



Comparing the Efficacy of Breast Milk and Coconut Oil on Nipple Fissure and Breast Pain Intensity in Primiparous Mothers: A Single-Blind Clinical Trial

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Abstract

Background: Nipple fissure is a prevalent problem for breastfeeding mothers. Virgin coconut oil (VCO) is an herbal medicine that can heal microbial infections and wounds.

Objective: This study aims to evaluate the efficacy of VCO and breast milk on nipple fissures in primiparous mothers.

Design, Setting, Participants, and Intervention: A single-blind clinical trial was conducted with 106 breastfeeding primiparous mothers suffering from nipple fissures in health centers of Zarand, Kerman, from August 2020 to November 2020. The participants were selected randomly and allocated to two 60-member groups using block randomization. Mothers in the first group were asked to apply 0.5 mL of coconut oil on their nipples three times a day. Mothers in the second group were trained to apply three to four drops of their milk on their nipples after every breastfeeding session. The level of nipple fissures and pain intensity were examined using Storr's scale and visual analog scale, respectively. The results were analyzed using the chi-square test, repeated measures analysis of variance, and the independent samples *t*-test in SPSS 22. In this study, the significance level was set at $p < 0.05$.

Results: Within-group comparisons revealed a significant difference between baseline scores and the scores on the 7th and 14th days ($p < 0.001$). Between-group comparison indicated no significant difference in nipple fissure ($p = 0.419$) and pain intensity ($p = 0.405$) at baseline. Nonetheless, there was a significant difference on the 7th day ($p_{\text{fissure}} = 0.002$, $p_{\text{pain}} < 0.001$) and on the 14th day ($p_{\text{fissure}} < 0.001$, $p_{\text{pain}} = 0.036$).

Conclusion: Given its effect on nipple fissures, VCO may be used as a complementary substance to treat nipple fissures.

Trial Registration: This trial is registered with the Iranian Registry of Clinical Trials with the identifier: IRCT20190724044318N1.

Keywords: fissure, breast pain, Primipara, coconut oil, breastfeeding

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Introduction

BREAST MILK IS known worldwide as the safest and best way to feed infants.^{1,2} Mothers might sense pain, burning, and discomfort in their nipples during their first breastfeeding after delivery. A nipple fissure is a wound on a breastfeeding woman's nipples that may or may not bleed.³ It is a visible lesion that presents as scratches, cracks, sores, redness, swelling, or blisters on breastfeeding mothers' nipples and areolae.⁴ Nipple fissures have a prevalence rate between 34% and 96%.⁵⁻⁷ Intolerable pain due to nipple fissures results in anxiety, disruption in mother-infant relationships, and early breastfeeding cessation.

Cracked nipples might become a site for bacterial infection, resulting in breast mastitis or abscesses.^{5,8} If left untreated, fissures might result in complications such as bleeding and insufficient milk output, intense pain, breast abscesses, and mastitis. Thus, when nipples are inflamed or cracked, restorative steps must be taken to alleviate discomfort, heal the wounds, speed up recovery and breastfeeding, prevent infection, and restrict the infant's nourishment to breastfeeding.^{4,8}

There are a variety of topical interventions suggested to ease nipple pain. Breast milk application is an affordable, simple, and safe treatment that reduces nipple pain and its duration. Breast milk has been recommended to treat nipple fissure since it consists of various antibodies and antibacterial and anti-inflammatory properties.^{6,9,10}

Given the concerns regarding the harmful side-effects of industrial medicine, there is an increasing demand for herbal and natural medicine to treat breastfeeding complications, which requires introducing more effective and newer compounds. As complementary therapies, herbal products are high in antioxidants and effective anti-inflammatory compounds that help heal wounds. Virgin coconut oil (VCO) is one of several herbal products that have been used to treat microbial infections and wounds for years.¹¹ VCO is a clear to pale-yellow liquid extracted from ripe coconut and counts as a processed plant-based oil that can also be consumed orally.^{1,12} VCO can be very beneficial in treating skin disorders accompanied by impaired permeability, such as eczema and atopic dermatitis.¹³

VCO contains rich, saturated fats that aid retain the skin's moisture content. It is an all-natural, delicious-smelling moisturizer that soothes and nourishes without the risk of irritating the skin.¹⁴ Applying a coconut extract to human skin may enhance its protective barrier functions and has anti-inflammatory and antibacterial properties. Coconut oil fights *Candida albicans* (*C. Albicans*), suggesting it could be a treatment for Candidiasis. This may be due to the extract's barrier functions and anti-inflammatory properties.¹⁵

In a clinical trial, the use of turpentine in cracked nipples of nursing mothers reduced the pain intensity.¹⁴

Another study found that the use of jujube fruit lotion was more effective in relieving the pain caused by cracked nipples in nursing mothers compared to breast milk.¹⁶

A clinical trial was carried out to determine the impact of aloe Vera gel on nipple fissures in 110 breastfeeding mothers.

A study examined the impact of applying silver cups on nipple fissures. Two 20-member groups of intervention and control participated. The controls were given a standard care manual handbook, and the participants in the intervention

group were treated with silver cups. Both groups were handed questionnaires for daily examination. Visual breast reports on days 0 and 15 indicated that by the end of day 15, the intervention group improved better than the control group.¹⁷

Few studies have examined the effectiveness of VCO on human nipple fissures. Given the lesion's high prevalence, its direct impact on premature breastfeeding cessation, and the lack of an appropriate and definitive method to prevent and treat it, the present study was conducted to determine the impact of VCO on nipple fissure and pain induced by breastfeeding.

Materials and Methods

Study design

The present study is a single-blind (outcome assessor) randomized clinical trial with two experimental groups. The primary purpose is to compare the impact of breast milk and VCO on nipple fissure healing in primiparous mothers.

Study setting

The study was conducted on breastfeeding primiparous mothers referring to health care centers in Zarand, Kerman, on the third day of delivery from August 2020 to November 2020. They visited to screen their infants for hypothyroidism (a prevalent screening in Iran); meanwhile, nipple fissures and pain were also examined. The mothers signed written consent forms for participation after being informed about the research objective and methods.

Sample size

The sample size was computed based on the study conducted by Niazi et al in 2018, considering a between-group difference equaling $\delta=2$, the standard deviation of $\sigma_1 = \sigma_2 = 2.5$ for the nipple pain variable, and the first and second type errors equaling $\alpha = 0.05$ and $\beta = 0.20$. Hence, a minimum sample size of $n_A = 35$ per group was obtained according to the following equation.¹⁸

$$n_A = \frac{(\sigma_1^2 + \sigma_2^2) \left(Z_{1-\frac{\alpha}{2}} + Z_{1-\beta} \right)^2}{\delta^2} + \frac{Z_{1-\frac{\alpha}{2}}^2}{4} = 35 \quad (1)$$

Given the potential attrition, 60 women were considered per group and 120 people for both groups.

Flowchart of the study

The samples were selected from breastfeeding mothers referring to health care centers in Zarand, Kerman. In this study, 120 women who complained about difficulties in breastfeeding were recruited and assessed. Fourteen out of 120 (11.67%) were excluded: 2 women were excluded based on age (>40 years old), 8 women had no nipple fissures, 1 woman reported an allergy to coconut, and 3 women refused to participate in the study.

The study continued with 53 participants in the VCO group, of whom $n=3$ (5.6%) discontinued treatment: 2 discontinued due to excessive subjective pain on day 5, and 1 failed to respond to the telephone follow-up on day 7 and to have the final visit on day 15. Similarly, 5 (9.4%) out of 53 participants

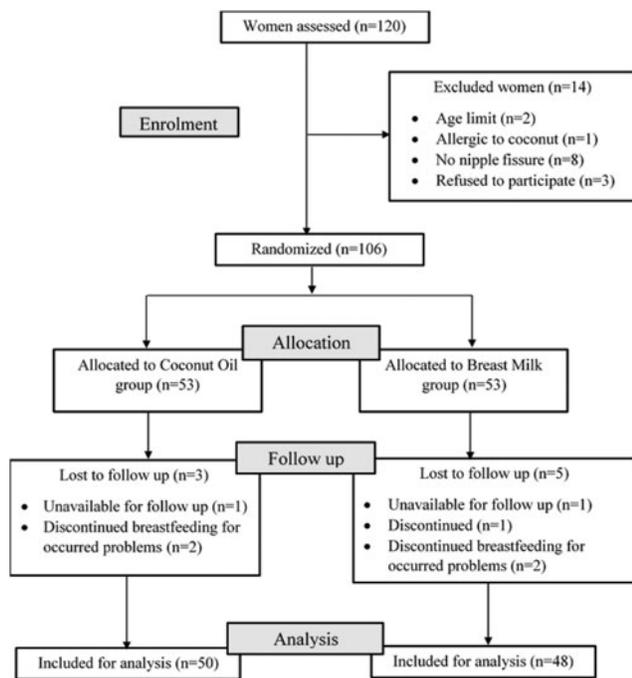


FIG. 1. Flowchart of the study.

in the breast milk group discontinued treatment: 1 participant did not respond to the telephone follow-up on day 7 and did not come for the final visit; 3 participants discontinued participation due to excessive pain (2 women on day 5 and 1 on day 6), and 1 participant used an alternative treatment such as tocopherol oil (vitamin E) to resume breastfeeding. Therefore, the statistical analysis was performed based on the data collected from the remaining participants: 50 in the VCO group and 48 in the breast milk group (Fig. 1).

Inclusion and exclusion criteria

The inclusion criteria involved mothers within their first 6 weeks after labor, nipple fissure, a score of three or higher on Storr's scale, age between 18 and 40 years, newborn being exclusively fed by breast milk, single-term delivery within normal weight range (2.5–4 kg), absence of maternal nipple abnormalities, no history of maternal surgery on nipple and areolae, absence of maternal mental illness and skin disease, absence of maternal sensitivity to VCO, and absence of neonatal oral, palatal, or maxillofacial abnormalities. Upon inclusion, a participant was excluded in cases of using breast pumps, experiencing nipple fungal infection or abscess, using other treatments, or cases where the infant was fed on anything other than breast milk. All mothers referring to the selected health care centers were examined using Storr's scale before the intervention. Eligible participants obtaining the score of 3 or higher on the scale entered the study.

Randomization and blinding

Random allocation sequences were determined using a computer program (www.random.org) by a research team member not involved in sample selection. Opaque sealed, sequentially numbered envelopes were used to conceal the

allocation. Eligible individuals were randomly assigned to two groups (VCO and breast milk) using block sizes of 4 and 6 with a 1:1 allocation ratio. Besides, the outcome assessor was blinded to the treatment given to any given participant. The data were collected from the participants on days 1, 7, and 14 of the experiments.

It should be noted that the sampling method in this study was multistage. The first two centers (2 and 4) were randomly selected (using coin toss) from the four health centers in Zarand. Proportionate to the number of patients referring to the gynecology and obstetrics unit, two health bases affiliated with each health center (two bases from the health center No. 2 and two bases from the health center No. 4) were randomly selected (using coin toss). Afterward, the samples were selected via the convenience sampling method from breastfeeding women referring to the centers for nipple fissure and breast pain. Finally, the participants were assigned randomly to one of the two groups of breast milk and VCO.

Intervention

The study intervention comprised VCO topical application on the nipple and the areolae. The oil used in this study was 100% pure VCO purchased from the Barij Essence Pharmaceutical Company in 30 mg bottles. Primiparous mothers who were in their first 6 weeks after delivery and referred to Zarand health care centers due to nipple fissures were examined in terms of pain intensity and fissures' degree.

Eligible mothers were recruited and divided into two groups. The author provided sufficient explanation to the intervention group regarding proper breastfeeding techniques and the way to apply VCO. After the intervention group, participants were informed of appropriate breastfeeding practices, and they were given brochures on good breastfeeding techniques and VCO application.

Mothers in the intervention group were instructed to apply 0.5 mL of VCO on their nipples and areolae three times daily (after breastfeeding). The VCO had to remain on the skin for 1 hour, and if the mother fed the infant before 1 hour was completed, the intervention had to be repeated after breastfeeding. The mothers were also guided to cleanse their nipples with lukewarm water and a cotton 1 hour after VCO application. Mothers in the intervention group were trained to apply three to four drops of their milk on their nipple and areolae after every breastfeeding session and let it dry.

To ensure that the intervention was implemented correctly, mothers were asked to refer to health care centers on days 7 and 14 after the intervention to examine their nipple fissures and pain. The intervention in both groups was separately followed out for 14 days.

The author sent a reminder text message to participants of both groups every day at 8 a.m. In case a mother failed to refer to the health care center for any reason at the end of the intervention, the author visited the mother at her house and examined her nipple fissure and pain. Demographic data of the participants were collected using a demographics form, which was completed via an interview with the mothers on their first day of referral. The questionnaire items included age, education, job, weight, the number of pregnancies, childbirth complications, the onset of breastfeeding after childbirth, breastfeeding frequency per day, and breastfeeding techniques.

Main outcome measures

In this study, the visual analog scale (VAS) was used to measure the pain caused by breast fissures and Storr's scale to evaluate the levels of nipple fissures. Notably, the validity and reliability of the VAS and Storr's scale have been confirmed by Carlsson and Storr, respectively.^{19,20}

The VAS

VAS was first introduced in 1921 by two employees of the Scott Paper Company.²¹ Two years later, Freyd published guidelines for constructing these scales, which involved using a line no longer than 100 mm.²²

In the current study, a VAS is used to measure the pain caused by breast fissures. This scale consists of a 100 mm horizontal line, on whose two extremes are written "no pain" and "the worst possible pain." Based on the pain intensity categorizations as none, mild, moderate, or severe, the following cutoff points on the VAS have been recommended: no pain (0–4 mm), mild pain (5–44 mm), moderate pain (45–74 mm), and severe pain (75–100 mm). The patient marks the intensity of pain she experiences by indicating a position along the continuum with the two end-points.

Storr's scale

Storr's scale was first introduced in 1988 by Gail Blair Storr.²⁰ In this study, the author used the scale to evaluate the severity of nipple fissures on a 5-point scale scored from 0 to 4. Fissure scoring is as follows: painless nipples in normal color are scored 0; slightly reddened nipples and pain at the breastfeeding onset are scored 1; reddened nipples and pain at breastfeeding onset as well as in intervals between breastfeeding sessions are scored 2; slightly cracked nipples with pain at breastfeeding onset as well as in intervals between breastfeeding sessions are scored 3; and nonbleeding cracked nipples with pain at breastfeeding onset and in intervals between breastfeeding sessions are scored 4.

Statistical analysis

The participants' demographic data were analyzed using descriptive statistics. The pain intensity in primiparous mothers was analyzed using the chi-square tests. To compare within-group and between-group changes in the symptoms at the three time points (day 1: preintervention; day 7: mid-intervention; and day 14: postintervention), we administered the repeated measures analysis of variance and the independent samples *t*-test. The statistical analysis was carried out using SPSS 26.0 (SPSS, Inc., Chicago, IL) ($p < 0.05$).

Ethical issue

The Medical Research Ethics Committee affiliated with Kerman University of Medical Sciences approved the present study protocol (Ethical code: IR.KMU.REC.1399.204) (No. 98000598). The participants were assured of the confidentiality and anonymity of the study. Moreover, the study protocol was registered on the Iranian Registry of Clinical Trials (Identifier: 20190724044318N1).

Results

Demographic and baseline clinical characteristics

Table 1 reports the demographic characteristics of the participants and the results of the chi-square test. The results revealed that the two groups did not differ significantly in terms of age ($p = 0.461$), economic status ($p = 0.617$), newborn's birthweight ($p = 0.283$), type of delivery ($p = 0.219$), average breastfeeding duration ($p = 0.366$), the first incidence of nipple fissure after childbirth ($p = 0.130$), and first breastfeeding after delivery ($p = 0.762$).

There was no significant difference between the two groups regarding nipple fissure score at baseline ($p = 0.419$). Seven days after the intervention, the nipple fissure score decreased in both groups, and this decrease was greater in the VCO group than in the breast milk group ($p = 0.002$). The results also revealed that this decreasing trend continued until the end of the intervention on day 14 ($p < 0.001$).

There was no significant difference between the two groups concerning pain intensity score at baseline ($p = 0.405$). Seven days after the intervention, the pain intensity score decreased in both groups, and this decrease was greater in the VCO group than in the breast milk group ($p < 0.001$). The results also

TABLE 1. CHARACTERISTICS OF THE STUDY POPULATION

Items	Breast milk group (n=48)	Coconut oil group (n=50)	p ^a
Age (year)			
≤20	9 (19%)	10 (20%)	0.461
21–30	25 (29%)	24 (32%)	
31–40	14 (52%)	16 (48%)	
Economic level			
Low	17 (35%)	19 (38%)	0.617
Middle	20 (42%)	20 (40%)	
High	11 (23%)	11 (22%)	
Birthweight (g)			
≤2,500	6 (13%)	6 (12%)	0.283
2,500–2,999	16 (33%)	18 (36%)	
3,000–3,499	23 (48%)	22 (44%)	
3,500–4,000	3 (6%)	4 (8%)	
Type of delivery			
Natural	28 (58%)	33 (66%)	0.219
Cesarean	20 (42%)	17 (34%)	
Average breastfeeding duration (minute)			
≤10	9 (19%)	7 (14%)	0.366
10–15	21 (44%)	24 (48%)	
15–20	18 (38%)	19 (38%)	
First incidence of nipple fissure after delivery			
1–10 Days	22 (46%)	19 (38%)	0.130
11–20 Days	15 (31%)	18 (36%)	
21–30 Days	7 (15%)	6 (12%)	
1–3 months	2 (4%)	3 (6%)	
3–6 months	2 (4%)	4 (8%)	
First breastfeeding after delivery			
Within half an hour	26 (54%)	29 (58%)	0.762
Half to 1 hour	16 (33%)	13 (26%)	
1–24 hours	6 (13%)	8 (16%)	

^aChi-square test.
On day 14 ($p = 0.036$).

TABLE 2. MEAN INTRAGROUP COMPARISON OF NIPPLE FISSURE AND PAIN INTENSITY PER DAY OF INTERVENTION

Items	Time	Breast milk (n=48)	Coconut oil (n=50)	p ^a	Time	Time × group	Group
Nipple fissure	Day 1—preintervention	3.56 ± 0.50	3.48 ± 0.51	0.419	<0.001	0.015	<0.001
	Day 7—mid-intervention	2.18 ± 1.21	1.48 ± 1.03	0.002			
	Day 14—postintervention	2.01 ± 1.12	1.16 ± 0.99	<0.001			
	p ^b	<0.001	<0.001				
Pain intensity	Day 1—preintervention	6.06 ± 2.26	5.76 ± 1.17	0.405	<0.001	0.049	<0.001
	Day 7—mid-intervention	3.97 ± 1.85	2.70 ± 1.52	<0.001			
	Day 14—postintervention	2.52 ± 1.05	2.04 ± 1.17	0.036			
	p ^b	<0.001	<0.001				

Data are shown as mean ± standard deviation.

^aThe independent *t*-test between groups.

^bRepeated measures analysis of variance (Bonferroni correction) within groups.

demonstrated that this decreasing trend continued until the end of the intervention on day 14 ($p=0.036$).

Moreover, the repeated-measures analysis of variance showed that changes in nipple fissure and pain intensity scores in both groups were significantly declining over time ($p<0.001$).

In addition, Table 2 indicates that the effect of measurement time on nipple fissure and pain intensity scores in primiparous mothers was significant ($p<0.001$). Therefore, it can be postulated that regardless of the group type, there is a significant difference between the mean scores of nipple fissure and pain intensity before, 7 days after, and 14 days after the intervention. The interactive effect between time and group is also significant ($p<0.001$).

Therefore, the difference between the mean scores of nipple fissure and pain intensity in primiparous mothers at different times varies according to the levels of the group. Furthermore, as displayed in Table 2, the group's impact on nipple fissure and pain intensity scores in primiparous mothers was significant ($p<0.001$). Therefore, it can be concluded that regardless of the measurement time, there is a significant difference between the mean scores of nipple fissure and pain intensity in the study groups.

Table 3 showed no significant difference between nipple fissure and pain intensity scores on days 7 and 14 of the intervention in the study groups. Therefore, breast milk and VCO interventions are effective and lasting over time in reducing nipple fissure and pain intensity.

Discussion

Nipple fissure is a common problem among breastfeeding mothers and is the second most prevalent reason for breastfeeding discontinuation. A variety of medicinal, non-

medicinal, and herbal remedies have been used to treat nipple fissure and pain. The purpose of this study was to compare VCO and breast milk for the treatment of nipple fissure and breast pain intensity in primiparous mothers.

Results revealed that VCO healed nipple fissures faster than breast milk. A considerable reduction in nipple injury, fissure, and pain intensity was observed on days 7 and 14 of intervention in mothers treated with VCO compared to mothers treated with breast milk, indicating that wounds healed faster with VCO than with breast milk. Pain intensity was lower in the VCO group than in the breast milk group; however, the effectiveness of two treatment methods on nipple fissure was confirmed on days 7 and 14, while there was no significant difference between days 7 and 14 in either treatment group.

This finding indicates that the effectiveness of the two treatment methods is stable and lasting on the 14th day. Several studies have established that particular herbal compounds are useful at relieving pain and rapidly healing wounds.^{14,20}

Coconut oil contains antibacterial fats, lauric, capric, and caprylic acids, so it has antifungal, antibacterial, and antiviral properties. The human body converts lauric acid to monolaurin. Studies have shown that it is very helpful in fighting viruses and bacteria.²³ Furthermore, VCO has shown a moderate inhibitory effect on writhing response induced by acetic acid, reflecting its analgesic activity.²⁴ We suggest that VCO's therapeutic properties result from its high saturated fatty acid, and polyunsaturated fatty acid contents.²⁵ Most VCO fats are medium-chain fatty acids such as lauric acid.²⁶ In addition, VCO is rapidly metabolized, and the lauric acids readily penetrate skin tissue. In sum, research demonstrates that different fats in VCO resulted in a reduction in nipple fissure and healing time. Furthermore, no allergic reaction was observed during VCO treatment, owing to its antiallergic properties.

TABLE 3. PAIRED COMPARISONS OF NIPPLE FISSURE AND PAIN INTENSITY SCORES AT DIFFERENT TIMES BETWEEN THE CONTROL AND INTERVENTION GROUPS

Items	Time	Breast milk		Coconut oil	
		Mean difference	p	Mean difference	p
Nipple fissure	Day 1–Day 7	1.375	<0.001	2	<0.001
	Day 1–Day 14	1.562	<0.001	2.320	<0.001
	Day 7–Day 14	0.188	1	0.320	0.522
Pain intensity	Day 1–Day 7	2.083	<0.001	3.060	<0.001
	Day 1–Day 14	3.542	<0.001	3.720	<0.001
	Day 7–Day 14	1.458	<0.001	0.660	0.090

The findings of this study and similar research indicate that VCO may be beneficial in treating nipple fissures due to its high content of saturated and unsaturated fatty acids, phenolic acids, terpenoids, and vitamins E and K, as well as its anti-bacterial, anti-inflammatory, and antiallergic properties.^{16,27–29}

Limitations of this study include that individuals have different pain thresholds, which were mitigated by randomizing participants. A potential confounding factor in the current study was inadequate breastfeeding and concerns about the use of the VCO, which were addressed through tutoring, brochure preparation, and providing the author's phone number to the participant. One of the study's strengths is that it is the first to comprehensively examine the effects of VCO on the nipple fissure and pain, with results comparable to those of breast milk.

Conclusion

The current study is the first to conduct a single-blind clinical trial to assess the effect of VCO on the nipple fissure in primiparous women. The results suggested that women who used VCO experienced less nipple pain than those using breast milk. Given the efficacy of VCO in relieving nipple fissures and pain and the absence of allergic reactions in this study, it indicates that VCO can be used as a complementary substance to treat nipple fissures. However, the findings of this study may pave the way for further research on VCO's analgesic and anti-inflammatory properties. Future research is needed to compare the effects of vitamin E and VCO on nipple fissures and discomfort during breastfeeding.

Consent to Participate

Written informed consent was obtained from all participants. All authors are midwives, nurses, health care providers, and baby friendly hospital initiatives who practice Breastfeeding Medicine, and they all have contributed to this document.

Ethical Statement

All procedures performed in studies involving human participants were in accordance with the ethical standards of the Institutional and National Research Committee and with the Declaration of Helsinki 1964 and its later amendments.

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Disclosure Statement

No competing financial interests exist.

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