Use of therapeutic breast pads compared to lanolin for the treatment of nipple damage and pain control in the post-partum period: A comparative randomized controlled, single-blind clinical trial



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OBJECTIVE: To compare the efficacy of a therapeutic breast pad versus the most frequently used topical treatment, lanolin ointment, to control nipple pain and optimize wound healing in breastfeeding mother's during the 7-day, postpartum period.

METHODS: A total of 106 women who delivered between 37and 48 weeks' gestation newborns, were Exclusive Breastfeeding (EBF) mothers and had the presence of erythema, cracks and/or pain affecting the nipples during the first 120 hours postpartum were randomly assigned to either the experimental group with therapeutic breast pads or the control group using lanolin ointment. The women were assessed daily by nurse midwives during their hospitalization and every other day after hospital discharge. Principle variables for assessment were initial pain, tissue integrity, time to heal and changes in both healing rates and pain levels throughout the 7-day period.

RESULTS: There were statistically significant differences between the right nipple in the experimental group (0.049) and the control (0.147) in the final tissue integrity measurements. The tissue integrity of the right nipple was greater in the experimental group versus the control by the end of the study. Final analysis demonstrated that cracks in the nipples were smaller than the control. Also, the time to closure in the experimental group was 5.3 days versus 6.2 days for the right nipple in the control, as well as the left nipple which was 4.9 days in the experimental group versus 5.8 days in the control group with a probability of 0.099. There was a statistically significant decrease in pain reduction between the experimental group and the control with the experimental group's pain reduced by 1.62 points versus the control group's pain which increased by 0.02. The experimental group experienced greater reductions in pain levels than the control group throughout the study. The women who used the Nursicare pads experienced 76% healing in the right nipple lesion versus 38.8% in the control group and 71.7% in the left nipple lesions versus 38.3% in the control group.

CONCLUSIONS: Nursicare® Therapeutic Breast Pads provide statistically significant decreases in time to heal and increased pain control for the treatment of nipple damage versus the most frequently used treatment which is lanolin ointment.

Key words: pain – polymeric membrane – SARS-CoV-2 – nipple – cracked – bleeding – therapy – Exclusive Breastfeeding – support – neonate – breastfeeding – persistent nipple pain – prevention – pregnant – erythema

BACKGROUND

As of the 12th of June 2021, approximately 50 million people across Europe have been infected by the initial SARS-CoV-2 virus and more than a million have died. In Spain alone, approximately 4 million people have been infected and in late 2020 a lockdown was established in most countries in an attempt to stop the spread of the virus. The greatest restrictions were placed on overall mobility, reorganizing healthcare activities in hospitals**,** many which were on the verge of collapsing under the ever-increasing surge of patients with complex respiratory issues, all caused by the virus. All population groups have been affected by these restrictions, but new parents have been affected in many ways including a decrease in activities related to pre- and post-natal education including one of the most important tools in the post-partum period – breastfeeding. Most of the breastfeeding activities were modified because of a lack of understanding how this new virus affected mothers and their newborns. This lack of data on transmission between an infected mother and her baby led to the implementation of excessive restrictions on vital initial and subsequent interactions between mother/baby and clinician/mother. A key support system for new mothers was interrupted during the most important time after giving birth.

During the first days of breastfeeding the new mother can become overwhelmed with self-doubt at their ability to provide ample nutrition to their newborn, and experience nipple pain, erythema, cracked and bleeding nipples, all of which can have a negative effect on their ability to continue breastfeeding. Without clinical support and physical relief, nursing mothers with these common issues put themselves at risk of repeated outside exposure during one of the largest pandemic episodes in our lifetime. Face-to-face support from healthcare workers is essential to initiate and maintain effective breastfeeding.

Key Facts

According to a consensus statement by the World Health Organization (WHO) and the United Nations International Children's Emergency Fund (UNICEF):

" Infants should be exclusively breastfed for the first 6 months of life to achieve optimal growth, development, and health. "

Before the pandemic, according to data from the Spanish National Institute of Statistics, the prevalence of exclusive breastfeeding in Spain after birth was:



This was before the pandemic and already these statistics are far below what is needed to benefit the health and well-being of both mothers and their newborn infants.

Benefits of Breastfeeding for the Newborn	Maternal Benefits of Breastfeeding
The benefits of breastfeeding to the newborn are well established and include: • Provide immunological advantages against various diseases • Supply all of the newborn's nutritional requirements • Promote gastrointestinal flora • Contributes to development of the mandibular muscles • Provides the newborn with a sense of well-being and safety, which helps them develop lifelong self-esteem and emotional intelligence	While the benefits of breastfeeding for the newborn are more intuitive, the benefits to the post-partum mother are not and include: • Prevention of postpartum hemorrhage. Oxytocin synthesis is stimulated by the newborn's sucking reflex which accelerates uterine involution and prevents the onset of postpartum depression • Prevention of both breast and ovarian cancers • Increases the rate of physiologic recovery to the mother's pre-pregnancy weight

Despite the enormous benefits, some problems can arise during Exclusive Breastfeeding or EBF. Persistent nipple pain is one of the most common etiologies experienced by breast feeding women. It affects the quality and volume of breastfeeding and can result in the mother abandoning breastfeeding early and completely.

It has been estimated that between 80 and 96% of mothers experience some type of pain during the first postpartum week. The principle causes of this pain are incorrect positioning of the infant during breastfeeding, the presence of flat or inverted nipples, the infant's excessive sucking force, infections, a lingual frenulum, use of a nipple shield and bottle feeding or pacifier use.

Nipple cracks are wounds appearing on the nipple or nipples during breastfeeding. These are usually accompanied by pain, inflammation, bleeding and/or exudate and are one of the main reasons for abandoning breastfeeding.

The greatest incidence is seen during the first seven days postpartum, although they can last for the first six weeks. Early management of the symptoms is an important factor for establishing successful and enjoyable breastfeeding, and prevention of complications such as mastitis and breast abscesses



41% of nipple cracks occur in the hospital between the first 48 to 120 hours postpartum

Historical Treatment Modalities

There is little evidence from prospective trials on the treatment of cracked nipples, but there is a wealth of suggestions. Some clinicians recommend health education during puerperium and the skin-to-skin method as this may promote better acceptance of the breast, reducing the appearance of cracks. Other methods available include the application of menthol essence, fatty acids, breastmilk, hydrogel dressings and pure lanolin. At present there is no consensus on the most effective method.

There is another treatment for cracked nipples and pain called polymeric membrane therapy. This therapy has been used for over 25 years to heal wounds and control pain and inflammation. The Nursicare® Therapeutic Breast Pads are part of the polymeric membrane therapy family of products but, are specifically designed for nipple care. They contain a cleansing surfactant, moisturizing glycerin, superabsorbent co-polymer, a hydrophilic matrix and an external semi-permeable film.

It is extremely important to have effective products available to treat this kind of problem especially when mobility and healthcare restrictions are implemented and solving problems face-to-face is not an option. Having effective, easy-to-use products that are proven to assist with rapid healing and resolution of nipple damage, yet decreases mother and newborn exposure, is a lifesaving measure that would be desperately needed, especially during a pandemic.

Previously, there were no randomized clinical trials on the Nursicare® pads that compared efficacy with any treatments used for cracked nipples. This clinical trial was performed to fill the gap. The aim of this study was to compare the efficacy of polymeric membrane therapy with the use of lanolin to control nipple pain and wound healing in women during the seven days postpartum

METHODOLOGY

This was a single-blind, comparative randomized controlled trial performed using pregnant women at the Viamed Montecanal Hospital, Zaragoza and approved by the Aragon Autonomous Community Research Ethics Committee (CIECA EC16/038).

Population

The patients included in the trial were pregnant women attended by two midwives attached to the research team. Inclusion criteria included EBF, full term birth {37 - 42 weeks' gestation) and presence of erythema, cracks and/or pain affecting the nipples during the first 120 hours postpartum. The exclusion criteria were abandoning EBF, supplementing with a bottle, use of a nipple shield and/or pacifier, congenital malformations of the mouth and short lingual frenulum.

Randomization and Sample Size

During the 30 days prior to the established date of delivery, women who had been informed about the trial and decided to participate freely and voluntarily in the trial gave their written informed consent. The women's names were anonymized by using a code and they were randomly assigned to either the experimental group or the control group using the Epidat program. Initially, 124 women were enrolled and randomized. The final study group selected included 53 patients assigned to the experimental group and 53 to the control group. There were 18 women excluded from the statistical analysis. Ten women were excluded because they were not EBF, and 8 women voluntarily withdrew citing high anxiety levels and insufficient time to combine the study monitoring with their new stage in life. The blinding of the randomization was maintained throughout the study and none of the women knew which group they had been assigned to. The attention and quality of care were identical for pregnant women who participated in the study and those who did not. None of the pregnant women were subjected to favorable treatment and/or discrimination.

Intervention

Within the first 24 hours postpartum the midwives made a first visit in hospital to each woman, gathered data on the variables and instructed on breastfeeding. Each study participant was given a kit containing either Nursicare® breast pads or lanolin ointment depending on the group the women had been blindly assigned whether experimental or control. They also received an information leaflet with instructions for use for the selected group. In addition to giving the women the leaflet the midwives gave each woman a detailed explanation of how and when to use the kit they had been given and answered all questions.

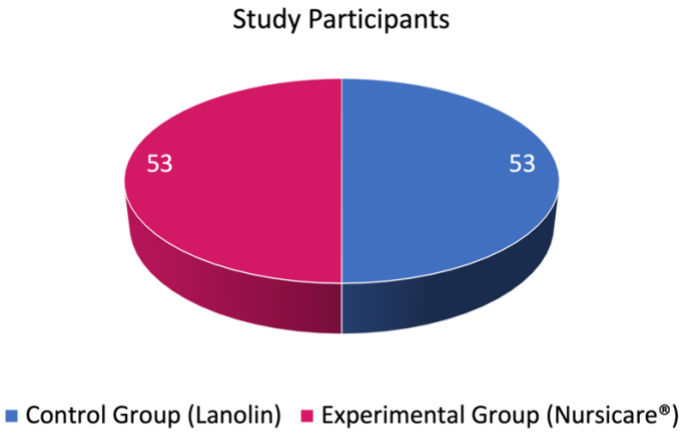
All the women were monitored for seven days after the birth. Monitoring was performed daily during the hospitalization period and on alternate days after hospital discharge. The data on the defined variables were collected at each visit and any doubts and/or questions the women might have had were answered or resolved.

STATISTICAL ANALYSIS

The principal variables used to evaluate the efficacy of Nursicare® pads in healing nipple wounds were pain and tissue integrity. The tissue integrity of the nipples, the time to heal and changes in pain levels during monitoring were compared. Statistical significance was calculated using the Pearson Chi-squared test for discrete variables and the Student T test for continuous variables. This was an intention to treat analysis.

Demographics

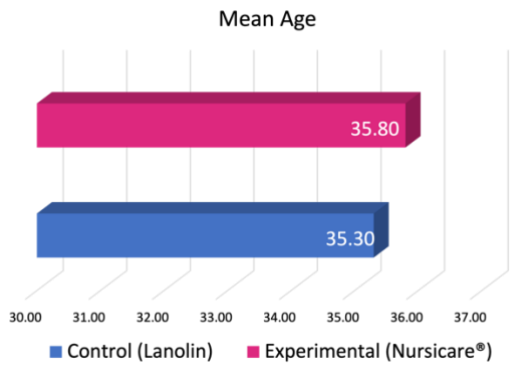
The final number of study participants who met all criteria was 106 with 53 in both the experimental and control groups. Neither of the groups presented significant differences in the variables at the start of the study (Graphic 1)



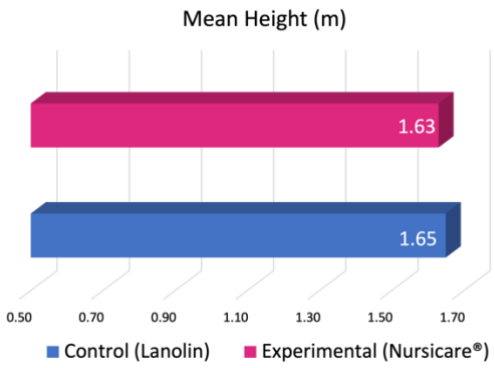
Graphic 1

The average age of the patients assigned to the experimental group was 35.8 years versus 35.3 years in the control group. (Graphic 2). The average height of the women in the experimental group was 2 cm smaller than the control (Graphic 3), the average weight in the experimental group was also 3.9 kg lower than the control group (Graphic 4), and the average BMI% was .9% higher in the

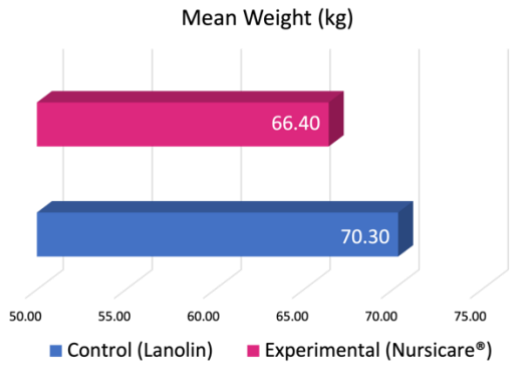
control group versus the experimental group (Graphic 5).



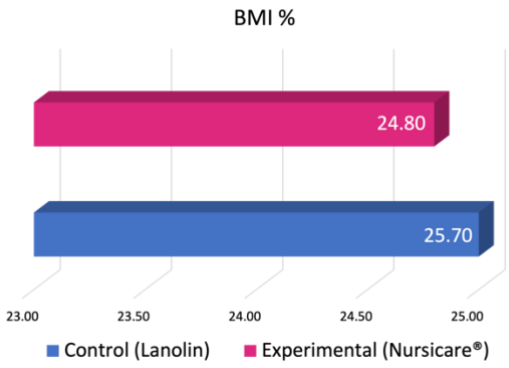
Graphic 2



Graphic 3

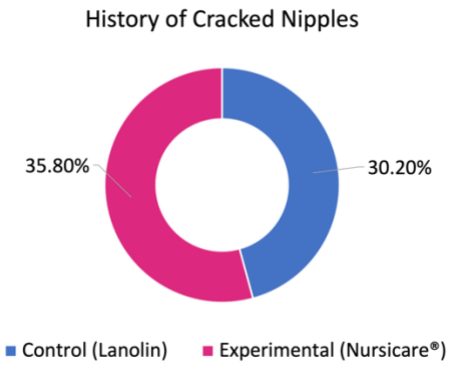


Graphic 4

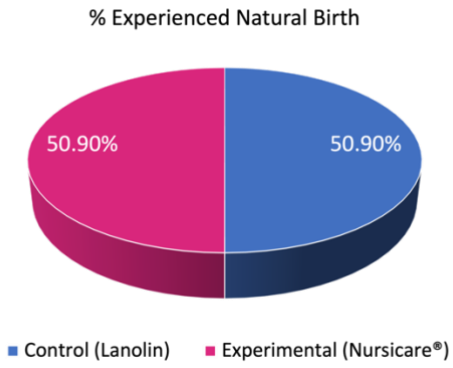


Graphic 5

Analysis revealed a history of cracked nipples in 35.8% of the women in the experimental group in comparison with 30.2% in the control group (Graphic 6). In both groups almost 60% of the pregnant women had a natural birth (Graphic 7).

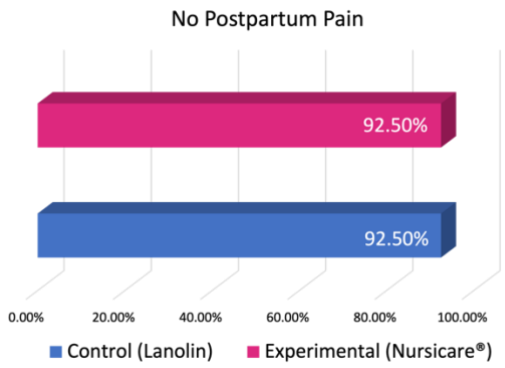


Graphic 6

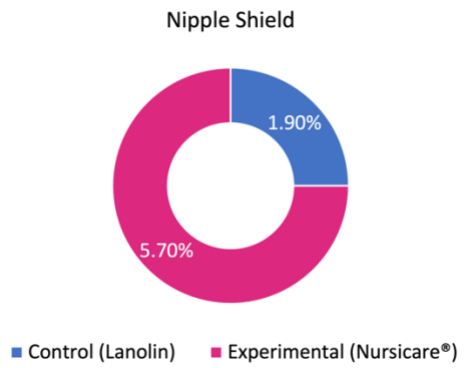


Graphic 7

During the immediate postpartum period, 92.5% of women had no pain (Graphic 8) . Of the 106 women, only 4 used a nipple shield, 3 in the experimental group and 1 in the control group (Graphic 9).

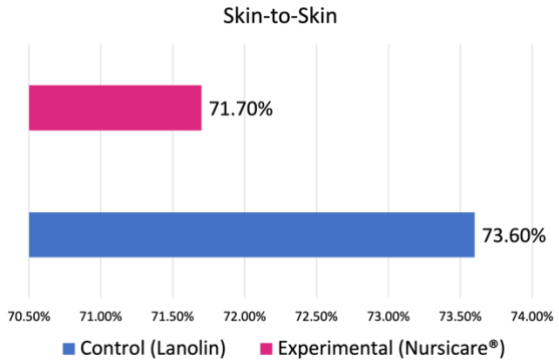


Graphic 8

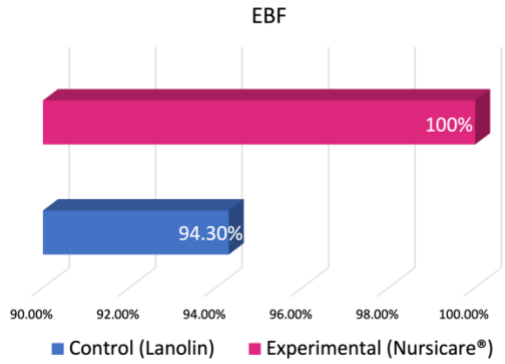


Graphic 9

Skin-to-skin contact after birth was experienced by 38 neonates belonging to the women in the experimental group and 39 neonates in the control group (Graphic 10). Exclusive Breastfeeding was practiced by 100% of the women in the experimental group compared with 94.3% in the control group (Graphic 11).



Graphic 10



Graphic 11

<u>Tissue Integrity</u>

There were no differences found between the experimental group tissue integrity of the right nipple (0.174) and the control group (0.178) at the start of the study (Table 1). There were statistically significant differences between the experimental group (0.049) and the control group (0.147) observed in the final tissue integrity measurements. The tissue integrity of the nipples was greater in the experimental group at the end of the study, showing that the cracks in the nipples were significantly smaller in size. The healing time in the experimental group (5.3 days) was shorter than in the control group (6.2 days).

76% of women who used Nursicare® pads experienced healing of the right nipple vs. 38.8% in the control and 71.7% experienced healing in the left nipple vs. 38.3% in the control

There were no statistically significant differences between the mean tissue integrity of the left nipple at the beginning or end of the study. However, the mean healing time was lower in the

experimental group (4.9 days) compared to the control group (5.8 days) with a probability of 0.099.

Table 1. Comparison of tissue integrity of the right and left nipples

	Experimental	Control	ρ Value	Difference (95% CI)
RIGHT NIPPLE				
Tissue integrity START	0.174	0.178	0.939	
Tissue integrity END	0.049	0.147	0.022	0.145 – 0.181
TIRN, difference START-END study	-0.125	-0.031	0,117	
Healing Time	5.3	6.2	0.055	
LEFT NIPPLE				
Tissue integrity START	0.091	0.138	0.239	
Tissue integrity END	0.063	0.120	0.214	
TILN, difference START-END study	-0.028	-0.017	0.855	
Healing Time	4.9	5.8	0.099	
Pain at start	4.04	3.77	0.534	
Pain at end	2.42	3.79	0.003	2.268 – 0.487
Pain reduction START-END	-1.62	0.02	0.003	2.730 – 0.552

TIRN – (Tissue Integrity Right Nipple) TILN – (Tissue Integrity Left Nipple)

Pain

At the start of the study, no differences in pain levels were observed between the two groups. By the end of the study there were statistically significant differences in pain reduction. The experimental group's level of pain reduced by 1.62 points, from 4.04 at the start to 2.42 at the conclusion. The control group's pain level increased by 0.02 points from 3.77 to 3.79. The experimental group had a greater reduction in pain levels than the control.

Of the postpartum women who used the Nursicare® pads, 76% experienced healing of the right nipple tissue lesion which was almost double the number of the women who used lanolin (38.8%). Of the participants in the experimental group, 71.7% experienced healing of the left nipple, compared to 38.3% in the control group (Table 2).

Table 2. Percentage of postpartum women with nipple tissue integrity and changes in healing during the study according to treatment group

	Start	End	Healing	Diff. (95% CI)	ρ[α]
RIGHT NIPPLE					
Experimental group	**3** 5.7%	**41** 77.4%	38 76.0%	19.2 – 55.3%	<0.001
Control group	**4** 7.5%	**23** 43.4%	19 38.8%		
LEFT NIPPLE					
Experimental group	**7** 13.2%	**40** 75.5%	**33** 71.7%	14.4% - 52.5%	<0.001
Control group	**6** 11.3%	**24** 45.3%	**18** 38.3%		

[α]Chi square test. Comparison of proportions

The women randomized to the Nursicare® group experienced statistically significant reductions in pain by 1.62 points, from 4.04 at the start to 2.42 at the conclusion. The control group's pain level increased by 0.02 points from 3.77 to 3.79

DISCUSSION

The most common types of nipple trauma occurring during the first week postpartum include erythema, edema, blisters, cracking and crusting. Lanolin is a whitish, waxy substance which creates a barrier to prevent skin moisture loss. It is tasteless, hypoallergenic, odorless and does not contain any impurities. Absorption by both the mucus membranes and skin is considered safe and it does not need to be removed before breastfeeding. It has been shown to be more effective than polyethylene and oil adhesive dressing for the treatment of nipple injuries. It has also had better results than breastmilk for the treatment of pain and nipple trauma over a 7-day period. However, a systematic review revealed that no one topical agent demonstrated superior results in the relief of nipple discomfort. The most important factor in decreasing the incidence of nipple pain is the provision of education in relation to proper breastfeeding techniques and suction. A randomized, multicenter clinical trial demonstrated that hydrogel dressings are a safe treatment that provides more effective nipple pain reduction than the commonly used lanolin ointment. A systematic review concluded that glycerin dressings, breast protectors with lanolin, lanolin alone or all-purposed nipple ointment significantly improved the mothers' perceptions of nipple pain.

The present study demonstrated that the use of Nursicare® Therapeutic Breast Pads had statistically significant positive effects on the treatment of cracked nipples. The women in the experimental group presented a greater reduction in lesion size during the 7-day study period, experienced a rapid healing process in comparison with the control group. It must also be emphasized that the reduction in pain levels was greater in the women who used the Nursicare® Therapeutic Breast Pads compared to those who used lanolin.

Study Limitations

Limitations of the study included the short duration of the intervention and alternate day monitoring after hospital discharge.

CONCLUSION

The use of Nursicare® Therapeutic Breast Pads was more effective than lanolin for treating nipple wounds, accelerating the healing process and reducing pain. This advanced therapy is indicated for the treatment of nipple wounds and pain relief, helping to decrease the problems encountered by postpartum women during breastfeeding. Due to interpersonal interaction restrictions during the pandemic, it is even more important to have clinical evidence to support the most effective treatments which are easy to explain and easy to use by people thus reducing hospital stay, minimizing pathogenic exposures and possibly prolonging the new mother's ability to continue breastfeeding.

The authors declare they have no relevant or material financial interests that relate to the research described in this paper and have authorized the use of their data for this publication.

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