



The Effect of Dexpanthenol on the Treatment of Nipple Injuries in Breastfeeding Mothers: A Randomized Control Trial

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Abstract

Background: Considering the importance of treatment of sour nipples in breastfeeding mothers, the aim of this study was to evaluate the effect of dexpanthenol creams on the treatment of traumatic nipples.

Materials and Methods: This study was a double-blinded, randomized, control trial, in which 82 postpartum mothers with nipple injuries who had attended health centers and Children's Hospital of Sanandaj, Iran, participated. The participants were randomly divided into two groups of dexpanthenol and control. Nipple pain and trauma was measured using Storr and Champion scale. Analysis was done through chi-square and ANOVA tests using SPSS software version 13.0. *P* value less than 0.05 was considered significant.

Results: The results of this study demonstrated that the mean score of pain and trauma in third, seventh, and fourteenth days of study in intervention group was decreased. In addition, there was significant differences in pain and trauma scores between dexpanthenol and control groups.

Conclusion: Dexpanthenol is advised as an effective, simple, and non-invasive technique with no side effects for the treatment of nipple fissures and pain.

Keywords: Breastfeeding, Dexpanthenol, Nipple

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Introduction

Breast milk is the best food for infants since it covers all nutritional requirements of babies (1). Breast milk also has developmental, social, economic, and health benefits (2). Breastfeeding is the key factor in reducing neonatal mortality and morbidity (3).

Healthcare providers encourage mothers to have exclusive breastfeeding especially for the first six months after birth. Exclusive breastfeeding has a lot of benefits to infants and mothers 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 as well (4).

According to the World Health Organization reports, 98% of the whole mothers are able to breastfeed their infants physiologically (5), however only 35% of them exclusively breastfeed their infants from birth to five

months of age (6). Nipple sore and fissure, which cause a bad experience in breastfeeding, are the main reasons why mothers stop breastfeeding (6). Nipple sore happens in about 80%-90% of breastfeeding mothers, 26% of them have highly painful nipple fissures and wounds (7); therefore, the treatment and control of these problems are very important.

Systematic reviews have documented that glycerin gel, dressings, breast shells with lanolin and lanolin alone, and all other ointments on maternal nipple pain are insufficiently effective (8, 9). It seems traditional therapies along with medical treatments may cure breastfeeding problems (10). Niazi et al, in a systematic review, used menthol, hot water compress, and teaching the ideal breastfeeding methods to prevent and treat nipple pain or fissure, though they did not examine the effect of dexpanthenol (11).

Dexpanthenol, or pantothenic acid, is a herbal compound that relieves skin sore and erythema. Topical dexpanthenol acts as a moisturizer, reduces the loss of water in epidermis, maintains the skin smoothness and elasticity, helps wound healing by preserving water through the epidermis, and exerts anti-inflammatory effects on skin erythema (12).

In a systematic review on the prevention and treatment of nipple pain and trauma, the authors evaluated the effects of pads of warm water, compresses of tea bag, warmth, applying their own milk as well as dexpanthenol, lanolin, vitamin A, collagenase, hydrogel, glycerin, humid occlusive covering, education about ideal latch on, correct position of breastfeeding, and no treatment, and finally reported that none of the employed methods was superior to others. They mentioned that the important factor in preventing nipple sore was the education of best breastfeeding positions (13).

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

Materials and Methods

The current double-blind, randomized, control trial was part of a research proposal (proposal code: 9342-93/4/4 and IRCT code: IRCT201403116709N16) (14) and was conducted on a population of postpartum mothers with nipple injuries to compare the effect of dexpanthenol cream on the treatment of painful nipples in these breastfeeding mothers. The participants were selected from mothers attending the health centers and Children's Hospital in Sanandaj, Iran.

Inclusion criteria for mothers were: exclusive breastfeeding, term delivery, having infants with normal weight, having infants under two months of age, gaining the minimum score of 1 in the Nipple Trauma Score (NTS) and Nipple Soreness Rating Score (NSRS) scales, having no medical complaints, no allergy to dexpanthenol, 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, psychological problems, and any nipple conditions that led to stopping the breastfeeding.

Based on the study of Ahluwalia et al (15) the study sample size was determined 34 for each group considering 95% confidence interval (CI) and 80% power using the two-group comparison technique. Lastly, estimating 20% dropouts, 41 women were selected for each group.

CONSORT guidelines were followed in the current study. The participants were randomly divided into two groups to receive dexpanthenol or placebo creams, using a table of random numbers. Placebo contained colorless and odorless, gelatinous substance that was made in

Laboratory of Pharmaceutics, Tabriz Faculty of Pharmacy. In the current study, computer-generated randomization scheme was applied according to fixed block sizes of 2 and 4, and the allocation ratio of 1:1. The groups were named A and B, and both subjects and researchers were both kept blind to the allocations. The tubes were filled with 50 mL of dexpanthenol produced in the Laboratory of Pharmaceutics, Faculty of Pharmacy, Tabriz University of Medical Sciences. The opaque pockets were numbered and then used in the sampling process. The dexpanthenol tubes contained 5% vitamin B-complex equivalent. Each participant in the study was provided with a wrapped and opaque pocket.

All mothers were educated about ideal breastfeeding positions and any possible allergy to dexpanthenol cream. Mothers were also 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 intervention, as well as on third, seventh, and fourteenth days of the study. Furthermore, the mothers were educated about how to fill the Champion and the Storr scales. In addition, follow-up phone calls were made one week after the study initiation to evaluate the patients' allergy to creams and any nipple problems. Any loss of follow-up after recruitment was documented. A chart was prepared to track the flow of participants throughout the trial.

During the study, participants were encouraged to fill out a researcher-made questionnaire. The first part of this questionnaire included sociodemographic and maternal information including age of mother, age at the time of marriage, mother's education level, job, and income. The second part included midwifery information such as the number of pregnancies, deliveries, children, duration of breastfeeding, and breastfeeding education attention. The questionnaire was filled out through interviews and before intervention. Another data collection tool was the Storr scale developed to measure the level of pain caused by nipple 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 (16). 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 (15). The minimum score (0) in the scale was considered as the absence of trauma and the highest score (5) was assigned to the severe trauma (17). The validity of the Champion scale to assess the trauma of nipple was confirmed by Champion (15) and the validity of the Nipple Soreness Rating Score (NSRS) was confirmed by the Storr (16). The reliability of the Champion and the Storr scales was determined in the current study by the test-retest method ($r > 0.7$) (15).

Data Analysis

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

Results

In the current study, 82 mothers with nipple problems were evaluated. Figure 1 shows the CONSORT flow diagram of the trial.

Participants were divided into two groups (the dexpanthenol and control). The mean (SD) ages of participants under 25 years in the dexpanthenol and control groups were 14 (35) and 17 (41.5); they were also 26 (65) and 24 (58.5) for the ones above 25, respectively. Table 1 shows the demographic characteristics of participants.

More than half of the participants in two groups had vaginal delivery and more than half were primigravid. Table 2 displays the obstetrics and breastfeeding characteristics of the studied mothers.

The current study used the Champion and the Storr scales to score the trauma and pain of sore nipples. According to Table 3, in the dexpanthenol group, the nipple pain score before intervention was 3.60, while it decreased to 1.31, 0.15, and 0 on the third, seventh, and fourteenth days of intervention, respectively. In intragroup comparison, the result of repeated measures ANOVA showed a significant difference between the mean pain scores at four timepoints in the dexpanthenol group (*P*<0.001), while in the control group, the scores at the same timepoints were not significantly different

Table 1. Demographical Characteristics of Participants

Demographical information	Dexpanthenol No. (%)	Control No. (%)	<i>P</i> Value ^a
Age (y)			
≤25	14 (35.0)	17 (41.5)	0.550
>25	26 (65.0)	24 (58.5)	
Mean (SD)	27.58 (5.33)	27.54 (5.64)	0.975 ^b
Age at the time of marriage (y)			
≤25	32 (78.0)	38 (92.7)	0.061
>25	9 (22.0)	3 (7.3)	
Mean (SD)	21.41 (4.13)	20.63 (3.22)	0.343 ^b
Mother's education level			
Elementary	19 (48.7)	12 (29.3)	0.093 ^c
High school	9 (23.1)	15 (36.6)	
University	11 (28.2)	14 (34.1)	
Mother's job			
Housewife	35(92.1)	33 (86.8)	0.455
Employed	3 (13.2)	5 (13.2)	
Income			
Equal income and expenses	32 (78.0)	29 (70.7)	0.012
Income higher than expenses	8 (19.5)	3 (7.3)	
Income lower than expenses	1 (2.4)	9 (22.0)	

^a Based on chi-square test; ^b based on one-way ANOVA; ^c based on two-tailed chi-square.

(*P*>0.05).

Table 4 shows the nipple trauma scores of participants. According to Table 4, the nipple trauma score in the dexpanthenol group had a descending trend. On the other hand, results of repeated measures ANOVA showed a significant difference between the nipple trauma scores at four timepoints in the intervention group (*P*<0.001), while in the control group, the scores at the same

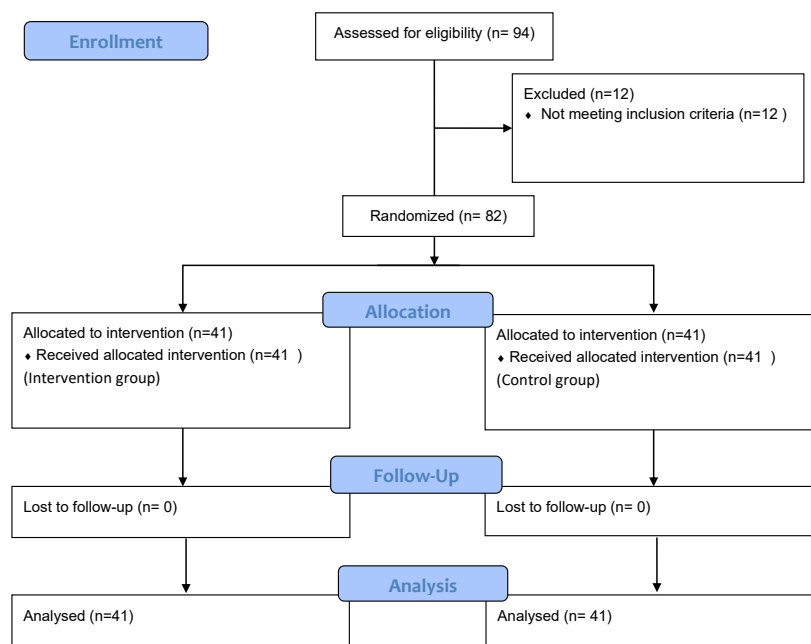


Figure 1. The CONSORT Flow Diagram.

Table 2. Obstetric and Breastfeeding Characteristics of Participants

Characteristics	Dexpanthenol No. (%)	Control No. (%)	P Value ^a
Number of pregnancies			
1	27 (65.9)	21 (51.2)	
2	6 (14.6)	14 (34.1)	0.120 ^b
≥3	8 (19.5)	6 (14.6)	
Number of deliveries			
1	26 (65.0)	21 (51.2)	
2	8 (20.0)	6 (28.6)	0.159 ^b
≥3	6 (15.0)	0 (0.0)	
Number of children			
1	13 (65.0)	16 (76.2)	
≥2	7 (35.0)	5 (23.8)	0.431 ^b
Mode of delivery			
Normal vaginal delivery	31 (79.5)	33 (86.8)	
Cesarean	8 (20.4)	5 (13.1)	0.030
Breastfeeding duration (month)			
Never	0 (0.0)	1 (5.6)	
<6	0 (0.0)	1 (5.6)	
6-12	0 (0.0)	6 (33.3)	0.128
>12	9 (100.0)	10 (55.6)	
Previous education about breastfeeding			
Yes	31 (81.6)	28 (77.8)	
No	7 (18.4)	8 (22.2)	0.684

^a Based on chi-square test; ^b Based on two-tailed chi-square.

timepoints were not significantly different ($P > 0.05$).

In comparison of dexpanthenol and placebo groups, the results showed that the differences between dexpanthenol and placebo groups were significant in terms of pain and trauma scores ($P < 0.001$).

Discussion

Given the important role of exclusive breastfeeding in the growth and development of babies, it is essential to treat

sore nipples and provide information about the effect of dexpanthenol for breastfeeding mothers; hence, the study aimed to evaluate the effect of dexpanthenol cream on the treatment of painful and traumatic sore nipples.

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

In a study in Turkey, Kuşcu et al compared the application of dexpanthenol, collagenase, and hot water and soap in relieving the pain of nipple injuries in breastfeeding mothers; the authors displayed that the pain score could decrease in the groups using dexpanthenol and collagenase compared with the group using hot water and soap, but they observed no significant differences between the dexpanthenol and collagenase groups (12). The results of their study were in line with those of ours; while the results of a systematic review by Morland-Schultz and Hill disagreed with our findings in that using dexpanthenol was not superior to other methods including warm water pad, tea bag compress, warmth, applying the own milk as well as lanolin, vitamin A and collagenase, hydrogel and glycerin therapy, humid occlusive covering, education about ideal latch-on and breastfeeding position, and no treatment in order to decrease the problem of nipples in breastfeeding mothers (13).

In our review of the literature, except for a systematic review by Kuşcu et al, no more studies were found around the effect of dexpanthenol on nipple problems. The reason for the lack of study on this particular herbal compound might be attributed to that dexpanthenol is a native plant to Iran and some other countries. More studies should be conducted to confirm the efficacy of dexpanthenol.

The current study was conducted on mothers with term and normal weight infants; therefore, the result

Table 3. Comparison of Pain Scores in Dexpanthenol and Control Groups at 4 Timepoints

Group	Prior-to-Intervention No. (%)	3rd-Day No. (%)	7th-Day No. (%)	14th-Day No. (%)	P Value ^b
Dexpanthenol	3.60 (1.14)	1.31 (0.56)	0.15 (0.36)	0	<0.001
Control	3.20 (0.82)	1.95 (0.83)	1.95 (0.83)	1.90 (0.83)	>0.05
P value ^a	>0.05	<0.001	<0.001	<0.001	

^a Based on Mann-Whitney U test; ^b Based on repeated measures ANOVA.

Table 4. Comparison of Trauma Scores in Dexpanthenol and Control Groups at 4 Timepoints

Group	Prior-to-Intervention No. (%)	3rd-Day No. (%)	7th-Day No. (%)	14th-Day No. (%)	P Value ^b
Dexpanthenol	3.80 (1.24)	2.05 (0.59)	0.22 (0.52)	0	<0.001
Control	2.95 (0.83)	1.92 (0.83)	1.86 (0.83)	1.81 (0.83)	>0.05
P value ^a	>0.05	0.543	<0.001	<0.001	

^a Based on Mann-Whitney U test; ^b Based on repeated measures ANOVA.

should not be generalized to the ones with preterm infants, and this was a limitation of the present study. Moreover, owing to the lack of studies on dexpanthenol, further studies around its effects on nipple problems are recommended.

Conclusion

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

Conflict of Interest Disclosures

The authors declare that they have no conflict of interests.

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Ethical Statement

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).

Authors contribution

Kazhal Masoudin: Wrote the proposal, Designed and performed experiments.

Mahnaz Shahnazi: Wrote the proposal, analyzed data, co-wrote the paper.

Mahin Kamalifard: Wrote the proposal, Designed experiments.

Shakiba Pourasad Shahrak: analyzed data, wrote the paper, submit the paper.

Fariba Esmaeli: Wrote the proposal, Designed experiments.

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Informed Consent

After explaining the study objectives to participants, the volunteers signed informed consent.

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