



The Effect of Lanolin Cream on Treatment of Traumatic Nipples in Breastfeeding Mothers: A Randomized Control Trial

Mahnaz Shahnazi¹ , Shakiba Pourasad Shahrak² , Fereshteh Fartash³ , Azizeh Fashbaf Khalili⁴ , Kazhal Masoudin^{5,*}

¹ Assistant Professor, Department of Midwifery, Nursing and Midwifery Faculty, Tabriz University of Medical Sciences, Tabriz, Iran

² PhD Candidate, Department of Midwifery and Reproductive Health, School of Nursing and Midwifery, Tehran University of Medical Sciences, Tehran, Iran

³ Lecturer, Department of Midwifery, Nursing and Midwifery Faculty, Tabriz University of Medical Sciences, Tabriz, Iran

⁴ Assistant Professor, Department of Midwifery, Nursing and Midwifery Faculty, Aging and physical Medicine research center, Tabriz University of Medical Sciences, Tabriz, Iran

⁵ MSC in Midwifery, Department of Midwifery, Nursing and Midwifery Faculty, Tabriz University of Medical Sciences, Tabriz, Iran

*Corresponding author: Kazhal Masoudin, MSC in Midwifery, Department of Midwifery, Nursing and Midwifery Faculty, Tabriz University of Medical Sciences, Tabriz, Iran. E-mail: K_masoudin@yahoo.com

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Abstract

Introduction: Nipple problems are the most important reason for early cessation of breastfeeding among mothers. Considering the high prevalence of nipple problems, the present study aimed at evaluating the effect of lanolin cream on the treatment of traumatic nipples.

Methods: This double-blind randomized controlled trial was carried out on 80 breastfeeding mothers that attend health centers and the children hospital of Sanandaj-Iran. The participants were randomly divided into two groups (lanolin and control). The control group receives all supports of the intervention group but their cream contains colorless and odorless, Gelatinous. Nipple pain and trauma were measured using Storr and Champion scale. Analyses were carried out through the Chi-square, Wilcoxon signed-rank test, and U-Mann Whitney by using SPSS software version 13.

Results: There were no significant differences in pain and trauma score before intervention in lanolin and control groups which were ($P = 0.336$) and ($P = 0.21$), respectively; but, the results of the study demonstrated that the mean score of pain and trauma in the third, seventh and fourteenth days of study in lanolin group was decreased ($P < 0.001$). In intragroup comparison, there was a significant difference among the mean pain and trauma scores the four times in the lanolin group.

Conclusions: According to the results of the study, lanolin cream is an effective, simple, and non-invasive technique with no side effects for prevention and treatment in nipple fissures and pain.

INTRODUCTION

Breastfeeding is the most basic action for meeting the infant's nutrition necessities [1]. Breast milk has

developmental, social, economic, and health benefits for both mothers and Babies [2], including prevention of

obesity, diabetes, and asthma for children, and early weight loss and prevention of endometrial cancer for mothers; it is a way to partially control birth, too [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 fissures as well as clinical signs of erythema, edema, white or yellow blisters, dark spots, and ecchymosis [4]. Traumatic nipples related to breastfeeding are a common problem with an incidence of 29 to 76% that may lead to premature weaning [5]. It is estimated that the prevalence of nipple pain arising from breastfeeding is between 34% to 96% [6]. Therefore, the treatment and prevention of these problems are very important. Awareness of risk factors enable health providers to assist mothers with breast difficulties, and a history of withdrawal or inexperience in breastfeeding and help them to have successful breastfeeding especially in the first days of their infant life [7].

For treatment and control of nipple problems, traditional therapies along with medical treatments is recommended [8]. In a systematic review was done by Niazi et al. (2010), researchers evaluated the effect of menthol, hot water compress, and taught the ideal breastfeeding methods to prevent and treat nipple pain or fissure [9]. In a systematic review (2005) on the prevention and treatment of nipple pain and trauma, the authors assessed the effect of pads of warm water, compresses of tea bag, warmth, applying the mother milk as well as dexpanthenol, lanolin, vitamin A, collagenase, hydrogel, glycerin, humid occlusive covering, education about ideal latch-on, wright position of breastfeeding and no treatment, finally, they reported that none of the employed methods was superior to others; they mentioned that the important factor to prevent nipple sore was the education of ideal breastfeeding position [10].

One of the traditional treatments is lanolin. There is evidence that Lanolin with retaining moisture to the skin can lead to the repair of sore nipples [11]. Lanolin is a yellow wax that is reserved from the fatty glands of animal wool [12]. Purified lanolin protects the natural moisture of the nipple and prevents dryness and fissure, so it relieves nipple pain [13].

In research was done by Pereira (2008), the authors showed that lanolin along with education of correct breastfeeding position is the most effective method in the treatment of traumatic and painful nipples [14]. While in research was carried out by Mohammadzadeh (2005), they revealed that the duration of nipple healing in the lanolin group was longer [13].

Treatment of sore nipples is difficult because of the repeated sucking of the breast by infants. Continues sucking not only enter the microorganism to the fissure of nipple's skin but also, nipple exposes with infant's oral

flora [15]. Although the researches on this difficulty is high until now it is not reported a suitable treatment for it [16].

Considering the high prevalence of nipple problems and essential need for the early management of sore nipples, and the antonym information about the effect of lanolin on nipple problems, the present study aimed at evaluating the effect of lanolin creams on the treatment of traumatic nipples.

METHODS

The current double-blind, randomized, control study was conducted on a population of postpartum mothers with nipple injuries, to compare the effect of lanolin cream on the treatment of painful nipples in breastfeeding mothers. The participants were selected from mothers attending the health centers and children's hospital in Sanandaj, Iran.

Mothers' inclusion criteria were: having exclusive breastfeeding, having term delivery, having an infant with normal weight, having infants with less than two months, gaining the minimum score of 1 in the NTS and NSRS scales, having no medical complaints, no allergy to lanolin, and no nipple complications such as flat and depressed nipples. The exclusion criteria were: having babies with tongue and tooth complications, using pacifiers and plastic nipples, the mother's psychological problems, and any nipple condition that leads to stopping breastfeeding.

According to Ahluwalia [17], the study sample size was 34 for each group considering 95% confidence interval (CI) and 80% power using the two-group comparison technique. Lastly, by the estimation of 20% dropouts, 40 mothers were selected for each group.

$$n = (z\alpha + z\beta)^2 [p_1(1 - p_1) + p_2(1 - p_2)] / d^2$$

$$d = p_1 - p_2$$

p_1 : prevalence of pain before intervention

CONSORT guidelines were followed in the current study. This study was double-blinded. The participants were randomly divided into two groups to receive lanolin or placebo cream, using a table of random numbers. In the current study, a computer-generated randomization scheme was applied according to fixed blocks sizes of 2 and 4, and the allocation ratio of 1:1. The groups were named A and B since subjects and researchers were both blind to the allocations. Then, the tubes were filled with 50 mL of lanolin produced for the study group and 50 mL colorless and odorless, gelatinous substance for the control group in the Pharmaceutics Laboratory of Pharmacy Faculty, Tabriz University of Medical Sciences. The research supervisor numbered the opaque pockets and the researcher used them in the sampling process. The lanolin tubes contained 5% vitamin B-complex equivalent. Neither the researcher nor the participants were aware of the assignment sequence and the position of each subject.

An expert researcher examined the breast of the mother to identify sour nipples then mothers were educated about ideal breastfeeding positions and any possible allergy to lanolin cream by the researcher. Mothers were educated about washing their hands with lukewarm water and soap and then rubbing the cream on the nipples, three times a day, immediately after lactation for two weeks. The data was collected before the intervention, as well as the third, seventh, and fourteenth

days of the study. The mothers were educated about how to fill the Champion and the Store scales. In addition, follow-up telephone interviews were carried out one week after entering the study to evaluate the patient's allergy to creams and any nipple problems. Any loss to follow-up after recruitment was documented. A chart was made to track the flow of participants through the trial.

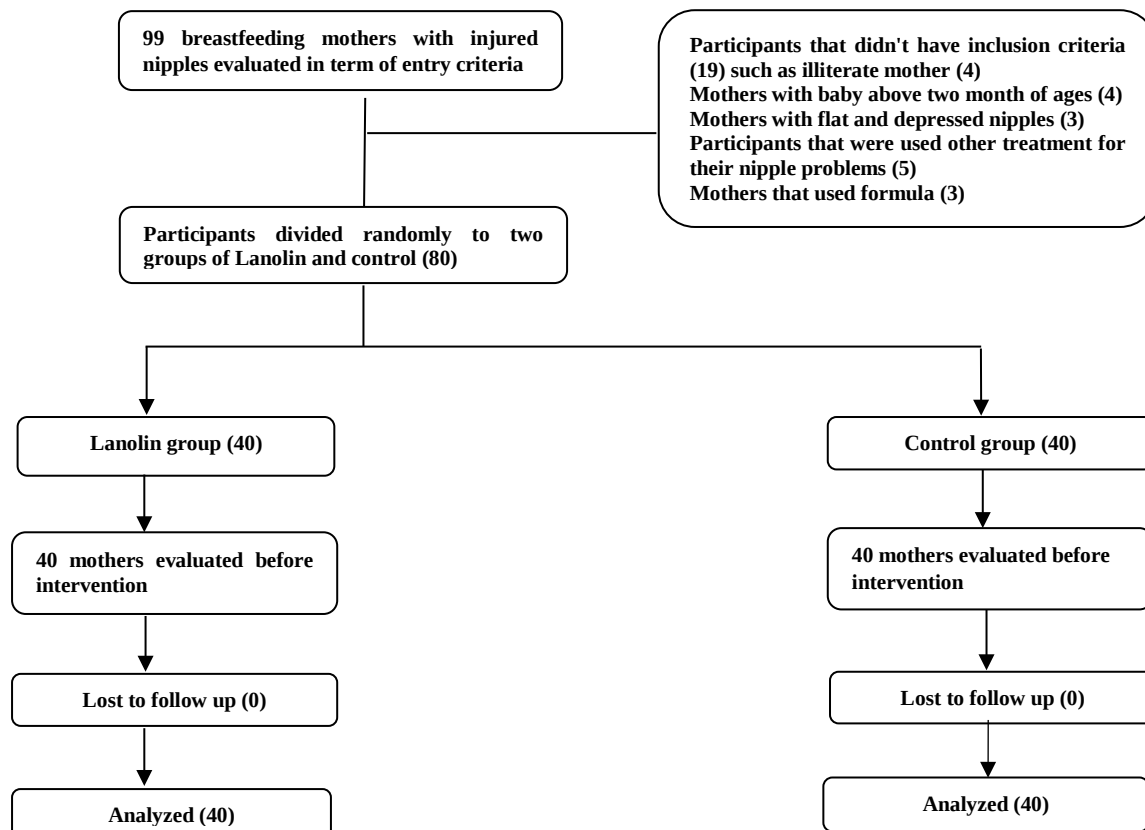


Figure 1. Consort Flow Chart

In the study, participants were encouraged to fill the researcher-made questionnaire. The first part of this questionnaire included socio-demographic and maternal information; i.e., age of mother, age at the time of marriage, mother's education, and job. The second part contained midwifery information such as the number of pregnancies, deliveries, children, duration of breastfeeding, and breastfeeding education. The questionnaire was filled through interviews and before intervention. Another data collection tool was the Store scale developed to measure the level of pain caused by nipples fissure. Participants used this numerical scale to express their level of pain. The minimum score (0) was considered as having no pain and the maximum score (5) was considered as having the highest level of pain [18]. The third tool for data gathering was the Champion scale. This numerical scale was used to determine the trauma of nipples. The breastfeeding mothers used this scale and its numerical scale to assess

the nipple trauma [17]. The 0 in the scale was considered as absence of trauma and the highest score (5) was assigned to severe trauma (6). The validity of the Champion scale (nipple trauma score) to assess trauma of nipple was confirmed by Champion [17] and the validity of the Nipple Soreness Rating Score (NSRS) was confirmed by the Store [18]. The reliability of the Champion and the Store scales was determined in the current study by the test-retest method ($r > 0.7$) [17].

Data analysis was performed with SPSS version 13.0. Values were expressed as the mean (SD), and one-way ANOVA was used to compare variables in the two groups. The chi-squared test was used to calculate the association. P-value < 0.05 was considered the level of significance in all analyses. Kolmogorov-Smirnov test was used to check the normality of data.

RESULTS

In the current study, 80 mothers with nipple problems were evaluated. Figure 1 shows the CONSORT flow diagram of the trial.

Table 1. Comparison of Demographic, Obstetric and Breastfeeding Characteristics between Participants

Characteristic	Control N (%)	Lanolin N (%)	P*
Marriage age (year)			
< 20	17 (40.5)	19 (45.2)	0.446
20-25	22 (52.4)	17 (40.5)	
≥26	3 (7.1)	6 (14.3)	
Mother Education			
Elementary	5 (11.9)	8 (19)	0.800 [§]
High school	22 (52.4)	21 (50)	
University	15 (35.7)	13 (31)	
Mother job			
House wife	34 (80.95)	36 (94.7)	0.431
Having job	8 (19.05)	6 (5.3)	
Number of pregnancy			0.070 [§]
1	22 (52.4)	21 (50)	
2	14 (33.3)	11 (26.2)	
≥3	6 (14.3)	10 (23.8)	
Number of children			0.738 [§]
1	29 (70)	28 (70)	
2	10 (25.4)	14 (30)	
3	3 (4.6)	0	
Mode of delivery			1
Normal vaginal delivery	36 (85.7)	35 (83.3)	
Cesarean	6 (14.3)	7 (16.7)	
Breastfeeding duration (month)			0.364
≤ 12	8 (44.4)	7 (38.9)	
>12	10 (55.6)	11 (61.1)	
Previous education about breastfeeding			0.684
Yes	32 (82.1)	35 (87.5)	
No	10 (17.9)	7 (12.5)	

* According to Chi-square test

[§] According to two-tailed Chi-square

Table 2. Comparison of Participant's Nipple Pain in Four Stages of Study

Groups / Time of Scoring	Before Intervention	Third Day	Seven th Day	Fourteen th Day	P*
Control					
0	0	0	0	0	<0.001
1	5 (11.9)	5 (11.9)	5 (11.9)	6 (14.3)	<0.001
2	8 (19)	8 (19)	11 (26.2)	16 (38.1)	<0.001
3	12 (28.6)	18 (42.9)	18 (42.9)	17 (40.5)	<0.001
4	7 (16.7)	7 (16.7)	8 (19)	3 (3.6)	<0.001
5	10 (23.8)	4 (9.5)	0	0	<0.001
Lanolin					
0	0	1 (2.4)	34 (81)	42 (100)	<0.001
1	3 (7.1)	26 (61.9)	8 (19)	0	<0.001
2	10 (23.8)	9 (21.4)	0	0	<0.001
3	13 (31)	5 (11.9)	0	0	<0.001
4	12 (28.6)	1 (2.4)	0	0	<0.001
5	4 (9.5)	0	0	0	0.005
P**	0.336	<0.001	<0.001	<0.001	

*According to Wilcoxon Test

**According to U-Mann Whitney

1. Comparison of pain before intervention and third day 2. Comparison of pain before intervention and seventh day 3. Comparison of pain before intervention and fourteenth day 4. Comparison of pain in third and seventh days 5. Comparison of pain in third and fourteenth days 6. Comparison of pain in seventh and fourteenth days

Participants were divided into two groups (the lanolin and control). Most of participants in the lanolin group were under 20 years of age (45.2%), and in the control group, most of mother were between 20-25 years old (52.4%). More than half of participants had vaginal delivery in two groups and more than half of them were primigravida. Table 1 shows the demographic, obstetric

and breastfeeding obstetric and breastfeeding characteristics of participants.

The current study used the Champion and the Store scales to score the trauma and pain of sore nipples. Table 2 compares pain scores in study groups. According to the U-Mann Whitney test, before the intervention, the pain score between groups was not significantly

different ($P=0.336$). While after the intervention the pain score between groups was significantly different ($P<0.001$) and the pain score in the lanolin group was decreased more than control group. In intragroup comparison, the result of the Wilcoxon test showed a significant difference among the mean pain scores at the four-time points in the lanolin group ($P<0.001$).

Table 3 compares the nipple trauma scores of participants in four-time the study. According to this table, the nipple trauma score in the lanolin group had a

descending trend. On the other hand, the results of the U-Mann Whitney test showed a significant difference among the nipple trauma scores at the four-time points in the intervention group ($P<0.001$), while in the control group, the scores at the same time points were not significantly different ($P=0.21$). Also, in intragroup comparison, the result of the Wilcoxon test showed a significant difference among the mean pain scores at the four-time points in the lanolin group ($P<0.001$).

Table 3. Comparison of Participant's Nipple Trauma in Four Stages of Study

Groups / Time of Scoring	Before Intervention	Third day	Seven th day	Fourteen th day	P*
Control					
0	0	0	0	2 (4.8)	0.07
1	2 (4.8)	3 (7.1)	3 (7.1)	1 (2.4)	0.003
2	8 (19)	7 (16.7)	6 (14.3)	16 (38.1)	<0.001
3	11 (26.2)	10 (23.8)	19 (22.6)	17 (40.5)	0.05
4	5 (11.9)	18 (42.9)	14 (33.3)	6 (14.3)	<0.001
5	16 (38.1)	4 (9.5)	0	0	<0.001
Lanolin					
0	0	0	19 (22.6)	39 (92.9)	1. <0.001
1	3 (7.1)	10 (23.8)	16 (38.1)	3 (7.1)	2. <0.001
2	4 (9.5)	20 (47.6)	7 (16.7)	0	3. <0.001
3	13 (31)	8 (19)	0	0	4. <0.001
4	12 (12)	4 (9.5)	0	0	5. <0.001
5	10 (23.8)	0	0	0	6. <0.001
P**	0.21	<0.001	<0.001	<0.001	

*According to Wilcoxon Test

**According to U-Mann Whitney

1. Comparison of trauma before intervention and third day 2. Comparison of trauma before intervention and seventh day 3. Comparison of trauma before intervention and fourteenth day 4. Comparison of trauma in third and seventh days 5. Comparison of trauma in third and fourteenth days 6. Comparison of trauma in seventh and fourteenth days

DISCUSSION

According to the importance of exclusive breastfeeding in the growth and development of infants, it is essential to treat sore nipples and provide information about the effect of lanolin for breastfeeding mothers; hence, it was decided to evaluate the effect of lanolin on the treatment of painful and traumatic sore nipples. The mechanism of lanolin in the treatment of nipples is its moisture effect on skin that prevents dryness and fissure [19].

The results of the present study showed that lanolin was effective in treating nipple pain or trauma. The mean nipple pain score in the lanolin group on the pretreatment day was 3.60, on the third day was 1.31, on the seventh day was 0.15, and on the fourteenth day was 0. In the lanolin group, the trauma score had also a descending trend in the study period.

Dennis et al., (2012) compare all-purpose nipple ointment (APNO) and lanolin on nipple pain among breastfeeding mothers. They showed that there were no significant differences in mean pain scores at one week after the study and the mothers in the lanolin group stated more satisfaction with their breastfeeding [20]. In a study (2018) Neto et al. used the highly purified anhydrous lanolin and expressed breast milk to compare their effect in breastfeeding mothers with nipple pain and difficulties; the authors revealed that nipple pain in the lanolin group was decreased. Lanolin was effective

than using breast milk in mothers with traumatic nipples, too [1]. Also, in a study was carried out by Abou-Dakn et al., (2011), the researcher showed that lanolin, combined with breastfeeding education, was more effective than expressed breast milk plus breastfeeding education, in decreasing nipple pain and promoting healing of nipple trauma [21]. Vierra (2013) showed that using lanolin cream with breast milk or without it can heal the painful breast in comparison with using only breast milk, hydrogel, adhesive polyethylene film dressings, a chlorhexidine spray including alcohol, and distilled water [22]. The results of these three studies were similar to those of the current study, but some studies have different results from the present research. For example, in a randomized control trial was done by Sayyadmelli et al., (2007), the authors compared the effect of peppermint and lanolin on the prevention of nipple fissure in primiparous; the result of the study revealed that nipple fissure was less in the peppermint group than the lanolin or placebo group and the relative risk of nipple fissure in the lanolin group was higher than in the peppermint group [23]. In a comparison to peppermint and lanolin, maybe peppermint was more effective but lanoline is an effective substance which is showed in the current study. Deniss (2008) showed that the rate of pain in the ointment group was less than the lanolin group, but this was not significant. In this study 78% of pain release in

the ointment group and 71% of pain declines in the lanolin group were observed [6]. In a systematic review (2021), the authors compared herbal medicine (Olive oil, Aloe vera, Calendula officinalis, jujube oil, mint, frankincense, sagez, and Portulaca oleracea) with non-herbal medicine (lanolin, hydrogels, breast milk, and collagenase); the results showed the effectiveness of breast milk and herbal medicine on nipples fissure and pain, but they mentioned that it is needed more studies to describe this effectiveness [24]. In a study was done by Mohammadzadeh et al., (2005) to evaluate the effect of breast milk and lanolin on sore nipples, the authors suggested that, using breast milk on sour nipples after lactation is effective in the treatment of sore nipples. This study has some limitations such as there was not any scale for determination of scored sour nipple and scoring was done by a researcher who was aware of study groups [13]. Learning the right positions of Breastfeeding to mothers can prevent the sour nipples and it helps to the treatment of injured nipples [14]. Also, in the study was carried out by Pezeshki et al., (2020), that compares the effect of Aloe Vera extract, breast milk, Calendit-E, Curcumin, Lanolin, Olive oil, and Purslane on the treatment of sore nipples, it is shown that Aloe vera gel and purslane cream, Calendit-E cream, and curcumin are more effective in healing the sore nipples [25].

The current study was conducted on mothers with term and normal weight infants; therefore, the result should not be generalized to the ones with preterm infants, and it was a limitation of the present study. Also, due to the lack of studies on lanolin and controversy in the results of studies, further studies on the effects of lanolin on nipple problems are recommended.

CONCLUSION

The present results showed that Lanolin can reduce the intensity of nipple pain and relieve nipple fissure in breastfeeding mothers. Therefore, the application of Lanolin could be an effective, simple, and noninvasive technique with no side effects and could be particularly important in the treatment of nipple fissures and pain.

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CONFLICT OF INTEREST

There is no conflict of interest.

ETHICAL CONSIDERATION

The current study protocol was approved by the Ethics Committee of Tabriz University of Medical Sciences (code: 9342-93/4/4); the study was also registered in the Iranian Registry of Clinical Trials (IRCT code: 201403116709N16). It was performed in accordance with the current and seventh editions of the Declaration of Helsinki [26]. Participants were informed about the study goals and methods, the confidential and secure data handling, and their voluntary participation, and informed consent was obtained before the study.

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AUTHORS CONTRIBUTIONS

Conceptualization: MS, KM, SPS. Data curation: KM. Formal analysis: AFK, MS. Funding acquisition: Tabriz University of Medical Sciences. Methodology: MS, FF. Project administration: MS, SPS. Visualization: MS, KM. Writing original draft: SPS, FF. Writing review & editing: SPS.

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