The Effect of Topical Application of Mothers' Breast Milk versus Barrier Cream on Healing of Diaper Dermatitis in Infants

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Abstract

Background: Diaper Dermatitis (DD) is a prevalent skin condition among infants. In recent times, various complementary skin-care approaches have been recommended, including alternatives like sunflower oil and human breast milk. Despite these natural options, certain chemical formulations persist in use, posing potential harm or providing little benefit. **Aim:** To evaluate the effect of topical application of mothers' breast milk versus barrier cream on healing of diaper dermatitis in infants. **Design:** A Randomized Controlled Trial design was used. **Subjects:** A purposive sample of 62 infants and their mothers were included. **Setting:** The study was conducted at the Pediatric Clinic affiliated to El-Fardoos Primary Health Care Center at Mansoura city, Egypt. **Tools of data collection:** Two tools were used for data collection: A structured questionnaire sheet for infants and their mothers and severity scale for DD were used for data collection. **Results:** Mild to moderate pre-lesion scores were comparable between both groups with no statistically significant difference. The post-lesion scores on the 7th day for the breast milk group were significantly different from the barrier cream group (p=0.005). **Conclusion:** Breast milk delivers more effective results than barrier cream, in the treatment of infants with mild to moderate DD. **Recommendations:** The study recommends developing a standardized protocol for the application of breast milk, for the prevention and treatment of DD.

Key words: Topical Application, Barrier cream, Breast milk, Diaper dermatitis, Infants, and Mothers.

Introduction

Diaper dermatitis (DD) stands as the prevalent dermatological issue in infancy, commonly recognized as diaper rash. Its spectrum extends from mild erythema to skin breakdown and open wounds due to exposure to excrement, moisture, and friction leading to the physical breakdown of the epidermal barrier, contributing to DD. Additionally, a decrease in skin acidity correlates with compromised barrier integrity, reduced antimicrobial defenses, and heightened inflammation in this condition, causing discomfort for infants and distress for parents. The diagnosis relies on clinical observation, manifesting as an acute inflammatory eruption in the diaper area. Globally, the frequency of diaper dermatitis is noteworthy, leading to a substantial number of healthcare visits [(1)].

Diaper dermatitis is influenced by factors such as exposure to urine and feces, occlusion, warmth, microorganisms, and friction. Increased risk is associated with

frequent diaper soiling, diarrhea, stomach upset, prolonged wetness due to infrequent diaper changes, and absence of barrier cream. Numerous trials face methodological challenges, with a key obstacle being the evaluation of DD severity a crucial aspect for outcome measurement. The demand for objective and reliable assessment methods has been underscored in addressing this issue [(2)].

Diaper dermatitis manifests in three main types: chafing dermatitis, irritant contact dermatitis, and diaper candidiasis. Commonly referred to as diaper rash or nappy rash, DD signifies skin inflammation within the diaper-covered area. Its prevalence in infants aged 1–12 months varies from 7% to 35%, peaking in the 9 to 12 months age group. Despite its common occurrence, there is limited high-quality evidence regarding effective prevention or treatment strategies for DD. It frequently arises in general pediatric practice, affecting 16% of children with primary or secondary skin concerns, yet only 7% of DD cases seek medical advice. Additionally, a cluster of skin disorders emerges due to the impact of physical, chemical, enzymatic, and microbial factors within the diaper environment [(3)].

The inherent characteristics of the diapering environment and the nature of intact skin pose challenges to maintaining the integrity of healthy skin. Achieving this goal remains difficult with existing diapering practices. Moist occlusion in this environment promotes skin compromise and elevates the occurrence of skin friction. Diapering, while undoubtedly effective and convenient for containing an infant's excreta, exposes the skin to continuous conditions it was not inherently designed to withstand. As a result, infant skin often struggles to withstand this prolonged exposure, leading to potential adverse effects [(4)].

Various illnesses can lead to skin problems in the diaper region, encompassing those directly triggered by diapers or the diaper environment, some exacerbated by diaper use without a clear causal link, and others unrelated to the diaper or its surroundings. While certain conditions are confined to the diapered skin area, others may extend beyond, indicating systemic diseases [(5)].

The primary goals in managing diaper dermatitis involve expediting the recovery of compromised skin and preventing the recurrence of rashes. To achieve these objectives, it is essential to increase the frequency of diaper changes, particularly every 3–4 hours during infancy, providing ample fresh air to the baby's bottom. If needed, consider changing the diaper brand, ensure thorough drying of the skin after cleaning, and apply a generous layer of zinc oxide formulations. In cases where the skin is infected with candida albicans, it is advisable to use antifungal ointments devoid of corticosteroids [(6)].

Contemporary solutions of DD involve the use of barrier creams like zinc oxide and petrolatum to shield against, prevent, and treat diaper dermatitis. These creams create a lipid film on the skin's surface, aiding in stratum corneum repair and preventing skin irritation. Specifically, topical zinc oxide cream emerges as an effective choice for both the treatment and prevention of diaper dermatitis. Its attributes include anti-inflammatory properties, promotion of wound healing, and a robust barrier effect safeguarding the skin from irritants, excessive moisture, and friction [(7)].

Over centuries, breast milk has been utilized as a natural remedy for achieving smooth skin. Rich in vitamins A, E, D, K, and B complex, particularly effective vitamin E, breast milk exhibits healing properties beneficial for addressing minor illnesses and injuries. The antibodies present in breast milk act as antibacterial agents, combating bacteria and viruses when topically applied to affected areas. Its natural composition imparts softness to the skin, with research indicating the role of antibodies, proteins, calcium, and vitamin B12 in preventing complications such as dry skin, eczema, and fragility. The lactic acid found in milk, commonly used in skin creams & lotions, contributes to a softening effect on the skin [(8)]. Preventing DD is paramount, and scholars emphasize the ABCDE approach (air, barrier, cleansing, dry diaper, and education) as a primary strategy. Key preventive measures include extended air exposure, use of barrier creams with Zinc oxide and Petroleum, cleaning with water or gentle cleansers, changing diapers every 2–4 hours, and educating on proper diaper hygiene. Employing barrier creams, opting for super absorbent disposable diapers, and avoiding soap and alcohol-containing products are crucial elements of prevention. Additionally, breastfeeding offers substantial benefits in reducing DD by preventing its occurrence, and aiding the healing process [(9-10)].

Significance of the study

Breast milk, recognized as a traditional and cost-effective pharmacotherapy, has been utilized across diverse societies for its widespread availability. Expanding beyond its role in infant and maternal health, recent studies, identified through a literature search spanning to December 2022 across scientific databases, indicate positive outcomes in the treatment of various health issues for individuals beyond infancy and highlight the potential of breast milk as a viable and safe alternative treatment. This becomes particularly significant for societies with limited access to conventional medical care, offering an accessible solution for allergic skin conditions and mucous tissue damage in both infants and mothers. Given its global availability and cost-free nature, exploring the topical application of breast milk emerges as a valuable avenue, not only for the prevention but also for the treatment of ailments [(11)]. Exploring the potential of topically using breast milk for DD is crucial so this study specifically aimed to evaluate the impact of breast milk on the healing process of diaper dermatitis, emphasizing the importance of leveraging this natural resource to protect infants from further DD.

Aim of the study

This study aimed to evaluate the effect of topical application of mother s' breast milk versus barrier cream on healing of diaper dermatitis in infants.

Research hypotheses

H_0 The study posits that applying mother breast milk topically will not affect the healing of diaper dermatitis in the study group.

H_1 Suggests that the effects of applying mother breast milk are equivalent to using barrier cream for the healing of infants' diaper dermatitis, indicating no distinguishable difference between the study and control groups. On the other hand, **H_2** Proposes that the topical

application of mother breast milk will enhance the healing of diaper dermatitis in the study group compared to the control group using barrier cream.

Method

Research design

A Randomized Controlled Trial (RCT) design was used in this study. In RCT, participants are randomly assigned to an experimental (study) group or a control group and a direct comparison is made between groups. As the study is conducted, the only expected difference between the control and experimental groups in an RCT is the outcome variable being studied [(12)].

Study setting

The study was conducted at the Pediatric Clinic affiliated to El-Fardoos Primary Health Care Center (PHC) in Mansoura City, Dakahlia Governorate, Egypt. The clinic works daily and receives children with different medical conditions.

Study subjects

The study subjects included; a purposive sample of 62 mothers of 62 infants who experienced DD and sought care at the previously mentioned study setting. They assigned randomly into two equal groups (31 infants in the study and 31 in the control groups) over four months commencing from the first of May 2023 and terminated at the end of August of the same year.

The alignment ensured matching between the study and control groups, in terms related to mother and the infants. The mothers inclusion based on criteria includes; breastfed mothers' at age, gender, educational level, occupation approximately similar between both groups to avoid bias.

Infants aged 6 to 12 months with mild to moderate DD, utilizing disposable diapers, and without any known systemic diseases, as well as the absence of systemic drug use, were considered eligible for inclusion in the study. The exclusion criteria involved having a fungal infection, using cloth diapers, and displaying sensitivity to the study drug.

Both groups underwent a seven-day follow-up, with visits scheduled on the third, fifth, and seventh days of the intervention. The follow-up occurred three days per week for each group to prevent any cross-contamination of data between them.

Sample size

Utilizing information from the literature[(13)], and considering a 5% significance level and 80% study power, the sample size can be determined by the formula:

$$n = \frac{2(Z\alpha/2 + Z\beta)^2 \times p\,(1-p)}{(d)^2}$$

In this formula, (p) represents the pooled proportion from a previous study; (d) is the expected difference in the proportion of events; $Z_{\alpha/2}$ =1.96 for 5% significance level and Z_{β} is 0.84 for 80% study power. Thus, the calculated sample size is

$$n = \frac{2(1.96 + 0.84)^2 \times 0.778\,(1-0.778)}{(0.30)^2} = 30.1.$$

Therefore, a sample size of 31 in each group is required.

The infants selected for the study were randomly assigned to either receive barrier cream or use breast milk on the affected

area for seven days, employing a manual randomization block technique. The randomization blocks were created according to the specified steps:

- The researchers created a list comprising numbers from 1 to 62.
- Subsequently, each number from 1 to 62 was transcribed onto individual pieces of paper.
- Each paper was then rolled up until the number became obscured, after which all the papers were mixed and consolidated into a large ball.
- The 62 pieces of paper were divided randomly and blindly into 3.1 blocks, each containing 20 random numbers.
- From each block, 10 random numbers were blindly selected for assignment to the control group, with the remaining 10 assigned to the study group.
- Following this, the researchers recorded the sequence of cases on the previously prepared list, indicating "Study" or "Control" in front of each number. This sequence was maintained for reference during the data collection process.

Tools of data collection

Two tools were utilized in the current study namely:

Tool 1: A Structured Questionnaire Sheet for Infants and their Mothers, which contained two parts: **Part one:** Infants and Mothers Characteristics. Both were completed via interviews with mothers on the initial day. Including infants' age, gender, method of feeding, in addition to mother's educational level and occupation.

Part two: Infants' State of Care which include; number of diaper change per day and type of diaper. The researchers developed it after examining current literature and comparable studies [4-5-14].

Tool 2: Severity Scale for Diaper Dermatitis:

It was adopted from **Waili et al., (2005)** [15]. The tool assesses the number, location, and severity of lesions, employing Al-Waili's five-point scale for rash severity: 0=None, 1=Mild erythema, 2=Moderate erythema, 3=Moderate erythema + maceration, 4=Severe erythema + pustules or ulceration. The researchers completed tool (2) on the initial day and during follow-up visits on the 3rd, 5th, and 7th days of the intervention. Throughout the study, any emerging signs or symptoms were documented.

Validity and reliability

A jury of five experts in Dermatology and Pediatric Nursing examined the content validity of the study tool (1), and all necessary modifications were made. Using Cronbach's alpha and test-retest methods, tool (1) was checked for its internal consistency and reliability. The Structured Questionnaire Sheet has a Cronbach's alpha of 0.781, with a correlation coefficient (r) of 0.445. The study tool (2) is a standardized valid and reliable tool that adopted from **Waili et al., (2005)**.

Pilot study

To validate the study tools' feasibility and practicality, a preliminary study was undertaken with ten percent (n=7) of the overall participants before commencing data collection. This process also aids in estimating the interview duration in advance. Adjustments were made based on insights gained from the pilot study, ensuring necessary modifications. Notably,

participants involved in the pilot study were excluded from the complete study sample to prevent any potential data contamination.

Procedure

- Mothers in the control group were instructed to cleanse the infant after urination or defecation using warm water, gently pat the infant dry, apply a barrier cream containing 20% zinc oxide in a cream base composed of olive and castor oils, and regularly change diapers. Additionally, to assess skin sensitivity, a small amount of ointment was administered on the child's arm (1 × 1 cm) and monitored after 20 minutes to verify the absence of any allergic reactions.
- Mothers in the control group received a single tube of barrier cream and were advised to apply it sparingly on affected areas twice daily for 7 days.
- In the study group, mothers were instructed to follow the same care for their infants while substituting breast milk for the barrier cream. Specifically, they were advised to gently rub hindmilk, richer in fat content and obtained towards the end of breastfeeding, onto affected areas after each feeding session. The mothers were instructed to let the milk dry before re-diapering and were directed not to use any topical treatments or creams.
- To standardize diaper usage, the researchers provided all mothers with a sufficient quantity of the same brand of diapers for the study duration. Mothers consistently maintained a daily diary, documenting details such as diaper changes, wet diapers, and the cleansing process. A positive therapeutic outcome was defined by an improvement in scores, indicating, for instance, the transformation of a moderate rash into a mild one or the disappearance of a mild rash. Lesions that exhibited no improvement within the seven-day study period underwent conventional therapy, and instances of treatment failure were properly noted.

- Mothers from both study and control groups were instructed to bring their infants for clinical evaluation on the 3rd, 5th, and 7th days post-commencement of the treatmen.

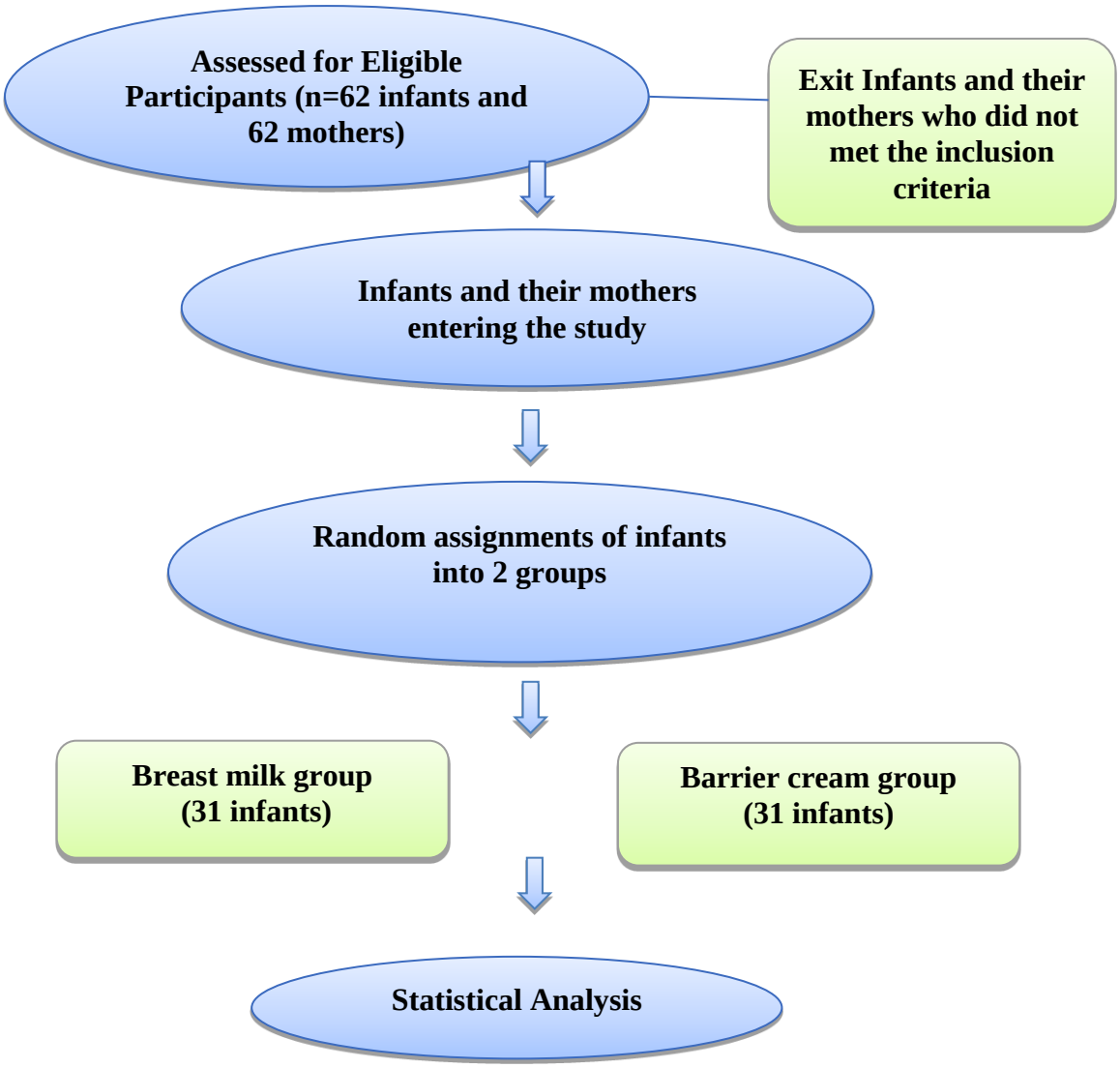

Figure (1): The Flowchart of the Study Phases

Ethical considerations

Ethical approval for the study was secured from the Research Ethical Committee of Mansoura Faculty of Nursing under Reference No. p. 0459. Additionally, permission to conduct the study was granted by the head of the Primary Health Care Center, following a comprehensive explanation of the study's objectives. Mothers provided informed consent after a thorough presentation of the study goals. The researchers explicitly assured that the study posed no physiological or psychological harm to infants. Privacy and confidentiality of all collected data were diligently maintained throughout all phases of the study. Importantly, infants' mothers retained the right to withdraw from the study at any point without incurring any responsibility.

Statistical analysis

The gathered data underwent coding, tabulation, and analysis employing the Statistical Package for the Social Sciences (SPSS) version 22.0. The data was computerized and subjected to relevant descriptive and inferential statistical tests. The statistical analysis adhered to the

latest, dependable, and valid statistical methodologies. Specifically, the Chi-Square test was employed to evaluate distinctions between the study and control groups. For the analysis, the significance level was set at 5%; hence, $p \leq 0.05$ was considered statistically significant.

Results

Table (1) illustrated that the base line characteristics of two groups are similar as the mean ages of the studied infants in the breast milk and barrier cream groups were 9.9 ±1.7 and 9.8 ±1.6 months respectively. There were no significant gender and weight differences observed between both groups.

Table (2) shows that all mothers are breast feeding their infants. The mean ages of the studied infants' mothers in the breast milk and barrier cream groups were 24.9±0.9 and 24.2±0.1 years respectively. In both groups, all mothers were housewives. More than two-thirds of mothers in both groups had a higher level of education (67.8 % and 70.9%, respectively). All mothers utilized the same brand of disposable diapers and changed them six times a day. None of the infants' mothers used any soaps and powders for them.

The presentation of lesion scores for pre- and post-treatment comparisons between the human breast milk and barrier cream groups are detailed in **Table (3) and Figure (1).** Pre - treatment, no significant finding was found between the mother milk and barrier cream groups in relation to lesion score of DD.

During the study, among the 31 infants in the breast milk group with scores of 1 or 2 (indicating mild or moderate erythema), 80.6% demonstrated improvement, achieving a score of 0 (no erythema) by the seventh day. In comparison, the barrier cream group witnessed an improvement in 41.9% of infants. Statistical analysis using the Chi-Square test on the 3rd, 5th, and 7th days post-intervention revealed a significant difference in the breast milk group (p=0.019, 0.008, and 0.005, respectively). However, no significant difference was observed in the barrier cream group.

Upon reviewing **Tables (4) and (5)**, it becomes evident that there is no association between the characteristics attributes of the studied infants (including age, gender, and weight) and the lesion scores both before and on the 7^{th} day post-treatment.

Table 1. Percentage distribution of the study and control group regarding socio-demographic characteristics of infants (n=62)

	Breast milk group (31)		Barrier cream group (31)		Chi – Square	
	n	%	n	%	χ^2	*p*
Breastfed mothers	31	100	31	100		
Mothers age						
25 – 30 years	28	90.3	26	83.9		
31 – 35 years	3	9.7	5	16.1		
Mean ±SD	24.9±0.9		24.2±0.1		0.073	0.856
Mothers occupation						
Housewives	31	100	31	100		
Mothers education						
Technical	10	32.2	9	29.1		
Higher education	21	67.8	22	70.9	0.067	0.856
Number of diaper changes						
6 times / day	31	100	31	100		
Type of diaper (disposable same brand diaper)	31	100	31	100		
Using soap / powder	0	0	0	0		

*Significant at $p \leq 0.05$

Table 2. Percentage distribution of the study and control group regarding socio-demographic characteristics of the mothers (n=62)

	Breast milk group (31)		Barrier cream group (31)		Chi – Square	
	n	%	n	%	χ^2	*p*
Breastfed mothers	31	100	31	100		
Mothers age						
25 – 30 years	28	90.3	26	83.9		
31 – 35 years	3	9.7	5	16.1		
Mean ±SD	24.9±0.9		24.2±0.1		0.073	0.856
Mothers occupation						
Housewives	31	100	31	100		
Mothers education						
Technical	10	32.2	9	29.1		
Higher education	21	67.8	22	70.9	0.067	0.856
Number of diaper changes						
6 times / day	31	100	31	100		
Type of diaper (disposable same brand diaper)	31	100	31	100		
Using soap / powder	0	0	0	0		

Table 3. Percent distribution of Lesion Scores between Breast Milk and Barrier Cream Groups Pre & Post Treatment (n=62)

	Breast milk group (31)		Barrier cream group (31)		Chi – Square	
	n	%	n	%	χ^2	*p*
Pre – treatment						
Mild erythema (Score 1)	17	54.8	12	38.7		
Moderate erythema (Score 2)	14	45.2	19	61.3	1.619	0.203
Post – treatment (3rd day)						
None (Score 0)	14	45.2	4	12.9		
Mild erythema (Score 1)	12	38.7	18	58.1		
Moderate erythema (Score 2)	5	16.1	9	29.0	7.898	0.019*
Post – treatment (5th day)						
None (Score 0)	19	61.3	7	22.6		
Mild erythema (Score 1)	10	32.3	21	67.7		
Moderate erythema (Score 2)	2	6.5	3	9.7	9.642	0.008*
Post – treatment (7th day)						
None (Score 0)	25	80.6	13	41.9		
Mild erythema (Score 1)	4	12.9	15	48.4		
Moderate erythema (Score 2)	2	6.5	3	9.7	10.358	0.005*

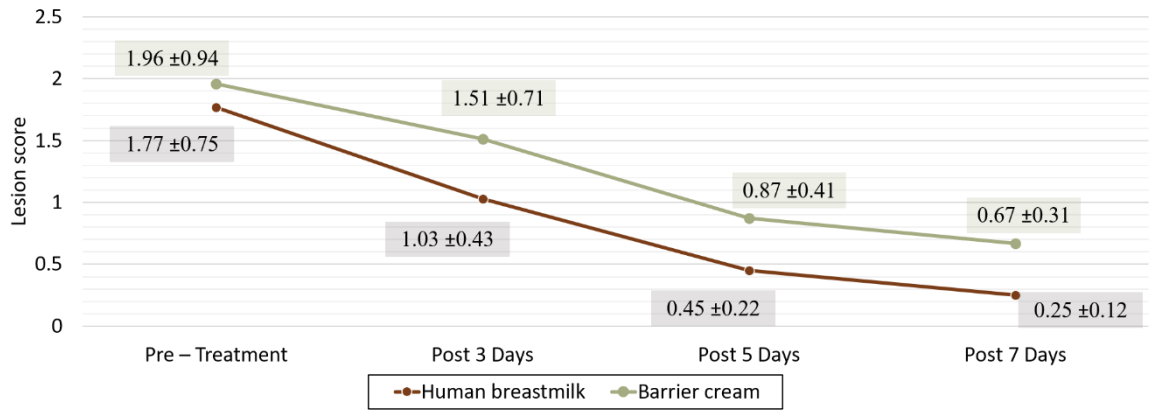

Figure 1. Comparison of Lesion Scores between Breast Milk and Barrier Cream Pre & Post – Treatment

Table 4. Association between the Infants' Characteristics and Lesion Scores at Pre – Treatment (n=62)

	Breast milk group (n=31)				Barrier cream group (n=31)			
	Mild erythema (Score 1)		Moderate erythema (Score 2)		Mild erythema (Score 1)		Moderate erythema (Score 2)	
	N	%	n	%	N	%	n	%
Age (Months)								
7 – 9	8	47.1	7	50.0	6	50.0	10	52.6
10 – 12	9	52.9	7	50.0	6	50.0	9	47.4
Fisher's test	χ^2=0.027, *p*=0.870				χ^2=0.020, *p*=0.886			
Gender								
Boy	9	52.9	7	50.0	7	58.3	9	47.4
Girl	8	47.1	7	50.0	5	41.7	10	52.6
Fisher's test	χ^2=0.027, *p*=0.870				χ^2=0.354, *p*=0.552			
Weight (Kg)								
7 – 9	8	47.1	8	57.1	6	50.0	11	57.9
10 – 12	9	52.9	6	42.9	6	50.0	8	42.1
Fisher's test	χ^2=0.313, *p*=0.576				χ^2=0.185, *p*=0.667			

Table 5. Association between the Infants' Characteristics and Lesion Scores at 7 Days Post – Treatment

	Breast milk group (n=31)						Barrier cream group (n=31)					
	None (Score 0)		Mild erythema (Score 1)		Moderate erythema (Score 2)		None (Score 0)		Mild erythema (Score 1)		Moderate erythema (Score 2)	
	n	%	n	%	n	%	n	%	n	%	n	%
Age (Months)												
7 – 9	11	44.0	3	75.0	1	50.0	9	69.2	5	33.3	2	66.7
10 – 12	14	56.0	1	25.0	1	50.0	4	30.8	10	66.7	1	33.3
Fisher's test	**χ^2=1.329, p=0.514**						**χ^2=3.895, p =0.143**					
Gender												
Boy	14	56.0	1	25.0	1	50.0	6	46.2	8	53.3	2	66.7
Girl	11	44.0	3	75.0	1	50.0	7	53.8	7	46.7	1	33.3
Fisher's test	**χ^2=1.329, p =0.514**						**χ^2=0.445, p =0.800**					
Weight (Kg)												
7 – 9	11	44.0	3	75.0	2	100.0	9	69.2	7	46.7	1	33.3
10 – 12	14	56.0	1	25.0	0	0.0	4	30.8	8	53.3	2	66.7
Fisher's test	**χ^2=3.331, p =0.189**						**χ^2=2.052, p =0.358**					

Discussion

Infants face an elevated susceptibility to DD due to their underdeveloped skin. The peak occurrence of DD typically transpires between 9 to 12 months of age, affecting approximately 50% of infants and constituting around 25% of visits to primary care physicians for dermatologic concerns in the first year of life [(16)]. This research aimed to assess the impact of applying mother breast milk versus a barrier cream (containing 20% zinc oxide) on the recovery of infants experiencing DD. As per the findings, both groups exhibited an improvement in dermatitis severity over the seven-day study, with a noticeable trend towards greater relief in the group treated with breast milk. In light of the preceding details, efforts were made to extensively match the characteristics of both infant groups and their mothers. This included aligning factors such as age, gender, weight, daily diaper changes, diaper brand, and cleansing methods for infants, along with considerations for breast feeding mothers' age, education level, and occupation to enhance result reliability. This alignment is corroborated by the outcomes presented in Tables 4 and 5, revealing no associations between demographic characteristics and lesion scores before and after treatment on the seventh day. Notably, our findings indicate a significant disparity in dermatitis erythema lesion scores on the seventh day, attributable to the topical application of breast milk. These results are in line with numerous studies [(13-19-20)] investigating the efficacy of breast milk in treating DD,

either independently or in comparison with various chemical or natural products.

No significant disparity was identified in the pre-treatment lesion scores between infants undergoing treatment with breast milk and those treated with barrier cream, as indicated in Table 3. However, when assessing infants with mild (score 1) and moderate (score 2) erythema post treatment, breast milk demonstrated superior efficacy in comparison to barrier cream. Statistical distinctions in the clinical effectiveness of treatment methods were observed among infants exhibiting slight erythema on the 3rd, 5th, and 7th days post-treatment, as outlined in Table 2.

Upon assessing the clinical enhancement of infants concerning the timeframe, improvement was documented in both groups, as indicated in Table 2. This observation is believed to be linked to the criteria for considering a reduction by one point in lesion score as an indicator of improvement, along with the documentation of diaper area observations in terms of the number of days. These findings from relevant studies [5-6-20] suggested that the presence of a variety of vitamins and minerals in breast milk makes the skin soft and smooth and prevents dryness and fragility, thereby preventing the penetration of foreign microorganisms through the skin. Breast milk accomplishes this function by its natural lactic acid that artificially exists in many skin creams and lotions. Additionally, fatty acids of breast milk have hydrophobic properties preventing skin penetration and damage caused by urea and enzymes in the stool and urine.

In a systematic review of non-nutritional applications of maternal milk [17], the review findings indicated the potential of various components in human milk, showing promise in preclinical investigations and currently undergoing active clinical evaluation. The therapeutic and protective functions of unprocessed breast milk are notably crucial in regions lacking convenient access to medical resources for mothers and infants.

A review of the literature uncovered a similar study, the study conducted in Egypt by **Madian & Ouda, (2019)** [18]; they employed methodologies similar to those utilized in the present trial. Notably, this study compare the effect of breast milk versus distilled water and alcohol on the umbilical cord separation. The conclusion of the Egyptian study aligns with our findings, indicating that applying breast milk to the umbilical cord results in a shorter separation time compared to distilled water. Moreover, breast milk demonstrated a reduction in the incidence of omphalitis and bacterial colonization, aligning with the effects observed with distilled water. This parallel finding emphasizes the suggestion that breast milk serves as a practical, economical, and highly effective therapeutic solution, commonly utilized in traditional and natural therapies. Health professionals have documented the positive outcomes of utilizing fresh colostrum and human milk to address conditions such as conjunctivitis, chapped nipples, rhinitis, and infections affecting the skin and soft tissues [17].

Similarly, an Iranian study by [19] reviewed the anti-inflammatory properties of human milk when topically applied to dermal and optical diseases, and concluded that Topical Human Milk (THM) is effective in curing various types of skin damage, among them is DD. Moreover,

THM appears to be an effective, safe, and available treatment compared to conventional chemical treatments. This study suggests THM as an alternative remedy to minimize the frequent use of chemical-based treatments.

The study indicated that the use of mother breast milk demonstrated greater efficacy than the barrier cream formulation for treating DD. This outcome aligns with the findings of **Seifi, et al., (2017)** [20] who conducted a study comparing Human Breast Milk (HBM) treated study group with a control group where no other topical products were applied throughout the study. They reported a statistically significant decrease in rash development among infants treated with HBM compared to the control group. They concluded that breast milk serves as an effective, safe, and convenient remedy for DD.

In a study by **Amiri-Farahani, Sharifi-Heris, & Mojab, (2020)** [14] that compared human milk and topical application of 1% hydrocortisone in the treatment of DD and included children in the first 2 years, a total of 141 children were conducted with two groups applying 1% hydrocortisone for 7 days and applying topical human milk to the dermatitis area after each breastfeeding. Dermatitis status was noted using a scale on days 3 and 7 of the study and there was no significant difference in groups after topical application of the drugs tested, and they stated that the use of human milk in the treatment of DD is as effective and safe as hydrocortisone 1% ointment ($p < 0.001$).

Contrary to the results reported by **Gozen, et al., (2014)** [13], which highlighted that barrier cream is more effective than human breast milk in treating DD, especially in newborns with moderate to severe dermatitis, the current study presents conflicting findings. The disparity in outcomes between the two studies is attributed to variations in the methods employed for diaper rash treatment and assessment criteria. Specifically, the present study focused on infants with mild to moderate degrees of DD lesions. This discrepancy in the severity of cases and the differing approaches to treatment and evaluation likely accounts for the contradictory results observed between the two studies. In addition there trial included a combination of 40% zinc oxide and cod liver oil and shown that was more effective in rash treatment differ from those of the current study. The variation in post-treatment lesion scores between the two studies may be due to the low concentration of zinc oxide formulation of just 20% and the absence of cod liver oil in the formulation in the current study.

Zinc oxide, recognized as one of the most efficacious active ingredients for maintaining skin health, has demonstrated notable improvements in the treatment and prevention of DD. Frequently utilized as a topical barrier product, zinc oxide is widely employed by physicians and caregivers of infants. The effectiveness of topical protective barrier creams, particularly those with a lower concentration of zinc oxide (20%), is evident in the observed improvements, as highlighted in a Turkish study by **Yildiz, et al., (2023)** [21] on "Pediatricians' Knowledge, Attitudes, and Therapeutic Approaches Regarding Diaper Dermatitis: A Common Condition with Many Different Practices" and emphasizes the valuable role of zinc oxide in enhancing

skin health and its significance in the management of DD.

Relevance to clinical practice

Preventive measures are crucial to safeguard the skin health and overall well-being of infants, given the potential adverse effects of antibiotics and chemical skincare formulations. It is advisable to minimize the use of such chemical products, including zinc oxide, in infants. However, addressing DD and achieving clinical improvement often requires non-chemical approaches, especially in cases of mild to moderate dermatitis. Recommendations based on study findings and literature suggest key practices for protecting infants' skin: limit the use of chemical skincare and antibiotics, change diapers frequently, allow for increased fresh air exposure, choose diapers with high absorbance, ensure loose diaper fitting, avoid powder to prevent respiratory system allergy, cleanse the diaper area with warm water or water-soaked wipes instead of alcohol-containing wipes, provide daily baths, add oil to bath water for skin moisturization, apply a thin layer of breast milk after cleaning the diaper area, regularly assess the skin in infants on antibiotics, and promptly treat any signs of erythema with breast milk.

Limitations

Nevertheless, it is imperative to recognize the study's constraints. Due to the study conditions, the researcher faced challenges in selecting samples from infants with similar cultural and economic backgrounds, along with comparable feeding methods. Furthermore, the investigation excluded children with fungal and bacterial infections, highlighting the need for additional studies focusing on this specific population. Additionally, the researcher acknowledged limitations associated with individual variations in treatment response.

Conclusion

Based on the present study findings, the study concluded that breast milk emerges as a beneficial, secure, and practical solution, displaying greater efficacy than barrier cream in treating mild to moderate dermatitis in infants.

Recommendations

The current study recommends the following:

- Developing a standardized protocol for the application of breast milk, including frequency, quantity, and method of application for the prevention and treatment of DD.
- Long- term follow-up studies are recommended to assess the potential for recurrence of DD after treatment with breast milk.
- Larger sample sizes are essential to compare diverse rash treatment methods and validate them with evidence-based research results, addressing the current gap in knowledge.

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