

The Effect of nipple soreness treatment with Purslane Cream and Lanolin on Frequency and duration of Breastfeeding in nursing mothers: A Randomized Clinical Trial

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ARTICLE INFO	ABSTRACT
<p><i>Article type:</i> Original article</p>	<p>Background & aim: Despite the global efforts to promote breastfeeding, women report some problems leading to stop breastfeeding in the early postpartum. Nipple soreness is considered as one of the main causes of early breastfeeding discontinuation. Treatment of this problem could keep breastfeeding for a prolonged period of time. Therefore, the present study aimed to investigate the effect of nipple pain treatment with lanolin and purslane cream on frequency and duration of breastfeeding.</p> <p>Methods: This double-blinded, randomized clinical trial was conducted on 86 breastfeeding women with nipple soreness who attended healthcare clinics in Mashhad, Iran, in 2016. The participants were randomly allocated to two equally sized group (43 in each), receiving purslane cream and lanolin for eight days. The correct method of breastfeeding and using the cream were trained to both groups. The nipple pain score was measured before intervention and on the third and eighth days post-intervention using a numeric pain rating scale. The subjects were also trained to record the duration and frequency of breastfeeding during the study period. Data were analyzed by SPSS version 22 using t-test, Fisher's exact test, Chi-square, and Wilcoxon tests.</p> <p>Results: Two study groups were identical in terms of the pain intensity before intervention. There was a significant difference concerning the pain intensity between the two groups on days 3 and 8. The pain intensity in the purslane cream group was significantly lower than the lanolin group ($P < 0.001$). The frequency of breastfeeding in the purslane group after the fourth day was significantly higher than the lanolin group ($P = 0.017$). However, there was no significant difference between the two groups regarding the duration of breastfeeding ($P = 0.423$).</p> <p>Conclusion: Improving nipple pain by purslane cream can promote the frequency of breastfeeding. As a result, it can be considered as an effective agent in treatment of nipple soreness in nursing mothers.</p>
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Introduction

Breast milk has always been known as the best food for infants (1). Breastfeeding diminishes the incidence of gastrointestinal,

respiratory, and urinary tract diseases, thereby reducing the rate of hospitalization and mortality in infants, especially in poor

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countries (2-5). Other important impacts of breastfeeding are the enhanced intelligence quotient (IQ) and better brain development (6). Moreover, the risk of breast, ovarian, and endometrial cancers reduces in breastfeeding mothers. Breastfeeding also contributes to accelerating the uterus return to its primary condition and subsequently decreases bleeding (7).

According to the recent estimates of World Health Organization (WHO), although 98% of women are physiologically capable of breastfeeding (8), only 35% of infants around the world are breastfed since birth until the fifth month (9). Despite the global measures to encourage breast milk choice and augment the breastfeeding duration and frequency, women report the problems leading to quit breastfeeding in the postpartum period (10).

Nipple pain is known as one of the major causes of early breastfeeding discontinuation before the supposed time (11). The latter issue can reduce the production and output of breast milk through multiple mechanisms. Mothers who are experiencing nipple discomfort may breastfeed their newborn less often or the reflection of milk drainage might be inhibited by pain. This inadequate milk intake also results in reduced milk production and puts the infant at risk for nutritional deficiencies (12).

Based on the available reports, 90% of breastfeeding women experience the nipple pain (11). Wagner (2013) introduced the sore nipple in postpartum period as one of the reasons for stress and concern in mothers (13). Pain causes the production and secretion of breast milk to lessen due to the inhibitory effect on oxytocin. The ultimate result is maternal stress and breastfeeding cessation (14, 15). Stress can develop a range of physical (fatigue) and psychological (anxiety) changes in mother (16). The hypothalamic-pituitary-adrenal axis is more susceptible to stress among women in puerperal period. Some studies have pointed the close relationship between stress and anxiety with prolactin secretion (17).

Pain can also lead to overall interference with maternal activity, mental distress, sleep

disorder, and impaired mother-infant bonding (18). The treatment should be performed in order to relieve pain and succeed to continue lactation (19). There are several interventions, including training correct breastfeeding techniques, topical use of hydrogel, glycerin, and breast milk to attenuate the nipple pain. None of the mentioned interventions have therapeutic superiority (20-21).

Allen (2003) reported that breastfeeding leads to nipple skin dryness and ultimately cracking and ulcers (22). Lanolin is a recommended treatment for nipple fissure and pain with wound healing efficacy in the moist environment, as well as anti-inflammatory and antimicrobial properties. The literature has reported controversial effects of lanolin on nipple pain treatment. In a study by Jackson (2016), lanolin was ineffective in treatment of pain and nipple fissure (15, 23).

Abou-Dakn et al. (2011) in a study titled "Positive Effect of HPA Lanolin Versus Expressed Breast Milk on Painful and Damaged Nipples during Lactation" found that lanolin was more effective in treating nipple fissure and pain, compared to the expressed breast milk (23). Irritation, itch, and infection are among the side effects of lanolin that have been mentioned in some studies (24, 25).

Herbal products are one of the first choices to cope with illness and relieve pain, which have long been used in many countries, including Iran. These products are assumed to have less side effects and are more acceptable (26). Purslane is one of the known plants in traditional and herbal medicine. Chan et al. (2000) showed significant analgesic and anti-inflammatory effects for this plant, comparable to the impact of diclofenac sodium (27). Rao et al. (2012) attributed the anti-inflammatory and analgesic effects of purslane to the flavonoid, tannin, saponin, and terpenoid compounds (28). A study performed in Taiwan showed no toxicity for this plant (29).

It is of high importance to promote exclusive breastfeeding as one of the priorities for the health programs around the world, including Iran. On the other hand, nipple pain is prevalent in breastfeeding women and no treatment has been approved

for this problem. Moreover, nipple fissure is a common cause of decline in breastfeeding. With this background in mind, the present study aimed to determine the effect of nipple fissure treatment with lanolin and purslane cream on the frequency of breastfeeding.

Materials and Methods

This double-blinded, randomized clinical trial was conducted on 86 eligible women. The participants referred to the four health centers affiliated to Mashhad University of Medical Sciences (i.e., Shahid Qodsi, Khaje Rabi, Shahid Motahari, and Sakhteman 1), Mashhad, Iran for neonatal hypothyroidism screening test in 2016. The study was approved by the Ethics Committee with the code of 950010 and was registered on the Iranian Registry of Clinical Trials as IRCT2015042421915N1.

The sample size was estimated as 25 in each group based on a pilot study and the formula for comparing sample means with 95% confidence interval and 80% test power to detect a two-score difference and a standard deviation of 2.5. Finally, 86 people entered the study considering the possibility of dropouts.

During the multistage sampling, two regions were first randomly determined among the five regions with health centers in Mashhad. Then, based on the rate of referrals to the hypothyroidism screening units, two centers were randomly selected from each of the two regions and the final sampling was performed in four health centers. In the third step, the research units were chosen simply from the breastfeeding women with sore nipple, who were referred to the selected health centers on the third to fifth days after delivery to perform the neonatal hypothyroidism screening test.

Necessary explanations regarding the research design and method, how to use the medication, as well as the risk of hypersensitivity were given to the participants. Written informed consents were taken and the individuals were assured about the confidentiality of information in order to comply with ethical issues. In addition, the volunteers were completely free to leave the study at any time during the project. The patients were

randomly assigned in to one of the two groups of purslane cream and lanolin using a table of random numbers.

The inclusion criteria entailed: 1) Iranian nationality, 2) living in Mashhad, 3) having singleton term neonate, 4) being literate and capable of making phone calls, 5) exclusive breastfeeding, 6) not having nipple abnormalities (e.g., flattening, indenting, bulging, or any apparent nipple deformity), 7) absence of known psychological problems, 8) no history of diabetes or internal and surgical problems (i.e., cardiac, renal, infectious, digestive, endocrine, neurological, muscular, and coagulation problems), 9) not having oral fungal infection or neonatal abnormalities in the mouth, palate, jaw and face, 12) obtaining the score of 2 or higher in the numeric pain rating scale.

The exclusion criteria included: 1) unwillingness to continue the study, 2) maternal breast abscess and infection, 3) using pacifier, feeding bottle, and plastic nipple, 4) infantile disease and oral fungal infection during the study, 5) maternal infectious diseases or allergy to purslane cream and lanolin, 6) failure to refer on the determined dates for any reason, 7) using other treatments such as rubbing milk, antibiotics, and cold or hot compresses during the study period, 8) not applying the medication for one day or less than three times a day, and 9) failure to complete the parental diary of infant behavior form in at least 24 hours.

The purslane plant was collected from the farms around Mashhad and was confirmed to be purslane by the Faculty of Pharmacy at Mashhad University of Medical Sciences with the Herbarium Code of 12-1615-240. The aerial parts of the plant were separated, washed, and dried in a dryer at 40 °C for 2 days. In the next step, 300 g of the powdered plant was poured into extraction thimbles and extraction was carried out with 70% alcohol by maceration method. The solvent was removed by rotary evaporator device to obtain a concentrated extract in the pharmacology laboratory.

Finally, 1 g of concentrated extract was obtained from each 10 g of the powdered plant, and 2% purslane cream was produced by combining a specific amount of purslane extract with Cold Cream (USP). The lanolin used in this study was prepared from Farabi Company, Iran. The medications were packaged and encoded as A and B by a pharmacist in 30 g jars of the same shape and size.

Both the participants and researchers were unaware of the treatment type in each group. On the same day, after completing the consent form, the researcher instructed mothers in both groups individually about the correct method of breastfeeding (including the correct position of mother, how to put the breast in the mouth of the baby, and the method of hugging the baby) using educational pamphlets. Afterwards, each mother breastfed her baby in presence of the researcher to be evaluated regarding the correct method of breastfeeding. In addition, the pain intensity experienced during breastfeeding was measured using a pain ruler.

The researcher asked the mother to apply the cream on her arm eight hours before usage to detect any possible hypersensitivity. In case allergy did not occur, the medicine was rubbed on the nipple skin as much as a knuckle three times a day immediately after breastfeeding for seven days, so that a thin layer of cream covered the entire nipple fissure. The researcher completed numerical scale of the pain in person before pre-intervention, as well as the third and eighth days' post-treatment.

The parental diary of the infant behavior pattern was presented to the research units in order to record the duration and frequency of breastfeeding during the study period and deliver the form on the upcoming sessions. During this period, the researcher had phone calls with the mothers to ask the process of recovery and whether or not they had complications. In case of any problem or failure, the mother was referred to the clinician.

In this research, the data collection tools included interview and examination form. The form encompassed 22 questions concerning the demographic data, such as residence,

educational level, age of infant, type and method of feeding, in addition to nipple anomalies. Moreover, 23 questions formed the midwifery inventory about age, body mass index, type of delivery, predominant breast in breastfeeding, and history of breastfeeding. Other items entailed the numeric pain rating scale, in addition to the parental diary of infant behavior form, including the duration of breastfeeding per meal and the frequency of breastfeeding.

Validity of the demographic and midwifery questionnaire, as well as the interview and examination form was determined by content validity using the views of seven faculty members. The inter-rater agreement method was utilized to determine the reliability of the interview and examination form, which was 0.98 and 0.90, respectively. The parental diary of infant behavior is an international standard tool containing a four-line ruler, each of which representing 6 hours of the day with an accuracy of 5 minutes. Barr et al. confirmed the validity and reliability of this tool in 1998 (30).

The pain intensity was recorded using the numeric pain rating scale by expressing maternal pain score on the graded ruler. This tool is graded from zero to 10, indicating zero, 1-3, 4-7, and 8-10 as no pain, mild, moderate, and severe pain, respectively. Ferreira-Valente et al. (2011) and Phan et al. approved the validity and reliability of this standard scale using the test-retest method (12, 31).

During the study, 6 people were excluded because of meeting the exclusion criteria. The reasons for drop out included nipple infection (n=2) and irregular use of lanolin (n=1) in the lanolin group, as well as failure to use the purslane cream on time (n=3) in the purslane group.

All the collected data were analyzed by SPSS version 22 using the t-test, Fisher's exact test, Chi-square, and Wilcoxon tests. In all tests, the confidence interval was 95% and $P < 0.05$ was considered as significant.

Results

At the end of the study period, results of 80 out of 86 participants entered the statistical analysis.

Table 1. Distribution of demographic characteristics of the participants in the two study groups

Variables	Groups		Independent t-test
	Lanolin Mean ± SD	Purslane Mean ± SD	
Maternal age (years)	29.2±6.8	27.5±6	P=0.244, t=1.173
BMI (Kg/m ²)	25.8±4.6	24.6±3.7	P=0.2, t=1.291
Birth weight (g)	3297±431.2	3245±369.6	P=0.566, t=0.576
	Median ± interquartile range	Median ± interquartile range	Mann-Whitney test
Age of baby (day)	4.4±0.8	4.2±0.8	P=0.358, Z=0.919
	Frequency (percentage)	Frequency (percentage)	Chi-square test
Occupation of mother	Housekeeper Employee	28 (70.0) 12 (27.5)	31 (77.5) 9 (22.5) X ² =0.581 P=0.446
Type of delivery	Vaginal section Cesarean section	28 (7) 12 (3)	29 (72.5) 11 (27.5) X ² =1.91 P=0.549

The findings of this study demonstrated that the means of maternal age (P=0.244), maternal BMI (P=0.200), neonatal birth weight (P=0.566), neonatal age (P=0.358), maternal occupation (P=0.446), and the type of delivery (P=0.549) were not significantly different between the two groups (Table 1).

There was no significant difference between the two groups before and after the intervention regarding pain intensity in the right (P=0.613) and left (P=0.969) breasts. The

results of Wilcoxon test showed a significant difference in the pain intensity of each group on days 3 and 8, compared to pre-intervention and the pain intensity decreased significantly in both groups (P<0.001).

A significant difference was found regarding the pain intensity between the two groups based on the Mann-Whitney test on days 3 and 8. Moreover, the pain intensity was significantly lower in the purslane group than the lanolin group (P<0.001) (Table 2).

Table 2. Frequency distribution of the participants based on the pain intensity during breastfeeding in the study group's pre-intervention and days three and eight post-intervention

Groups Pain intensity	Lanolin			Purslane			
	Frequency (percentage)			Frequency (percentage)			
	Pre-intervention	Day 3	Day 8	Pre-intervention	Day 3	Day 8	
Right breast	No (0)	0 (0)	8 (20)	16 (40)	0 (0)	32 (80)	40 (100)
	Mild (1-3)	4 (10)	9 (22.5)	15 (37.5)	4 (10)	7 (17.5)	0 (0)
	Moderate (4-7)	26 (65)	20 (50)	9 (22.5)	23 (57.5)	1 (2.5)	0 (0)
	Severe (8-10)	10 (25)	3 (7.5)	0 (0)	13 (32.5)	0 (0)	0 (0)40
Left breast	no (0)	0 (0)	4 (10)	19 (47.5)	0 (0)	32 (80)	40 (100)
	Mild (1-3)	3 (7.5)	13 (32.5)	9 (22.5)	1 (2.5)	8 (20)	0 (0)
	Moderate (4-7)	22 (55)	15 (37.5)	10 (25)	23 (57.5)	0 (0)	0 (0)
	Severe (8-10)	15 (37.5)	8 (20)	2 (5)	16 (40)	0 (0)	0 (0)

The frequency of breastfeeding in the two groups of lanolin and purslane was compared by the statistical tests during the study days. The difference of breastfeeding frequency in each group was significant based on Friedman test during 7 days (P<0.001). Comparison of the two groups in terms of the breastfeeding frequency

revealed a significant difference between the two groups (P=0.017). The frequency of breastfeeding in the purslane group after the fourth day was significantly higher than the lanolin group (Table 3).

The duration of breastfeeding (in minutes) was also compared between the two groups of lanolin and purslane. According to the results

of our study no significant difference was observed (Table 4).
between the two groups ($Z=1.22$ and $P=0.222$)

Table 3. Comparison of research units based on the frequency of breastfeeding in the study groups pre-intervention and days three and eight post-intervention

Variables	Lanolin	Purslane	Mann-Whitney test
	Median (interquartile range)	Median (interquartile range)	
Frequency of breastfeeding (day 1)	6 (1)	6 (1)	$P=0.999, Z=0.001$
Frequency of breastfeeding (day 2)	5.6 (1)	7 (1)	$P=0.794, Z=-0.261$
Frequency of breastfeeding (day 3)	7 (1)	7 (1)	$P=0.373, Z=-0.89$
Frequency of breastfeeding (day 4)	5.7 (1)	8 (1)	$P=0.554, Z=-0.592$
Frequency of breastfeeding (day 5)	8 (75.2)	8 (1)	$P=0.017, t=-2.396$
Frequency of breastfeeding (day 6)	8 (75.2)	9 (1)	$P=0.003, Z=-3.022$
Frequency of breastfeeding (day 7)	8 (1)	9 (1)	$P=0.001, Z=-3.399$
Changes in day 7 compared to day 1	2 (2)	3 (2)	$P=0.006, Z=2.72$
Friedman test	$P<0.001, X^2=94.06$	$P<0.001, X^2=155.96$	

Table 4. Distribution of the breastfeeding duration among the research units in the study groups

Variables	Lanolin	Purslane	Mann-Whitney test
	Median (interquartile range)	Median (interquartile range)	
Duration of breastfeeding (day 1)	14.6 (6.7)	14.1 (4)	$P=0.373, Z=0.89$
Duration of breastfeeding (day 2)	16.6 (5.3)	15.7 (5)	$P=0.279, Z=1.083$
Duration of breastfeeding (day 3)	17.1 (4.05)	16.2 (4)	$P=0.193, Z=1.299$
Duration of breastfeeding (day 4)	15 (3.1)	14.6 (4)	$P=0.049, Z=0.294$
Duration of breastfeeding (day 5)	15 (4.3)	14 (3.3)	$P=0.017, Z=2.396$
Duration of breastfeeding (day 6)	15.5 (3.3)	13.9 (3.9)	$P=0.101, Z=-1.66$
Duration of breastfeeding (day 7)	14.2 (4.1)	14.6 (3)	$P=0.081, Z=-3.375$
Changes in duration of breastfeeding at the end of the period compared to day 1	4.7 ± 0.97	1.9 ± 0.23	$P=0.222, Z=1.22$
Friedman test	$P=0.18, X^2=8.891$	$P=0.008, X^2=17.503$	

Discussion

Based on the results of the present study, use of "purslane cream" significantly attenuated the nipple pain intensity at three days after administration, compared to lanolin. In contrast, the frequency of breastfeeding in the purslane cream group increased after the fourth day, which was significantly different from the lanolin group. Furthermore, the duration of breastfeeding in the purslane cream group showed a significant difference on the seventh day, compared to the pre-intervention ($P<0.008$). On the other hand, the difference regarding the latter factor was not significant between the two groups.

The frequency of breastfeeding is 8-12 times within 24 hours during the first 2-4

weeks of birth and the duration of breastfeeding is usually 20-45 minutes in the first month of birth (32). In the current study, the median frequency of breastfeeding was 6 times in the first day, which increased by 9 times after treatment in the purslane group and 8 times in the lanolin group. The reason for this reduction in the frequency of breastfeeding before the intervention can be attributed to the nipple pain. As a result, the frequency of breastfeeding augmented after the pain relief.

Dennis et al. (2012) in a study comparing the effect of all-purpose nipple ointment (APNO) and lanolin on the nipple pain showed that the nipple pain diminished in both treatment groups one-

week post-intervention. However, there was no statistically significant difference between the two groups. The duration of breastfeeding increased up to 20% in the APNO group and 15% in the lanolin group (25).

Herd et al. (1986) compared chlorhexidine with placebo and showed greater efficacy for the chlorhexidine in relief of the nipple pain. In this study, the duration of breastfeeding significantly improved in the treatment group, in comparison with the placebo group (33). These findings can be explained by the fact that if the nipple of mother is painful during breastfeeding, the mother's fear of pain during breastfeeding may lead to a reduction in the duration and frequency of breastfeeding (34). Therefore, treating sore nipple can prevent the anxiety and stress of the mother, thereby modulating the stress hormones, facilitating and activating the breastfeeding pathways in the mother. The results of these two mentioned studies were in line with the present study.

Buchko (1994) highlights that there is no relationship between sore nipple and breastfeeding duration, and 14% of those with minimal pain selected formula-feeding for their baby (35). The results of Buchko et al. are different from the present study. Small sample size and selection of the research samples among the primiparous women, as well as the demographic differences between individuals can be considered as the factors influencing the outcome of this research. The primiparous women suffer from more difficulties for continuing breastfeeding, such as child care and lack of prior experience and skills in breastfeeding.

Randomization and application of standard tools for examining the nipple pain were the strength points of the present study. On the other hand, the limitation of this study was the individual differences in pain threshold, which was controlled by random allocation of subjects to the two groups. Further study is recommended regarding the effect of nipple pain relief on the duration of exclusive breastfeeding.

Conclusion

According to the findings of this study,

the purslane cream was more effective in relieving the pain caused by nipple fissure. Consequently, the frequency of breastfeeding was significantly higher in the purslane group than in the lanolin group. The results obtained in this study can be exploited as supplementary information for previous studies and as reference for other researches in the field of maternal and neonatal health.

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Conflicts of interest

The authors declare no conflicts of interest.

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