

THE EFFECT OF CHAMOMILE OINTMENT ON THE HEALING OF BREASTFEEDING MOTHERS' NIPPLE SORE- A RANDOMIZED CONTROLLED CLINICAL TRIAL

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ABSTRACT

BACKGROUND AND AIM

Breastfeeding is an important factor in the reduction of death and disease attaching during neonatal period. Mother's nipple sore (MNS) makes the breast feeding experience unpleasant and even leads to the lack of continuity in lactation. We wanted to study the effect of chamomile ointment on the healing of breastfeeding mothers' nipple sore.

METHODS

This randomized controlled clinical trial was conducted on 106 eligible women who visited the selected health centers affiliated to Alborz University of Medical Sciences, Alborz, Iran, from November 2017 to May 2018. For creating randomization list, the method of permuted block randomization with a block size of four, was applied. A total of 106 subjects were randomly divided into two equal groups of 53 women grouped as chamomile ointment group and lanolin ointment group. For severity of nipple fissure, Storr scale was used, and to measure the intensity of pain, visual analog scale (VAS) was used. We compared outcomes between the two groups using repeated measures ANOVA. Analysis of covariance (ANCOVA) was used for comparing outcomes between the two groups adjusted on the baseline measures. Analysis of data done by SPSS software, version 22 and also p-value<0.05 was considered to be statistically significant.

RESULTS

The two study groups were balanced based on the baseline demographic characteristics. The evaluation of statistical analysis in order to compare the score mean of nipple sore symptoms (NSS), and nipple sore pain (NSP), 3- and 7-days after intervention indicated that the reduction of NSP in lanolin group was 1.87 ± 0.14 , and chamomile group was 0.47 ± 0.14 , with a p-value<0/001. Reduction of NSS in lanolin group was 0.99 ± 0.09 , and chamomile group was 0.70 ± 0.09 , with p-value<0/041. Reduction of NSP & NSS was significant after treatment with chamomile ointment.

CONCLUSIONS

The present study showed that chamomile ointment was more effective than lanolin in healing and controlling MNS during one-week follow-up, without resulting in any side effects.

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BACKGROUND

Breastfeeding (BF) is an important factor in the reduction of mortality and morbidity during neonatal period, and is effective in the diminution of sudden neonates' death syndrome, gastroenteritis, atopic dermatitis and respiratory infections. Mother's nipple sore (MNS) is a common complaint among BF mothers and it is the second significant reason for premature elimination of BF after feeling of inadequate breast milk, as well as it is the most important reason for mother's tendency towards bottle feeding.¹ The nipple ache is protective response of damaged tissue after Vasospasm of vascular tissue, decreased capillary blood flow to tissue, swelling and oedema. The nipple ache during BF is

intense and intolerable.² The MNS and the resulted ache cause the considerable reduction in lactation and increase mother's stress and her skin would be prone to secondary bacterial and fungal infections.³ MNS is caused due to inappropriate neonates' mouth contact with mother's breast, utilization of detergents and disinfectants, repeated breast washing, taking breast out of neonates' mouth and frequent trauma because of sucking.⁴ The healing of MNS due to neonates' daily increasing nourishment requirements, lack of breast milk flow in the first days after birth, continuous sucking and being exposed to the mother's skin flora and neonates' mouth, makes it prone to infection.⁵ Two types of treatments for curing of nipple sore is recommended which include: healing of sore in dry form (By heat and sun light) and wet form (applying breast milk, suitable creams and ointments).⁶ Lanolin which is the derived fat from sheep's wool and has cosmetic and therapeutic applications, is the single medicine that its efficiency demonstrated in the curing of nipple sore and via water absorption and moisturizing optimizes the healing. Furthermore, the preservative agents of chemical medicines affect the rate of sore healing.⁷

Timely treatment of MNS results in the diminishing of nipple infection, mastitis and abscess, increase of lactation period and mother satisfaction. In none of the research, it has been introduced complete effective method for nipple sore

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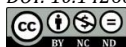
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treatment and nipple sore still remains as an important clinical problem.⁸ The world health organization recommends the use of traditional medicines in its programs. In general, plant components are effective in the process of ache and inflammation diminution by restricting inflammatory paths, reducing the secretion of Prostaglandins and nitric oxide.⁹

Chamomile is an annual, aromatic and herbal plant that belongs to Asteraceae family and is one of the most ancient medicinal plants known by human so far, and its usage dates back to ancient Greece. Chamomile has been introduced as a medicinal plant in overall credible pharmacopoeias and its flower therapeutic aspects has been evaluated. This plant grows wildly throughout the world. Recently this plant has extensively been distributed in Europe, West Asia, North Africa, North and South America, and Australia.¹⁰ Chamomile is applied internally or externally for wound treatments, Eczema, burns, skin irritation, and Rheumatic pains.¹¹ The main components of chamomile plant include Alfa bisabolol, Bisabolol oxide, spiro ether, Chamazulene, and flavonoids such as Apigenin and Luteolin. Bisabolol and flavonoid have anti-inflammatory, pain killing and tranquilizer effects.¹²

Up to now, no clinical trials have assessed the effect of chamomile ointment on the healing of Breastfeeding mothers' nipple sore in Iran. Considering the incidence of MNS and its effect on lactation, the present study aimed to evaluate the effectiveness of chamomile on the healing of Breastfeeding MNS.

METHODS

This study is two-groups, triple-blind (Researcher, samples and statistics analyst are unaware about type of intervention in the groups) randomized Controlled clinical trial, conducted in Karaj comprehensive health centers from November 2017 to May 2018, To calculate the sample size, considering the variable, the symptoms severity as per Storr scale, is considered as a preliminary outcome, considering that the number of two groups and also the three measurement times are considered in this study. Using G * Power software (Software output is attached) to calculate the sample size for repeated measures ANOVA and assuming a probability of a first - type error 5%, the probability of a Second - type error of 10%, The amount of effect of 0.25, and a correlation between time to 0.5, total samples were equal of 47, which Assuming 10 % fall the total number of 106 people, 53 people in each group. It should be noted that if the comparisons between the two groups were considered 7 days after the study, with a standard deviation of 0.45 in each group and a difference between the score of 0.3, and assuming the probability of the first type error being corrected the number of 50 people in each group will have 80% power.

The standard deviation is based on a review of the literature that reported the standard deviation of the score from 0.2 to 0.6.^{13,14} Considering the deletion of the group with zero score, we considered the standard deviation of 0.45 to score 1- 4.

Inclusion Criteria

At least 18 years old, Nipple fissure with 1-4 score for Store, Single delivery, The term baby, The natural weight of the baby (2500-4000 gr), Infant without congenital malformation; palate, jaw and face and short frenulum,

Exclusive breastfeeding Absence of nipple abnormalities such as nipple and breast or nipple surgery; very small or large breast, Lack of maternal immunodeficiency diseases; diabetes and hypertension, Lack of mother's neurological diseases and depression, Insensitivity to chamomile and lanolin ointments.

Exclusion Criteria

Sickness and bedridden baby, Mastitis; abscess or puerperal fever, Infant's being infected to oral infections Taking antibiotics, other topical ointment; or analgesics. The sequence was generated based on blocks of 4 that are balanced and not classified. For creating randomization list the method of permuted block randomized with a block size of four, was applied. Considering the number of samples that were 106 women, 27 blocks (27×4), created using online website (www.sealedenvelope.com). In order to considering the concealment in the randomization process, exclusive codes were applied on the ointments tubes and the desired codes were also created by the software.

The researcher (midwife), samples & Statistical Analyst is not informed of the type of Treatment used in the studied groups.

Chamomile ointment, 1.5 percent, manufactured by Razak laboratory. The produced ointment was filled into the same tubes and handed over to mothers. Lanolin ointment manufactured by Farabi pharmaceutical company and then filled into the same 20g tubes by pharmacist and handed over to mothers. During the intervention the researcher, in all samples in both intervention groups, was observing the mother BF and she was instructing the correct manner of BF to all mothers and for inspecting of possible allergic status, 8 hours prior to the application of medicine, it was being tested in inner part of the arm. Prior to the application of medicine, it was ordered to wash up the hands, the ointments were applied 3 times a day (Every 8 hours) in the amount of one finger (1g) on the areola and nipple. Until the next BF the ointment was remaining on the nipple. The treatment period continued 7 days. The symptoms of nipple sore (Redness, sore, bleeding and ache) in both chamomile and lanolin ointments, prior to intervention, was evaluated and compared by tools. Storr scale was used for assessing the severity of nipple sore in this study. The Storr scale has been validated in 1988 by Storr using the content validity method and by measuring its Cronbach's alpha coefficient.¹⁵ It has five degrees, from zero to four as follows: A painless nipple = 0, a slightly reddened nipple =1, a reddened nipple with pain = 2, a nipple beginning to develop fissure with pain =3 and a nipple fissure with pain at the beginning of and in the intervals between BF =4. The scale has also been confirmed for use in Iran by many studies by measuring its content validity. In a study to determine the reliability of the tool Storr Equivalence Reliability Method (Simultaneous Observation Test). It was used and approved with an agreement rate of 92%.¹⁶

Nipple pain was assessed using Visual Analog Scale. This measure is a standard tool and its validity has been confirmed¹⁷ and the reliability of the test was confirmed by a re-test method.¹⁸

This scale has 10 points; point zero was given for 'no pain' and the score of ten showed extremely severe pain. Previous studies have shown that the pain scale has adequate validity and it has been used in several studies for the assessment of the severity of breast pain. In one study, Tafazoli et al.

examined the parallel-forms reliability of the scale.¹⁹ and the reliability of the VAS tool was calculated by Ali Tavakoli et al. 2005 through Cronbach's alpha and a reliability coefficient of

0.7 was calculated.²⁰ The validity of the instrument for determining the pain level was determined with a confidence coefficient of 82% to 91%.²¹

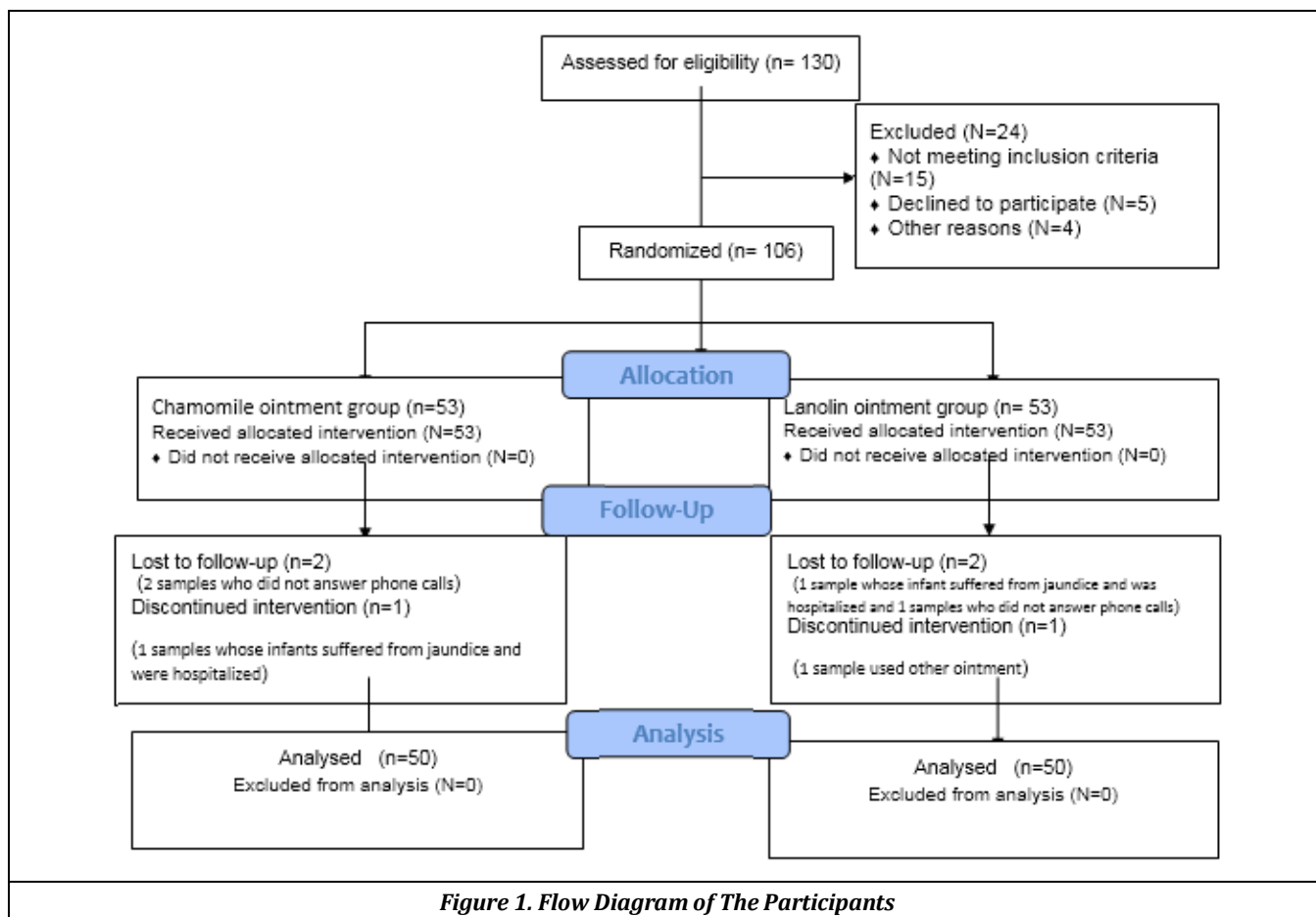


Figure 1. Flow Diagram of The Participants

Quantitative Variable	Chamomile Ointment	Lanolin Ointment	p-Value
	Mean ± SD	Mean ± SD	
Maternal Age	27.44 ± 4.67	27.98 ± 4.98	0/578*
Maternal Height	164.38 ± 8.35	163.74 ± 5.95	0/660*
Maternal Weight	73.24 ± 11.66	75.40 ± 9.10	0/304*
Neonatal Weight in Birth	3.169±0.361	3.170 ± 0.293	0/990*

Table 1. Comparison of Demographic Characteristics of The Participants

*Independent t-test

Statistical Analysis

Continuous variables were expressed as mean ± SD and categorical variables were summarized as frequencies and percentages. The analysis of categorical variables was done using the Chi-square test or Fisher's exact test, as appropriate. Comparison of continuous variables between two groups was done using independent t-test. We compared outcomes between two groups during three time using repeated measures ANOVA. Analysis of covariance (ANCOVA) was used for comparing outcomes between two groups adjusted on the baseline measures. All statistically significant analyses were conducted in SPSS version 22 (IBM Company, USA). A P value less than 0.05 was considered statistically significant.

This study Conducted After obtaining the license and approval of ethic committee of Iran university of medical sciences and registration of the research in Iranian Registry

of Clinical Trials and obtaining license from selected health and therapeutic centers, From the mothers, who were eligible and willing to participate in this experiment, the written informed consent form was obtained.

RESULTS

The study participants' demographic and Obstetrical information is presented in Table 1 & 2 accordingly, no significant difference was found between the two groups with the results of Independent t-test regarding the mean Maternal age, height, weight and Neonatal weight (P>0.05). Also Fisher's exact test indicated no significant difference between the intervention and control groups in terms of Educational level, Job status, Socio-economic status, Number of deliveries, Time of fissure, and the results of Chi Square test revealed no significant difference between the two groups in Type of deliveries and neonatal age(P>0.05).

Among 130 enrolled participants, 106 subjects were eligible for inclusion, and 100 patients completed the study. [Fig.1]

Characteristic	Sub Group	Chamomile Group	Lanolin Group	p-Value
		N (%)	N (%)	
Educational Level	Under high-school	7 (13.92)	12 (23.54)	0/098*
	high-school	32 (64.13)	34 (68.52)	
	collegiate	11 (21.95)	4 (7.94)	
Job Status	Housekeeper	47 (94)	50 (100)	0/242*
	Employed	3 (6)	0	
Socio-Economic Status	Low	2 (4)	0	0/107*
	Medium	39 (78)	46 (92)	
	High	9 (18)	4 (8)	
Number of Deliveries	1	26 (52)	30 (60)	0/140*
	2	21 (42)	18 (36)	
	3	3 (6)	0	
	4	0	2 (4)	
Neonatal Age (Day)	3	5 (10)	7 (14)	**0/097
	4	16 (32)	8 (16)	
	5	20 (40)	22 (44)	
	6	3 (6)	10 (20)	
	7	6 (10)	3 (6)	
Type of Deliveries	C/S ^a	35 (70)	33 (66)	0/668**
	NVD ^b	15 (30)	17 (34)	
Time of ffssure (Day)	1	7 (14)	12 (24)	0/489*
	2	24 (48)	23 (46)	
	3	15 (30)	12 (24)	
	4	2 (4)	3 (6)	
	5	2 (4)	0	
Number of Breast Feeding	6-8	22 (44)	29 (58)	0/012**
	8-10	17 (34)	21 (42)	
	10-12	11 (22)	0	

Table 2. Comparison of Control and Intervention Groups With Regard To Qualitative Variables

^aCaesarean section, ^bnormal vaginal delivery, * Fisher's exact test, **Chi Square test

	Days	Chamomile Group N=50 Mean ± S.D.	Lanolin Group N=50 Mean ± S.D.
NSP ^a	0	6.84 ± 2.54	6.64 ± 2.73
	3	2.14 ± 1.36	3.98 ± 2.16
	7	0.50 ± 0.81	1.84 ± 1.65
NSS ^b	0	3.14 ± 0.94	3.16 ± 0.89
	3	1.22 ± 0.95	2.10 ± 0.81
	7	0.70 ± 0.68	1.00 ± 0.88
Repeated ANOVA	p-Value		
		NSP ^a	NSS ^b
	Time	<0.001	<0.001
	Group	0.228	0.336
	Time & group	0.019	0.001

Table 3. Comparison of Score Mean ± S.D. of Nipple Sore Pain (NSP) and Nipple Sore Symptoms (NSS), Before Intervention, 3 and 7 Days after Intervention

^aNipple sore pain. ^bNipple sore symptoms

	Chamomile Group N=50 Marginal Mean± (S.E)		Lanolin Group N=50 Marginal Mean± (S.E)	Pp-Value
	Days			
NSP ^a	3	2.08 ± 0.16	4.03 ± 0.16	<0/001*
	7	0.47 ± 0.14	1.87 ± 0.14	<0/001*
NSS ^b	3	1.22 ± 0.08	2.09 ± 0.08	<0/001*
	7	0.70 ± 0.09	0.99 ± 0.09	0/041*

Table 4. Analysis of Covariance in Order to Compare Score Mean of Nipple Sore Symptoms, and Nipple Sore Pain, 3 and 7 Days After Intervention

^aNipple sore pain. ^bNipple sore symptoms *Analysis of Covariance (ANCOVA)

Significations are based on Ancova using baseline measure as a covariate.

The nipple sore pain was evaluated, before intervention on days 3 and 7, the results indicate that in both groups the mean of nipple sore ache has had descending trend, and on days 3 and 7 has reduced. The mean of nipple sore ache prior to the intervention, was almost the same in both groups (6.64 ± 2.73 in lanolin ointment group (LOG)), 6.84 ± 2.54 in chamomile ointment group (COG)). Evaluation of the means indicates that in COG, the means have decreased with sharper slope and higher value. The mean was 1.84 in LOG and 0.50 in COG on day 7. The symptoms of nipple sore evaluated three steps before intervention on days 3 and 7. The results indicated that in both groups, the mean of nipple sore symptoms such as wound, has had descending trend and diminished on days 3 and 7. The mean of nipple sore ache prior to intervention was the same in both groups (3.16 in LOG and 3.14 in COG). The mean evaluation indicated that the rate of nipple sore symptoms diminution in COG has more intensively decreased. The mean decreased from 3.16 to 1 in LOG, and from 3.14 to 0.70 in COG on day 7. (Table 3).

The results indicated that all double-comparison have been significant ($p < 0.001$). In comparison of the nipple sore ache, prior to the intervention, to two steps on days 3 and 7 and, the nipple sore ache rate on days 3 and 7, there has been significant difference ($p < 0.001$). In both groups the mean of nipple sore ache, in compare before intervention, decreased, Likewise the nipple sore ache, on day 7 in both groups in compare to day 3, decreased. (Table 4).

DISCUSSION

The overall objective of this research has been the determination of chamomile ointment effect on the healing of breast-feeding mothers' nipple sore, the two study groups were balanced based on the baseline demographic and clinical characteristics. The evaluation of statistical analysis indicated that the reduction of MNS and NSP after treatment with chamomile ointment was significant. Likewise, the mean score of NSP in the chamomile group was significantly lower in compare to lanolin group after intervention. And now we are comparing the related researches with the present one. In the study, contrast the effects of chamomile and calendula ointments on the neonatal diaper dermatitis. The research results indicated that the intensity of dermatitis was significantly lower in chamomile group.²² The results are consistent with the present study. Likewise, performed a research aimed at determination of chamomile ointment effect along with placebo on the healing of episiotomy ulcer, the positive effect of chamomile ointment in the healing of episiotomy ulcer, conforms to the present research.²³

About the effect of chamomile on pain relief, In a study by Pazandeh, aimed at investigating the effect of aromatherapy with chamomile essential oil on episiotomy pain, the chamomile essential oil consumption group reduced the mean pain on seventh and fourteenth days.²⁴ and In the study which examined the effect of chamomile on the intensity of acute phase of active labor, the results showed that the aroma of chamomile essential oil compared with the drug significantly reduced the intensity of pain in the active phase of labor.²⁵ conducted a study on chamomile tea to improve primary dysmenorrhea. Showed that drinking chamomile tea is effective in relieving menstrual pain due to primary dysmenorrhea.²⁶ In the research of Alamolhoda in the evaluation of Aloe Vera gel effect on the curing of nipple sore,

observed significant decrease in the ache score of Aloe Vera gel applied group, Aloe Vera contains components such as Flavonoids, and vitamins A and C, Considering the presence of the equal materials in chamomile and Aloe Vera, it can be said that the same process exists in chamomile with mentioned plant for decreasing of ache.²⁷ In a clinical trial conducted on children with atypical dermatitis in order to compare the cream containing chamomile and hydrocortisone 0.05%, chamomile recovery was found to be due to hydrocortisone.²⁸ Also, in a study on 61 patients with eczema, the comparison of chamomile cream and steroid and non-steroid drugs in the treatment of eczema showed that chamomile and hydrocortisone had the same effect and the duration of treatment in the chamomile group was lower.²⁹ The study aimed to compare the effect of chamomile and topical steroid solution on accelerating skin ulcer repair around colostomyoma on 72 patients with colostomy, indicating that recovery was faster with chamomile solution.³⁰

From the research constraints, the lack of control of the correct lactation and the nutritional status of those who are effective in wound healing are partly controlled by providing the same training in lactation and random selection of individuals.

The strengths of this study, as compared with previous studies, have prevented the mother from having a routine fissure Treatment (breast milk).

CONCLUSIONS

This study showed that chamomile ointment was effective in decreasing nipple sore intensity and pain. Hence, besides other methods, chamomile ointment can be useful in preventing and treating wound and sore without any side effects. Thus, it is recommended to be used for curing of nipple sore and continuation of lactation.

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