damage caused to the tissue. The breastfeeding mothers used this scale and its numerical scale to assess the extent of nipple trauma and its recovery.[18]

Lack of trauma was assigned the 0 score and larger numbers were recorded for deeper traumas. The scale ended with the maximum score (being 5).[9] Champion scale (NTS) to assess Trauma healing of the nipple. This tool has been used in various studies inside and outside the country, and its validity have been confirmed by Champion.[18] Storr scale (NSRS) to assess soreness healing of the nipple. This tool has

been used in various studies inside and outside the country, and its validity have been confirmed by Storr.[20] The reliability of the Store and Champion scales was measured using the test-retest method (r>0.7).[18] The data was analyzed using SPSS software ver.13 and the following test methods: test-retest method, Kruskal–Wallis method, Chi-square test, ANOVA, and repeated measures ANOVA. The significance level was assumed to be P<0.05.

Results

In this clinical trial, 150 breastfeeding mothers were assessed were assessed for eligibility and finally 126 mothers were included in the research (Figure 1).

Results of this study revealed that the three study groups were similar in demographic, social, and fertility properties. The mean (SD) age of study samples in the lanolin, peppermint, and dexpanthenol groups was 27.7 years (8.6), 27 years (6.1), and 27.2 years (5.9), respectively. The mean (SD) marriage age was 19.8 years (4.4), 20.4 years (3.5), and 21.6 years (4.2) for the lanolin, peppermint, and dexpanthenol groups, respectively. Table 1 shows and compares the demographic data between three groups.

More than half of mothers in the three groups had delivered once, and only in the dexpanthenol group 3 mothers (7.8%) had a history of four deliveries or more. Most mothers in the three groups had just delivered their first infants and most of the mothers had an experience of natural childbirth. Only 8 (20%), 4 (9.5%), and 7 (16.7%) patients in the lanolin, peppermint,

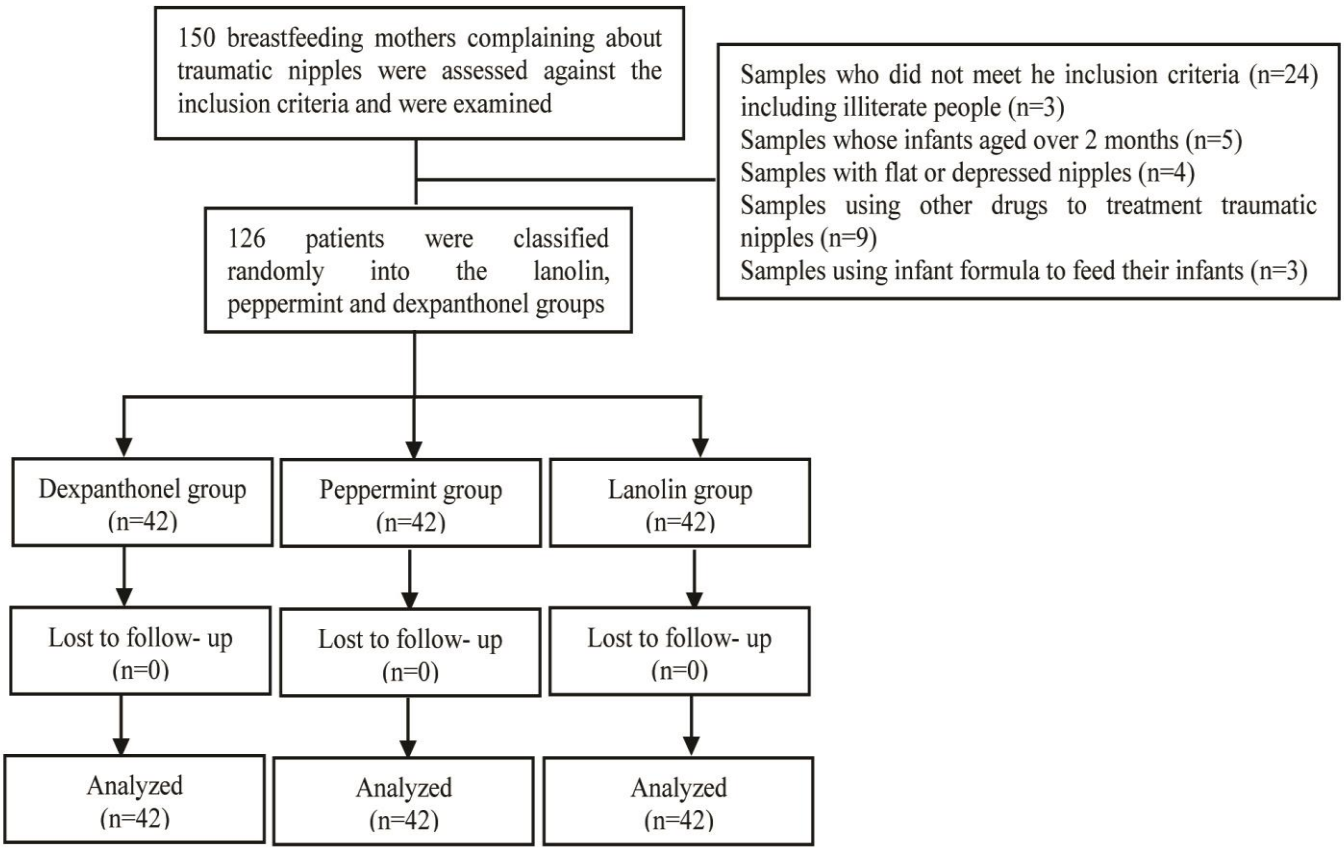

Figure 1. Consort flow diagram

The mean (SD) score of nipple pain in the lanolin, peppermint, and dexpanthenol groups prior to intervention was 3.12 (0.93), 3.07 (1.02), and 3.07 (1.02), respectively. The mean (SD) score of nipple pain on the third day of intervention was 1.29 (0.60), 1.26 (0.54), and 1.33 (0.65) for the lanolin, peppermint, and dexpanthenol groups, respectively. The mean (SD) nipple pain on the seventh day of intervention was 0.24 (0.49), 0.21 (0.47), and 0.14 (0.42) for the lanolin, peppermint, and dexpanthenol and dexpanthenol groups had a history of cesarean section. Most mothers in the three groups had no history of previous surgeries and only one participant in the dexpanthenol group (2.6%) had surgery history (Table 1).
groups, respectively. More than 80% of mothers entered the painless phase on the seventh day of intervention. The number of mothers who entered the aforementioned stage was 32 (78%), 33 (80.5%), and 37 (88.1%) in the lanolin, peppermint, and dexpanthenol groups, respectively. On the fourteenth day of intervention 100% of mothers in three groups entered the painless phase.

The result showed that the mean score of nipple pain at the prior to intervention stage, third, seventh, and fourteenth days of intervention was not significantly different between three group (P>0.05). But, repeated measures ANOVA showed a significant difference in comparison of the three time periods of intervention in each group (P<0.001) (Table 2).

The mean (SD) nipple trauma score prior to invention was 3.41 (0.89), 3.38 (0.89), and 3.36 (1.10) for the lanolin, peppermint, and dexpanthenol groups, respectively. One patient (2.4%) in the peppermint group and 4 patients in the lanolin and dexpanthenol groups (9.5%) experienced the worst nipple trauma conditions. The mean (SD) nipple trauma score on the third day of intervention was 2.00 (0.67), 2.09 (0.73), and 1.88 (0.77) for the lanolin, peppermint and dexpanthenol groups, respectively. One patient in the lanolin group (2.4%) and 2 patients in the dexpanthenol group (4.8%) entered the phase with no skin changes. The mean (SD) nipple trauma score on the seventh day of intervention was 0.22 (0.52), 0.19 (0.46), and 0.19 (0.50) for the lanolin, peppermint, and dexpanthenol groups, respectively. More than 80% of mothers entered the phase with no skin changes on the seventh day of intervention. The number of mothers entering the aforementioned stage was 34 (82.9), 34 (82.9%), and 36 (85.7%) in the lanolin, peppermint and dexpanthenol groups, respectively. On the fourteenth day of intervention 100% of mothers in the three groups showed no skin changes. No significantly statistical difference was found between nipple pain score in the three groups on the third, seventh, and fourteenth days of observation and on the start day (P>0.05) (Table 3).

However, the results of repeated measures ANOVA indicated a significant decrease in each group the comparison of the three phases (P<0.001) (Table 3).

In the research procedure all of the three groups were asked to first apply the cream to their forearms and administer the drug if no sign of sensitivity to the drug was observed after 24 hours. The patients showed sensitivity to none of the three drugs. No infant reaction was also observed in the three groups to nipples coated with the aforementioned creams. That is to say, the infants easily started and continued drinking breast milk. Therefore, no difference was made to the breastfeeding procedure and no complication was observed. There was also no statistically significant difference between the groups in terms of side effects when taking creams.

Discussion

Research results revealed the equivalent effects of the 0.2% peppermint, lanolin, and

Table 1. Comparison of social-personal and obstetric profiles of patients in the lanolin, peppermint and dexpanthenol groups

Personal information	Lanolin	Peppermint	Dexpanthenol	P
Age (years)				
15-29	28 (68.3)	30 (73.2)	30 (0.61)	0.505*
30-39	14 (31.7)	12 (26.8)	11 (36.6)	
≥ 40	-	0 (0)	1 (2.4)	
Mean (SD)	27.7 (8.6)	27 (6.1)	27.2 (5.9)	0.974†
First marriage age				
< 25	36 (85.7)	38 (90.2)	32 (76.2)	0.334*
≥ 25	6 (14.3)	4 (9.8)	10 (23.8)	
Mean (SD)	19.8 (4.4)	20.4 (3.5)	21.6 (4.2)	0.226†
Education				
Primary school	8 (19)	13(29.2)	16 (37.5)	
Secondary school	8 (19)	4 (9.8)	5 (12.5)	0.207§
High school	13 (31)	10 (24.4)	10 (22.5)	
University	13 (31)	15 (36.6)	11 (27.5)	
Mother's job				
Housewife	39 (94.7)	42 (100)	36 (92.3)	0.232*
Employed	3 (5.3)	-	6 (7.7)	
Family income				
Equal income and expenses	34 (81)	34 (81)	33 (78.6)	0.732*
Income higher than expenses	8 (19)	8 (19)	8 (19)	
Income lower than expenses	-	-	1 (2.4)	
Infant gender				
Female	22 (52.4)	20 (47.6)	20 (44.6)	0.671*
Male	20 (47.6)	22 (52.4)	22 (55.4)	
Number of pregnancies				
1	28 (66.7)	24 (57.1)	21 (50)	0.180*
2	6 (14.3)	11 (26.2)	11 (26.2)	
3≥	8 (19)	7 (16.7)	10(23.8)	
Number of deliveries				
1	28(65.9)	29 (68.3)	18 (47.4)	0.048*
2	8 (19.5)	12 (29.3)	12 (26.3)	
3≥	6 (14.6)	1 (2.4)	12 (26.3)	
Number of children				
1	30 (65)	28 (70)	22 (58.3)	0.251*
2≥	12 (35)	14 (30)	20 (41.7)	
Mode of delivery				
Natural	32 (80)	38 (90.5)	35 (83.3)	0.200*
C-section	10 (20)	4 (9.5)	7 (16.7)	
History of surgery				
Yes	9 (17.6)	4 (7.5)	1 (2.6)	0.055*
No	33 (82.4)	38 (92.5)	41 (97.4)	

All of the figures, except for the specified figures, are expressed as frequency (%).*Chi-square test; †One-way analysis of variance (ANOVA), § two-tailed Chi square test

Table 2. Comparison of mean (SD) score of pain in four time periods for the lanolin, peppermint, and dexpanthenol groups

Groups	Prior to intervention	3rd day	7th day	14th day	P†
Lanolin	3.12(093)	1.29 (0.60)	0.24 (0.49)	0	< 0.001
Peppermint	3.05 (1.02)	1.26 (0.54)	0.22 (0.47)	0	< 0.001
Dexpanthenol	3.07 (1.02)	1.33 (065)	0.14 (0.42)	0	< 0.001
P*	0.861	0.861	0.589		

†ANOVA with Repeated Measure, *ANOVA

Table 3. Comparison of trauma score in four time periods in the lanolin, peppermint and dexpanthenol groups

Groups	Before treatment	3rd day	7th day	14th day	P†
Lanolin	3.41 (0.89)	2.00 (0.52)	0.22 (0.52)	0	< 0.001
Peppermint	3.36 (0.89)	2.09 (0.73)	0.19 (0.46)	0	< 0.001
Dexpanthenol	3.36 (1.10)	1.88 (0.77)	0.19 (0.50)	0	< 0.001
P*	0.920	0.4	0.954		

†ANOVA with Repeated Measure, *ANOVA

dexpanthenol creams on the treatment of nipple pain and trauma. A thin layer of these creams was administered every 8 hours for two weeks. In the present study, according to the Store scale, the pain of participants in the lanolin group declined by 0%, 78%, and 100% on the third, seventh, and fourteenth days of intervention, respectively. Moreover, 2.4%, 80.5%, and 100% of reduction were observed in the peppermint group in the aforementioned days and 2.4%, 88.1%, and 100% of decline were observed in the dexpanthenol group, respectively. The results of the research by Dennis et al., were in line with the results of our study regarding the effectiveness of lanolin.[9] In the study by Abou-Dakn et al., 80% decline was observed on the seventh day and full recovery was obtained on the fourteenth day.[10] These findings are also consistent with our findings, but in their research the effect of peppermint water on the treatment of nipple pain was reported to be more than lanolin cream. Therefore, their study does not comply with our study in general and the difference in the results was resulted from the fully uniform intervention in our study. Moreover, in their research the groups were not equally exposed to intervention, because 100 patients in the lanolin group, 50 patients in the teabag group, and 50 patients in the peppermint group were undergone the intervention.

In the present study, according to the Champion scale, similar levels of improvement in term of nipple trauma resulted from administration of the peppermint, lanolin and dexpanthenol creams. In a study conducted by KuScu et al., the results of using dexpanthenol for the treatment and recovery of trauma were similar to our results. That is to say, dexpanthenol contributes to the healing of skin wounds through epithelialization and granulation. It also leads to wound improvement by storing water through the epidermis.[17] In the research by Dennis et al., the patients were mainly complaining about pain and 78% and 71% of pain declines were observed in the multipurpose ointment and lanolin groups on the seventh day of treatment, respectively.[9]

The results of their study are consistent with our study regarding the decreased pain symptoms. Vieira et al., conducted a systematic review and concluded that administration of lanolin with or without breast milk was the most effective intervention for the treatment of traumatic nipples as compared with other the

treatments such as breast milk, hydrogel, adhesive polyethylene film dressings, a spray containing chlorhexidine with alcohol, and distilled water.[21] In the other study by Mohammadzadeh et al., the duration of trauma recovery in the lanolin group was higher than the breast milk and control groups. Their study was not in line with our research. The reason for the difference between our results and the above research was the limitations that were found on this research.[22]

For example, no scale was used to determine the scores for nipple trauma andthe ranking was carried out under the supervision of a researcher, who was aware of the study groups. Therefore, nipple trauma was assessed with more precision in our study.

One of the advantages of this study was the innovation in using 0.2% peppermint essence in the form of cream for the treatment of traumatic nipples. Moreover, the recovery of patients on the 3rd, 7th, and 14th days of treatment was also followed.

Since no pre-term and abnormal infants were included in the study, the research findings cannot be generalized to these infants. Moreover, this research was not carried out in medical centers of villages, and other cities. Therefore, the trainings, the program resulted from the native specifications of Sanandaj City, and its results may not be applicable to other areas and cities of Iran.

The following recommendations are provided for future studies in this field.

1. Since few studies have been conducted in Iran and the world on traumatic nipple treatment, it is recommended to carry out further studies on this topic. Moreover, Iranian studies have solely focused on prevention of trauma.
2. It is recommended to conduct studies on the possible maternal and neonatal side effects of substances used for traumatic nipple treatment.

Conclusion

The contribution of peppermint to the treatment of traumatic nipples is similar to that of lanolin and dexpanthenol. Therefore, peppermint could be considered as an effective alternative to the treatment of traumatic nipples in patients willing to use herbal medicines.

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Ethical issues

None to be declared.

Conflict of interest

The authors declare no conflict of interest in this study.

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