

# New treatment for nipple soreness in breastfeeding mothers: A clinical trial study\*\*

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## ABSTRACT

**Background:** A common, early postpartum concern of the breastfeeding mother is nipple pain. Because of a lack of effective treatment and opposing results about lanolin, we decided to compare the effect of lanolin ointment and aloe Vera gel on nipple soreness treatment.

**Methods:** This clinical blind trial was performed in Mashhad, Iran, from February 2008 to May 2009. Sampling was nonrandom and purposive, and then samples were divided randomly into two groups. After first applying the preparation on their arms to check for allergy symptoms, mothers were instructed to then rub the preparation on their nipples three times a day for seven consecutive days, each application performed after feeding the baby. Mothers were to let the preparation dry and not to wash it before the next feeding. Researcher pretreatment at the third and seventh day filled out the Storr scale with interviews and examinations. There were no complications in mothers and infants because of the drug's usage. The data was then analyzed with Spss 11.5 and Mann-Whitney, Student's t-test, and t-paired tests.

**Results:** A total of 100 samples enrolled with 50 samples in the lanolin group and 50 samples in the aloe vera group. In aloe Vera group Nipple soreness scoring decreased significantly at the third day versus pretreatment ( $p=0.00$ ) and also at the seventh day versus pretreatment and the third day ( $p=0.000$ ). Nipple soreness scoring decreased significantly at the third day versus pretreatment ( $p=0.00$ ) and also at the seventh day versus pretreatment and the third day ( $p=0.000$ ,  $p=0.001$ ). The two groups were homogenous at the pretreatment day ( $p=0.711$ ), but there was a significant difference between the two groups at the third and seventh day ( $p=0.048$ ,  $p=0.003$ ).

**Conclusion:** Aloe Vera is more effective than lanolin on nipple soreness healing.

**Key words:** aloe Vera gel, breastfeeding, Nipple soreness, lanolin ointment, Storr scale

## Introduction

The benefits of breastfeeding for mothers and newborns have been well documented, but a common, early postpartum concern of the breastfeeding mother is nipple pain (1,2). Nipple trauma is defined as a discontinuity of nipple skin (3).

It is estimated that 80 to 90 percent of breastfeeding women experience some nipple soreness (4) and up to one-third of mothers who experience these symptoms may have stopped breastfeeding within the first six postnatal weeks(5). And it is commonly known that pain

acts as an inhibitory effect on the release of oxytocin and milk ejection (6,7,8).

Traditionally, lanolin was considered for preventing dryness and fissuring.(9) But some women cannot use it because of an allergy or because of various research studies reporting an opposing effect of lanolin on nipple soreness (10,11,12).

Aloe Vera has been proposed as an enhancer of wound healing based on animal research. It is a cell proliferant, a stimulate to epithelialization, and a chemical debrider (13). Aloe Vera has a positive influence on skin wound repair, anti-

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inflammation, antimicrobial, and immune-modulation.(14) It is beneficial to the treatment of disorders such as acne, dermatitis, colitis, psoriasis, diabetic wounds, herpes, and bedsores (15,16). Avizgan showed the mean treatment duration was longer in the control group than in the Aloe Vera group for bedsore treatment (17). In this study, we compared the effect of lanolin ointment and aloe Vera gel on nipple soreness treatment.

## Method

This single-blind clinical trial study was performed in the NICU ward of Ghaem Hospital in Mashhad, Iran, from February 2008 to May 2009.

Sampling was nonrandom and purposive, and then the samples were divided randomly into two groups: aloe Vera and lanolin. Sample size was determined with a 95 percent confidence interval and an 80 percent power analysis. The project was approved, and informed written consent was obtained in accordance with the Mashhad University of Medical Sciences.

The sample included healthy, lactating women who reported to the sheikh clinic because of nipple soreness that did not improve after treatment with an application of mother's milk, who earned at least a two according to the Storr scale, who resided in Mashhad, and who had the ability to read and write. Mothers were excluded from the study if they had preterm delivery, fever, breast infection, and nipple abnormalities, had twins, took other treatment, did not have a telephone, or were illiterate. In addition, infants who were fed infant formula, used a pacifier, had a mouth infection, had an abnormal mouth, or were more than six months old were also excused. Patients were discharged if they did not visit on the third or seventh day, did not use their treatment for one day, used the treatment less than twice a day, or had an allergy to lanolin or aloe Vera.

All candidates received comprehensive education about the study and its probable complications, and they corrected their breastfeeding technique at pretreatment and at the third and seventh days of the study.

Aloe Vera gel and lanolin ointment were unknown to the mothers. A brief description of the aloe Vera gel preparation is outlined in the appendix. Mothers were instructed to rub the preparation on their arms and then, if there were no allergy symptoms, to rub it on their nipples three times a day for seven consecutive days, each application performed after feeding the baby. The

mothers were to let the application dry and not to wash it before the next feeding. Researcher pretreatment at the third and seventh day filled out the Storr scale with interviews and examinations. All mothers were asked about the frequency of breastfeeding over the previous 24 hours.

Nipple soreness was defined based on the Storr scale that features five points from zero to four, and samples were included if scoring was two or higher.

A questionnaire was filled out, and mothers were asked about their age, BMI, parity, education level, activity, dominant breast, infant birth weight, and milker or sedative use. Follow-up telephone calls were conducted once every two days for interviews about complications and improvements. During the follow-ups, six samples were excluded because of a lack of regular drug usage. There were no complications in mothers and infants because of drug usage.

The data was then analyzed with Spss 11.5 and Mann-Whitney, Student t-tests, and t-paired tests.

## Results

A total of 100 samples enrolled with 50 samples in the lanolin group and 50 samples in the aloe Vera group. Mother age was between 16 and 40 years old with a mean of  $25\pm 7.23$ , and birth weight was between 255 to 4000g with a mean of  $3350\pm 250.22$ .

The groups were homogenous concerning mother education level, activity, dominant breast, mother BMI, age parity, infant birth weight, and frequency of breastfeeding in 24 hours ( $p>0.05$ ), but milk usage was significantly different in two groups ( $p=0.03$ ), and all the users were in the aloe Vera group.

Mean nipple soreness scoring in the aloe Vera group was 3.04 at pretreatment, 1.26 at the third day, and 0.26 at the seventh day. Nipple soreness scoring decreased significantly at the third day versus pretreatment ( $p=0.00$ ) and also at the seventh day versus pretreatment and the third day ( $p=0.000$ ).

Mean nipple soreness scoring in the lanolin group was 3.1 at pretreatment, 1.7 at the third day, and 1.02 at the seventh day, and nipple soreness scoring decreased significantly at the third day versus pretreatment ( $p=0.00$ ) and also at the seventh day versus pretreatment and the third day ( $p=0.000$ ,  $p=0.001$ ).

None of the mothers used sedation. The two groups were homogenous at the pretreatment day

( $p=0.711$ ), but there was a significant difference between the two groups at the third and seventh

## Discussion

Nipple soreness scoring decreased significantly at the third day versus pretreatment ( $p=0.00$ ) and also at the seventh day versus pretreatment and the third day. Nipple soreness scoring decreased significantly at the third day versus pretreatment and also at the seventh day versus pretreatment and the third day.

The two groups were homogenous at the pretreatment day, but there was a significant difference between the two groups at the third and the seventh day. Results showed agreement with a study Chitra had done to determine the effect of aloe Vera on wound healing in rats. Collagen content in the aloe Vera groups was significantly higher than in the control group ( $p<0.001$ ) (18).

Also, Aldehyde content in the aloe Vera groups was significantly higher than in the control group ( $p<0.001$ ). In the Chitra study, acceleration of collagen and aldehyde content was the criteria for wound healing, and their results confirmed our study results (18).

Avizgan performed a study to determine the effect of aloe vera gel on bed sore healing. Their results showed a significant difference between the two groups in wound healing ( $p=0.000$ ) (17). Their results confirmed our results in wound healing acceleration (17).

Jarrahi performed a study to determine the effect of topical aloe Vera on wound healing in rats. Aloe Vera gel accelerated wound healing in the case group versus the control group (19).

Julianne's study results did not confirm our results, and aloe Vera gel caused prolonged wound healing in cesarean sections versus the control group. Of course, a lot of samples dropped and affected their results (13).

In Pereira's study that evaluated the effect of lanolin on nipple soreness, nipple soreness improvement was significantly higher in the case group than the control group ( $p<0.001$ ), and their results confirmed our results (11).

Some research studies did not confirm our study results in the lanolin effects on nipple soreness.

The Brent study performed a comparison of lanolin and hydrogel on nipple soreness, but there was no significant difference between the two groups in nipple soreness healing ( $p>0.05$ ) (20).

Mohammadzadeh compared the effect of lanolin and breast milk on nipple soreness, and

day ( $p=0.048$ ,  $p=0.003$ ).

their study results showed that nipple soreness healing was significantly prolonged in the lanolin group versus the breast milk group ( $p=0.028$ ). (10)

In the Brent study, a lot of mothers who were treated with hydrogel were eliminated from the study because of breast infection, and this could have affected the results.

In the Mohammadzadeh study, there was no scale for nipple soreness grading, and this could have affected results.

## Conclusion

Aloe Vera is more effective than lanolin on nipple soreness healing.

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