

Effect of the Topical form of *Achillea millefolium* on Nipple Fissure in Breastfeeding Women: A Randomized Controlled Clinical Trial

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ABSTRACT

Background: Nipple fissure is one of the most common diseases in breastfeeding which leads to maternal pain and disruption of the mother-infant relationship. Since the most important consequence of nipple fissure is the deprivation of the infant from breast milk, it is very important to prevent and treat this condition. The aim of this study was to investigate the effect of the topical form of *Achillea millefolium* on nipple fissure in breastfeeding women referring to the comprehensive health centers of Hamadan, Iran.

Methods: This study was a randomized double-blind clinical trial that was conducted in Hamadan comprehensive health centers in 2018. Treatment methods were taught by the researcher to 80 eligible breastfeeding women who were randomly divided into two groups of 40 subjects. After breastfeeding, the intervention group covered their own nipples with a tea bag of *Achillea millefolium*, while the control group applied some of their own hindmilk on their nipple. These interventions were performed at least 4 times a day for 14 days. Checklists of store fissure scale, visual analog scale, and midwifery and demographic characteristic questionnaire were completed in both groups before the treatment and 4, 8, and 14 days after starting the treatment. The data were analyzed using SPSS software (version 16).

Results: The results showed that the intensity of fissure and the mean pain score in the two groups were not statistically significant in the pre-intervention phase. However, the scores of the intensity of fissure and pain in the *Achillea millefolium* group were lower than those in the breast milk group on days 4, 8, and 14 after the intervention, and these differences were statistically significant ($P < 0.001$).

Conclusion: The results of this study showed that the topical form of *Achillea millefolium* was more effective than breast milk in treating nipple pain and fissure.

Keywords: *Achillea millefolium*, Breast milk, Nipple fissure

Introduction

Breast milk plays an important role in the health of mothers and infants and helps the physical and mental development of infants (1). The benefits of nutrition with breast milk are known for both mother and infant. It reduces the risk of sudden infant death syndrome and respiratory infections. Moreover, it is always available and does not need to be warmed or sterilized (2, 3) and has a positive effect on

maternal body and mind. It also reduces the risk of breast and ovarian cancers in mothers (4, 5). The risk of anemia in mothers comes down with the early contraction of the uterus and amenorrhea. In addition to affecting the health of mother and infant, breast milk plays a significant role in the family and community economy by reducing costs related to milk purchase or health care (3). Therefore, the implementation of counseling

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sessions to encourage mothers to feed their infants with their own milk can be helpful (6).

One of the problems that may occur during breastfeeding, especially in early breastfeeding, is nipple fissure that may result in the deprivation of the infant from breast milk (7). The main causes of nipple fissure are incorrect breastfeeding, frequent milking, incorrect infant separation from the breast, and nipple dryness due to excessive washing, especially washing with soap and water (8, 9). It is estimated that 80-90% of breastfeeding women experience mild nipple pain which can become fissure if neglected (10). This pain not only is physical pain but also can interfere with the emotional relationship between mother and infant (11). On the other hand, breastfeeding avoidance and lack of milking cause severe pain, fever, swelling, abscess, and mastitis.

Topical ointments, solution, or spray of collagenase and lanolin and application of milk on the nipple are methods used to prevent and treat nipple fissure (9). *Achillea millefolium* plant is one of the most famous herbs which was used extensively in ancient medicine for the treatment of diseases (12). The main constituents of yarrow include sabinene, beta-pinene, 1,8-cineole, artemisia ketone, linalool, alpha-thujone, beta-thujone, camphor, borneol, fenchyl acetate, bornyl acetate, (E)-beta-caryophyllene, germacrene D, caryophyllene oxide, beta-bisabolol, delta-cadinol, chamazulene, flavonoids, and alkaloids (13). The most important therapeutic properties of *Achillea millefolium* are their antibacterial and anti-inflammatory features (14). A wide range of pathogens in humans whose amount of flavonoid is attributed (15).

The other therapeutic properties of this medication include menstrual pain relief, kidney function improvement, joint pain relief, face wrinkle prevention, treatment of shortness of breath, reduction of hair loss, vitiligo treatment, and disposal of intestinal and stomach worms (12, 16, 17). Moreover, this herb strengthens and protects the skin and is used for wound and skin damage healing (18). Therefore, this study was conducted with the aim of determining the effect of the topical form of *Achillea millefolium* on nipple fissure in breastfeeding women referring to the comprehensive health centers of Hamadan, Iran, and comparing it with breast milk.

Methods

This study was a randomized double-blind clinical trial. It was registered in the Iranian Clinical Trials Center with the IRCT code of

20180707040370N1. This study was conducted in all comprehensive health centers after obtaining the approval of the Ethics Committee and obtaining consent from participants from September to February. Based on a study performed by Alam-al-Hoda et al. (19), the sample size was estimated at 84 participants considering a 15% dropout and 95% confidence level.

The subjects were randomly divided into two groups of 42 subjects in each group and received *Achillea millefolium* tea bags or breast milk. Group assignment was performed by the balance block randomization method. Data collection tools included observation checklist and midwifery and demographic characteristic questionnaire completed verbally and by telephone before the intervention, as well as 4, 8, and 14 days after the intervention for both groups. In order to measure the nipple fissure, the checklist of fissure intensity named store scale rated on a four-point scale (i.e., 0-4) was used in the study. The fissure scoring is defined as follows: painless nipple with natural color (0 point), a little red nipple and pain just at the beginning of breastfeeding (1 point), red nipple and pain at the beginning of breastfeeding and between breastfeeding intervals (2 points), nipple fissure with pain at the beginning of breastfeeding and between breastfeeding intervals (3 points), presence of a wound or fissure with/without bleeding, along with pain, at the beginning of breastfeeding and between breastfeeding intervals (4 points) (20).

Visual analog scale was used to determine pain severity. This scale includes a 10-cm horizontal line, one end of which represents "the lack of pain", and the other end is "the most severe pain possible". The amount of pain was calculated using a graded ruler on which the subjects marked their pain. The inclusion criteria for the breastfeeding women were breast fissure with a minimum rank of 2 in the stores scale, a term infant, exclusive breastfeeding, no infantile infection with any kind of abnormalities in the mouth, palate, jaw, or face, absence of maternal infection with any kind of nipple abnormality or previous surgery of the nipple and areola, lack of addiction, and absence of any known psychological problems. The exclusion criteria were maternal diagnosis with mastitis, abscess, or fungal infections of the breast, infantile diagnosis with oral mucosa, maternal use of antibiotics, and use of a pacifier for infants.

Before the intervention, the correct method of breastfeeding was educated through distributing

pamphlets to all mothers. *Achillea millefolium* flower was obtained from Hamadan Pharmaceutical Medicines Market for the preparation of medicines. The plant was confirmed by the Department of Pharmacognosy of Hamadan University of Medical Sciences. For the ease of administration, the plant was ground and then packed. The participants in the intervention group were taught to first fill a cup with hot water and put the *Achillea millefolium* tea bags in water, remove it after getting wet, extract excess water from it, and then place it on the nipple and areola for 15 min and let it dry. In the control group, the subjects were recommended to place some of their own hind milk on the nipple and areola after breastfeeding (at least 4 times a day) and let it dry in the air. These methods were performed at least 4 times a day for 14 days.

The data were analyzed in SPSS software (version 16). We used Kolmogorov-Smirnov test and independent sample t-test or Mann-Whitney to compare the two groups. Friedman test was also used to investigate the changes in the intensity of fissure within groups, and Mann Whitney U test was used to analyze the scores of the intensity of fissure between the two groups. Repeated measures ANOVA tests, Bonferroni follow-up test, and independent sample t-test were used to investigate the changes in the mean of pain within groups, compare pain scores in different follow-up times, and examine the mean score of pain in the two groups, respectively. The significance level was considered 0.05.

Results

In total, 80 eligible breastfeeding mothers

divided into two groups of *Achillea millefolium* tea bags (n=40) and breast milk (n=40) participated in the study. However, two participants per group were missed during follow-up. Basic information of the participants in the two groups is provided in Table 1. Kolmogorov-Smirnov test was used to investigate the distribution of quantitative data, which were found to be homogeneous. Friedman test was used to investigate the changes in the intensity of fissure within groups. The results showed that the intensity of fissure in both groups decreased with the passage of time ($P<0.001$). Comparison of follow-up times in the breast milk group showed that there was a statistically significant decrease in the intensity of fissure 4, 8, and 14 days after the intervention, compared with that at the pre-intervention stage. Meanwhile, there was a significant decrease in the intensity of fissure on days 8 and 14 than on day 4, as well as on day 14 than on day 8. Comparison of follow-up times in the *Achillea millefolium* group also showed the same results.

Mann Whitney U test was used to investigate the scores of the intensity of fissure between the two groups. The results showed that the intensity of fissure in the two groups in the pre-intervention stage was not statistically significant ($P=0.21$). However, the score of the fissure intensity was lower in the *Achillea millefolium* group than in the breast milk group 4, 8, and 14 days after the intervention, and these differences were statistically significant ($P=0.01$, $P<0.001$, and $P<0.001$, respectively; Table 2).

The repeated measures ANOVA test was used to investigate the changes in the mean pain within groups, and the results showed that the mean

Table 1. Comparison of basic information of participants between the two study groups

Variable	Breast milk n=40	<i>Achillea millefolium</i> n=40	Test statistic	P-value
Mother's age, year	27.33 (6.20)	26.10 (6.25)	0.88	0.38
Job				
Employed	2 (5.0)	0 (0.0)		**49.0
Housewife	38 (95.0)	40 (100.0)		
BMI	23.87 (3.64)	26.19 (5.10)	-2.36	0.02
History of delivery				
Primiparity	17 (42.5)	23 (57.5)	1.8	0.18
Multiparity	23 (57.5)	17 (42.5)		
Infant's age, day	4.10 (5.04)	3.45 (3.20)	-0.21	*0.83
Satisfaction with breastfeeding				
Yes	6 (15.0)	5 (12.5)	0.11	0.75
No	34 (85.0)	35 (87.5)		
Infant sucking technique				
Correct	29 (72.5)	35 (87.5)	2.81	0.09
Wrong	11 (37.5)	5 (12.5)		

BMI: body mass index

* Mann-Whitney U test and the rest items, independent t-test

**Fischer's exact test and the rest, Chi-square test

Table 2. Comparison of the intensity of fissure separated based the study groups and follow-up times

Investigation time of the intensity of fissure	<i>Achillea millefolium</i> mean (SD)	Breast milk group Mean (SD)	Z	P-value*
Before intervention	3.68 (1.12)	3.98 (1.23)	-1.26	0.21
4 days after intervention	3.28 (1.11)	3.89 (1.20)	-2.49	0.01
8 days after intervention	2.05 (0.55)	3.78 (1.17)	-6.06	<0.001
14 days after intervention	1.23 (0.42)	2.48 (1.13)		
X ²	106.82	85.74		
P-value**	<0.001	<0.001	-5.47	<0.001
P-value***	(0.001) a (<0.001) b,c,d,e,f	(0.04) a (0.005) b,d (<0.001) c,e,f		

* Mann Whitney U test; ** Friedman test; *** Wilcoxon test (Before intervention - 4 days after intervention: a, before intervention - 8 days after intervention: b; before intervention - 14 days after intervention: c; 4 days after intervention - 8 days after intervention: d; 4 days after intervention - 14 days after intervention: e; 8 days after intervention - 14 days after intervention: f)

Table 3. Comparison of mean pain scores based on the study groups and follow-up times

Investigation time of the pain scores	<i>Achillea millefolium</i> mean (SD)	Breast milk group mean (SD)	t	P-value*
Before intervention	6.98 (1.86)	6.78 (1.51)	-0.53	0.60
4 days after intervention	4.45 (1.30)	6.15 (1.41)	5.62	<0.001
8 days after intervention	2.03 (1.17)	4.58 (1.43)	8.74	<0.001
14 days after intervention	0.40 (0.78)	2.65 (1.72)		
F	443.05	131.48	7.55	<0.001
P-value**	<0.001	<0.001		
P-value***	(<0.001) a,b,c,d,e,f	(<0.001) a,b,c,d,e,f		

* Independent t-test; ** repeated measures-ANOVA test; Bonferroni's follow-up test (Before intervention - 4 days after intervention: a, before intervention - 8 days after intervention: b; before intervention - 14 days after intervention: c; 4 days after intervention - 8 days after intervention: d; 4 days after intervention - 14 days after intervention: e; 8 days after intervention - 14 days after intervention: f)

score of fissure pain in both groups decreased with the passage of time ($P < 0.001$). However, the pain reduction rate was greater in the *Achillea millefolium* group than in the breast milk group. Comparison of follow-up times using Bonferroni follow-up test in the breast milk group showed that there was a statistically significant decrease in the mean pain scores 4, 8, and 14 days after the intervention in comparison to that obtained at the pre-intervention stage. Meanwhile, there was a significant decrease in the mean scores of fissure pain on days 8 and 14 than on day 4 as well as on day 14 than on day 8. Comparison of follow-up times in the *Achillea Millefolium* group also showed the same results.

Independent sample t-test was used to compare the mean pain scores between the two groups. The results showed that the mean pain score was not significantly different between the two groups at the pre-intervention stage ($P = 0.60$). Nonetheless, the pain scores were lower in the *Achillea millefolium* group than in the breast milk group 4, 8, and 14 days after the intervention, and these differences were statistically significant ($P < 0.001$; Table 3).

Discussion

The results of this study showed that there was a significant decrease in the intensity of fissure

and the mean score of pain after the intervention in both groups of breast milk and *Achillea millefolium* teabags ($P < 0.001$). However, the improvement in the *Achillea millefolium* group was faster than that in the breast milk group. Hemmati et al. (2002) investigated the effect of *Achillea millefolium* extract on rabbit skin wound healing and compared it with 1% phenytoin cream. In the mentioned study, a remarkable improvement was observed in the *Achillea millefolium* group compared to that in the phenytoin cream group ($P < 0.01$). The wound healing in the group treated with *Achillea millefolium* was also accelerated. This is consistent with the results of our study (21). In another study, Mohammadzadeh (2005) et al. evaluated the effect of lanolin cream on the improvement of nipple fissure. They showed an improvement in the breast milk group; however, pain and fissure intensity reduction was more significant in the *Achillea millefolium* tea bag group (22). Likewise, Sayyah Melli (2007) et al. compared the effect of peppermint extract and breast milk on the prevention of nipple fissure. They reported that the group of peppermint extract showed pain reduction at a more significant level than the breast milk group (23).

In another study, Kazemi Rad (2013) reported that cleared cream-E reduced the intensity of

fissure more than breast milk (24). The mean score of wound healing in the *Achillea millefolium* group was also higher than that in the breast milk group in the present study. In a study by Akbari (2014) et al., the improvement of pain and nipple fissure ulcer was lower in the breast milk group than in the menthol group (25). Another study was conducted by Ghareh Khani (2018) with the aim of comparing the effects of peppermint tea bags, peppermint cream, and extracted breast milk on the improvement of nipple fissure during breastfeeding. The results showed that the extracted breast milk was more effective than peppermint tea bags and peppermint cream in treating nipple fissure. The results of the present study are not consistent with those of the aforementioned research due to the faster improvement of breast fissure in the *Achillea millefolium* group (26).

Hajhashemi et al. (2018) compared the effects of *Achillea millefolium* and *Hypericum perforatum* on episiotomy wound healing in primiparous women. Levels of pain, redness, edema, and ecchymosis were lower in the recipients of *Hypericum perforatum* and *Achillea millefolium* than in the placebo group ($P < 0.05$). The results of the mentioned study confirm the effect of *Achillea millefolium* ointment on pain relief, as well as redness and wound healing, which is consistent with the results of our study (27).

The lack of cooperation of some of the subjects was the limitation of this study which was solved by more training and further explanation. Furthermore, the incorrect breastfeeding at home, non-observation of *Achillea millefolium* administration by health staff, and incorrect administration of *Achillea millefolium* tea bags could make the research process difficult to control. However, these problems were eliminated by verbal training and providing pamphlets at health centers.

Conclusion

According to the results of this study, it seems that *Achillea millefolium* plant is more effective than breast milk in the improvement of nipple fissure. This herb strengthens and protects the skin and has anti-inflammatory properties. Therefore, given the cheapness, availability, and easy administration (topical route) of this herb, it can be considered a useful agent for the faster improvement of nipple fissure.

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Conflicts of interest

All authors declare that they have no conflicts of interest.

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