

**HYDROCOLLOID DRESSING FOR DIAPER DERMATITIS IN NEONATES AND
YOUNG INFANTS HOSPITALIZED IN NEONATAL INTENSIVE CARE UNITS:
A QUASI-EXPERIMENTAL STUDY**

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Aksucu G, Yıldız S. Hydrocolloid dressing for diaper dermatitis in neonates and young infants hospitalized in neonatal intensive care units: a quasi-experimental study. *Health Prob Civil.* <https://doi.org/10.5114/hpc.2025.156327>

Tables: 4

Figures: 1

References: 15

Submitted: 2025 Sep 22

Accepted: 2025 Nov 18

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Summary

Background. Diaper dermatitis (DD) is among the most frequent dermatological problems in neonates and young infants, particularly in neonatal intensive care units (NICUs). This study aimed to examine the effect of hydrocolloid dressing on the healing process of DD.

Material and methods. A quasi-experimental controlled trial was conducted with 44 infants hospitalized in a NICU and diagnosed with DD (intervention group = 22; control group = 22). The intervention group received a hydrocolloid dressing, whereas the control group received a barrier cream containing 40% zinc oxide. The severity of DD was assessed using the Clinical Evaluation Scale for DD at baseline and at 24, 48, and 72 hours after care.

Results. Infants treated with hydrocolloid dressing had significantly lower mean DD scores at 24, 48, and 72 hours compared with those treated with zinc oxide cream (all $p<0.001$). The intervention group also demonstrated a significantly shorter healing time ($p<0.001$).

Conclusions. Hydrocolloid dressing was associated with faster improvement and shorter healing duration compared with zinc oxide cream in infants hospitalized in the NICU. Further randomized and blinded studies with larger samples are warranted to confirm these findings.

Keywords: hydrocolloid dressing, diaper dermatitis, NICU, quasi-experimental, zinc oxide

Introduction

Diaper dermatitis (DD) is one of the most common dermatological problems observed in neonates and young infants. It develops as a result of prolonged exposure of the skin in the diaper area to moisture, friction, urine, and feces [1]. In neonatal intensive care units (NICUs), the risk is further increased due to factors such as immature stratum corneum, frequent defecation, continuous exposure to moisture and irritants, and the use of antibiotics, which also make management more challenging [2].

Clinically, DD is characterized by erythema, edema, occasional erosion, and pain. Beyond physical discomfort, DD may also disrupt the infant's sleep and feeding patterns, thereby contributing to parental anxiety and stress [3,4].

Current Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN) and National Association of Neonatal Nurses (NANN) guidelines recommend frequent diaper changes, gentle cleansing, and the use of barrier agents (particularly zinc oxide) as first-line approaches for the prevention and management of DD [5,6]. Although barrier creams are widely used, hydrocolloid dressings, which have been commonly applied in wound care in recent years,

have attracted attention in pediatric skin care due to their properties that support wound healing. Hydrocolloid dressings are structurally easy to use and additionally provide several benefits, including supporting skin barrier repair, forming a protective barrier, preventing the penetration of harmful microorganisms, and reducing pain [7]. Furthermore, their ability to remain in place for several days with a single application reduces the caregiver's workload, which represents an additional advantage.

In a study conducted by Qiao and Ge [8], hydrocolloid dressings were reported to result in faster healing and fewer adverse effects compared with zinc oxide cream in the management of DD. However, clinical research on the use of hydrocolloid dressings for the treatment of DD remains very limited [8,9]. This highlights an important knowledge gap regarding the potential benefits of hydrocolloid dressings for the care of DD in NICU populations.

Aim of the work

The present study aimed to evaluate the effectiveness of hydrocolloid dressings compared to standard care using zinc oxide barrier cream in the treatment of DD among neonates and young infants hospitalized in the NICU.

The hypotheses were as follows:

- H1: Neonates and young infants treated with hydrocolloid dressings will have lower clinical evaluation scale scores for DD compared to those treated with 40% zinc oxide barrier cream.
- H2: Neonates and young infants treated with hydrocolloid dressings will have shorter healing times for DD compared to those treated with 40% zinc oxide barrier cream.

Material and methods

Study design

This study was designed as a quasi-experimental controlled trial with a pretest-posttest structure. Infants hospitalized in the NICU with a clinical diagnosis of DD were allocated to either an intervention group (hydrocolloid dressing) or a control group (zinc oxide cream). To minimize contamination between participants, data for the two groups were collected sequentially rather than simultaneously, as the NICU had a shared parental accommodation

area. The order of group allocation was determined by a simple lottery method, which served as an additional safeguard to reduce allocation bias. The severity of DD was evaluated at baseline and at 24, 48, and 72 hours after the intervention.

Population and sample

The study was conducted between November 2017 and March 2018 in the NICU of a training and research hospital with a Level III NICU in Istanbul, Türkiye. A total of 44 infants with a clinical diagnosis of DD participated in the study (intervention group = 22, control group = 22). Inclusion criteria were: (a) hospitalization in the NICU, (b) body weight greater than 1,000 g at the start of the intervention, (c) gestational age above 26 weeks, (d) DD diagnosis confirmed by a clinician, (e) clinically stable condition at enrollment, and (f) written informed consent obtained from parents or legal guardians. Exclusion criteria were: (a) congenital skin anomalies, (b) dermatitis due to other dermatological conditions, (c) systemic bacterial or fungal infections, and (d) receiving immunosuppressive treatment.

The sample size was calculated using data from previous similar studies [10,11] and analyzed with G*Power 3.1.9.2 software. Based on DD scores, with an assumed effect size of 0.877, 80% power ($\beta = 0.20$), and a significance level of 0.05 ($\alpha=0.05$), the required sample size was determined to be a minimum of 22 infants per group, for a total of 44 infants. After completion of the study, a post hoc power analysis was performed. At 72 hours, the healing rate was 95.5% in the intervention group and 0% in the control group; mean dermatitis scores were 0.05 ± 0.21 and 1.50 ± 0.71 , respectively. Based on these primary outcomes, analyses conducted with a two-tailed alpha of 0.05 indicated that the statistical power exceeded 0.99 and the effect size (Cohen's $d=2.77$) was very large. These findings confirmed that the achieved sample size was sufficient to meet the study objectives.

Data collection tools

The researchers developed the Information Form based on literature [10] and included 14 items to assess participants' sociodemographic and clinical characteristics. The severity of DD was assessed using the Clinical Evaluation Scale for Characterization of the Severity of DD, developed by Stamatas and Tierney in 2014 [4]. This clinical tool was designed for descriptive evaluation of DD and was not developed as a validated or psychometrically tested

scale. The instrument includes seven score points ranging from 0 to 3.0, with 0.5-point increments; higher scores indicate greater severity of dermatitis. Each score point corresponds to a specific grade and descriptive definition of the condition. For this study, scores were categorized into four severity groups: 0 = no DD, 0.5-1.0 = mild, 1.5-2.0 = moderate, and 2.5-3.0 = severe. For this study, complete healing was defined as a DD score of 0 on the Clinical Evaluation Scale.

Intervention

The intervention consisted of three phases. In the pre-intervention phase, parents were informed about the study, written consent was obtained, and baseline demographic and clinical data were recorded. After diaper area cleansing and drying, the severity of DD was assessed independently by the researcher and an experienced NICU nurse using the Clinical Evaluation Scale for Characterization of the Severity of DD. Blinding was not possible because removing the dressing early could cause irritation or erosion; therefore, removal was only done if the dressing was soiled or fell off. To reduce bias, both a researcher and an experienced NICU nurse independently assessed diaper dermatitis severity using a standard clinical scale. If the nurse was unavailable, the researcher took standardized digital photos and sent them to the nurse for scoring, ensuring consistent and objective evaluations.

In the intervention phase, infants in the intervention group received Comfeel® Plus Transparent hydrocolloid dressing (Coloplast A/S, Humlebaek, Denmark). Two rectangular patches were cut, rounded at the edges, and applied to the right and left gluteal-perianal areas, leaving the anus uncovered. The application was performed carefully to avoid direct hand contact and to ensure full skin adherence without air bubbles. Infants in the control group received a thick layer of Oksizinc® 40% zinc oxide ointment (Dermotek Lab., İstanbul, Türkiye) directly applied to the affected area.

In the post-intervention follow-up phase, infants in both groups were diapered with clean nappies, and diaper care was performed every three hours for 72 hours. Severity of DD was reassessed at 24, 48, and 72 hours using the same clinical scale. If a score of “0” was achieved before 72 hours, treatment was discontinued, and full recovery was recorded. In the intervention group, diaper care was performed over the hydrocolloid dressing, which was replaced if detached or contaminated. In the control group, Oksizinc® 40% zinc oxide ointment was reapplied after each diaper change.

Statistical analysis

Data analysis was performed using IBM SPSS Statistics 21.0. Descriptive statistics were presented as frequency, percentage, mean, and standard deviation. To compare baseline characteristics between the two study groups, Pearson's chi-square test or Yates' corrected chi-square test was applied for categorical variables, and the Mann-Whitney U test was used for continuous variables. Fisher's exact test and Yates' corrected chi-square test were performed to compare healing rates of DD between groups, while the Mann-Whitney U test was used to compare DD scores. For within-group comparisons of mean DD scores across four repeated measurements (baseline, 24, 48, and 72 hours), the Friedman test was employed, followed by Bonferroni-adjusted Wilcoxon signed-rank tests for pairwise analyses. A two-tailed *p* value of < 0.05 was considered statistically significant.

Results

The descriptive characteristics of the infants were comparable between the groups (*p*>0.05; Table 1). There were no significant differences between groups in the use of antibiotics, the mean number of antibiotics administered, or the duration of therapy (*p*>0.05; Table 1). Before the intervention, there was no significant difference in mean DD scores between the groups (*p*=0.286). At 24 hours, the mean score in the intervention group (0.73 ± 0.55) was significantly lower than in the control group (1.86 ± 0.49) (*p*<0.001). At 48 hours, scores remained significantly lower in the intervention group (0.16 ± 0.36) compared with the control group (1.75 ± 0.53) (*p*<0.001). At 72 hours, the mean score in the intervention group (0.05 ± 0.21) was again significantly lower than in the control group (1.50 ± 0.71) (*p*<0.001). Within-group analyses further showed significant decreases in scores over time in both groups (Friedman test, *p*<0.001), with more pronounced reductions observed in the intervention group (Table 2; Figure 1).

Table 1. Descriptive characteristics of the groups

Characteristics	Intervention (n=22)		Control (n=22)		χ^2	<i>p</i>
	n	%	n	%		
Gender						
Female	12	54.5	12	54.5	0.000	1.00 ^Y
Male	10	45.5	10	45.5		
Mode of delivery						
Vaginal	6	27.3	11	50.0	1.534	0.216 ^Y

Cesarean	16	72.7	11	50.0		
Gestational age						
≤31	9	40.9	6	27.3	1.074	0.585
32-36^a	3	13.6	3	13.6		
37^a	2	9.1	2	9.1		
38-40	8	36.4	11	50.0		
Postnatal age (day)						
1-14	13	59.1	10	45.5	1.391	0.499
15-30	3	13.6	6	27.3		
≥31	6	27.3	6	27.3		
Current weight (g)						
≤ 1500	2	9.1	1	4.5	0.977	0.614
1501-2500	7	31.8	5	22.7		
≥ 2501	13	59.1	16	72.7		
Feeding						
Breast milk	11	50.0	7	31.8	2.889	0.236
Formula	9	40.9	9	40.9		
Mixed	2	9.1	6	27.3		
Number of antibiotics						
None	3	13.6	4	18.2	5.558	0.062
1-2	17	77.3	10	45.5		
3-4	2	9.1	8	36.4		
Duration of antibiotic therapy (days)						
1-3	4	18.2	8	36.4	2.615	0.271
4-6	5	22.7	6	27.3		
≥7	13	59.1	8	36.4		
Characteristics	$\bar{x} \pm SD$		$\bar{x} \pm SD$		Z	p
Birth length (cm)	43.77 ± 6.69		44.93 ± 7.77		0.872	0.383
Head circumference (cm)	31.80 ± 4.36		31.77 ± 4.42		0.130	0.897
Birth weight (g)	2565.45 ± 1299.49		2556.05 ± 1125.10		0.000	1.000

Notes: χ^2 – Pearson chi-square test, Y – Yates' corrected chi-square test, Z – Mann-Whitney U test, a – due to the small sample size in the groups, categories were merged for the analysis.

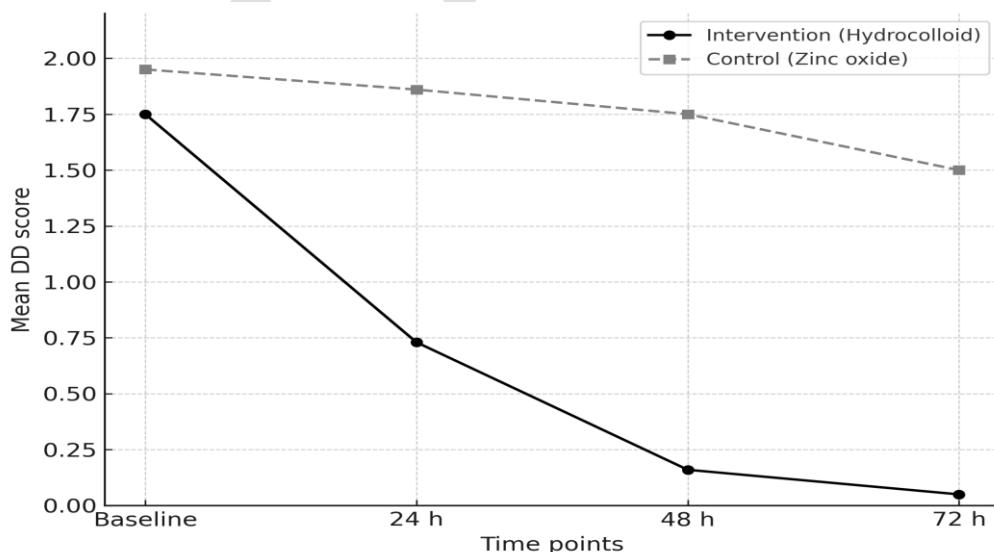


Figure 1. Mean DD scores of infants in the intervention and control groups over time

Table 2. Mean DD scores

Measurement time	Intervention (n=22)	Control (n=22)	Z	p
Baseline	1.75 ± 0.55	1.95 ± 0.49	1.066	0.286
24 h	0.73 ± 0.55	1.86 ± 0.49	5.071	0.000
48 h	0.16 ± 0.36	1.75 ± 0.53	5.710	0.000
72 h	0.05 ± 0.21	1.50 ± 0.71	5.878	0.000
Friedman	60.574	22.432	-	-
p	0.000	0.000	-	-
Difference	Baseline >24h > 48h >72h	Baseline >24h, 48h, 72h / 24h, 48h > 72h	-	-

Notes: Z – Mann-Whitney U test; bold values indicate statistically significant differences ($p<0.05$).

Post hoc pairwise comparisons indicated that in the intervention group, mean DD scores decreased significantly at each time point compared with the previous one (all $p<0.001$, except 48-72 hours where $p=0.025$). In the control group, significant decreases were observed from baseline to 24, 48, and 72 hours, and from 24 to 72 hours; however, the difference between 24 and 48 hours was not statistically significant ($p=0.059$; Table 3).

Table 3. Post hoc comparisons of mean DD scores

Time comparison	Intervention (n=22)		Control (n=22)	
	Z	p	Z	p
Baseline – 24 h	4.272	0.000	2.000	0.046
Baseline – 48 h	4.156	0.000	2.310	0.021
Baseline – 72 h	4.148	0.000	3.161	0.002
24 h – 48 h	3.729	0.000	1.890	0.059
24 h – 72 h	3.703	0.000	2.909	0.004
48 h – 72 h	2.236	0.025	2.668	0.008

Notes: Wilcoxon Signed Rank Test; bold values indicate statistically significant differences ($p<0.05$).

At 24 hours, the healing rate (defined as a DD score of 0) was 22.7% in the intervention group and 0% in the control group, with the difference being statistically significant in favor of the intervention group ($p=0.048$). At 48 hours, 77.3% of infants in the intervention group had recovered compared with 0% in the control group, and at 72 hours, the rates were 95.5% and 0%, respectively. Both the 48-hour and 72-hour differences were highly significant in favor of the intervention group ($p<0.001$; Table 4).

Table 4. Healing rates of DD by group and time

Time point	Outcome	Intervention (n=22)		Control (n=22)		χ^2	p
		n	%	n	%		
24 h	Healed	5	22.7	-	-	-	0.048^F
	Not healed	17	77.3	22	100.0		

48 h	Healed	17	77.3	-	-	24.540	0.000^Y
	Not healed	5	22.7	22	100.0		
72 h	Healed	21	95.5	-	-	36.439	0.000^Y
	Not healed	1	4.5	22	100.0		

Notes: χ^2 – Pearson chi-square test, F – Fisher's Exact Test, Y – Yates' corrected chi-square test.

Two observers independently assessed the DD scores of infants. Inter-rater reliability, evaluated using the intraclass correlation coefficient (ICC), demonstrated excellent agreement between the two observers at baseline and at 24, 48, and 72 hours, with ICC values ranging from 0.99 to 0.998 ($p<0.001$).

Discussion

This study demonstrated that hydrocolloid dressings were more effective than 40% zinc oxide cream in the treatment of DD among NICU infants, providing faster and more significant healing. Notably, significant reductions in DD scores were observed at 24, 48, and 72 hours in the intervention group, with a 95.5% healing rate at 72 hours. The shorter healing time may have positive implications for infant comfort, parental satisfaction, and reduced workload for healthcare providers.

Literature on the use of hydrocolloid dressings for DD is limited. Qiao and Ge [8], in a randomized controlled trial involving 210 infants, found that hydrocolloid dressings achieved significantly higher healing rates, fewer adverse events, and greater parental satisfaction compared with zinc oxide and mupirocin. Similarly, Giacaman et al. [9] reported that hydrocolloid dressings reduced pain and achieved complete healing in a case of severe erosive DD. The present findings are consistent with these studies, supporting the potential clinical value of hydrocolloids, particularly in resistant cases. However, the current evidence base remains limited, and further large-scale randomized trials are needed.

In addition to hydrocolloids, various alternative approaches have been investigated for DD management. A study conducted in Türkiye compared breast milk with barrier cream and found that 40% zinc oxide cream was more effective, particularly in moderate and severe cases [10]. Research from Iran demonstrated that breast milk alleviated DD symptoms but provided less improvement compared with barrier agents [11]. In addition, other studies that did not include direct comparisons with barrier creams have also reported that the use of breast milk was effective in improving diaper dermatitis symptoms [12,13]. Sharifi-Heris et al. [14] compared olive oil and calendula ointments, showing that both were similarly effective and

well-tolerated. More recently, O'Connor et al. [15] reported that diapers containing a shea butter-based emollient were as effective as those with petrolatum-based emollients and significantly reduced erythema. Taken together, these findings suggest that multiple strategies may provide benefit in DD management, although the consistency and strength of evidence vary.

In addition, data on antibiotic exposure were collected at study inclusion to characterize the clinical condition of infants in the NICU. While no significant differences were observed between groups, antibiotic use may influence skin barrier integrity as well as the risk or persistence of DD. These findings are presented descriptively because the study was not designed to evaluate causal associations between antibiotic therapy and the onset of DD. Future studies with longitudinal designs could further explore this relationship.

The strengths of the present study include its controlled design directly comparing hydrocolloid dressings with zinc oxide cream in a NICU setting and the use of repeated measurements to monitor short-term effects. Nevertheless, certain limitations should be acknowledged. Blinding was not feasible, which represents a methodological limitation; however, standardized dual assessments minimized potential observer bias. The quasi-experimental design and single-center setting may limit generalizability. Moreover, the follow-up period was restricted to 72 hours, preventing the evaluation of long-term outcomes such as recurrence or sustained skin integrity. Another limitation is the use of a descriptive clinical evaluation scale without established psychometric validation, which may affect the robustness of outcome assessment. Finally, the non-randomized allocation, although mitigated by sequential data collection and a lottery method to decide group order, still carries a potential risk of bias that should be considered when interpreting results.

Conclusions

This study demonstrated that hydrocolloid dressings were significantly more effective than 40% zinc oxide cream in reducing DD severity scores and accelerating healing among NICU infants. The rapid improvement observed highlights their potential as a clinically valuable alternative to conventional barrier creams. In practice, hydrocolloid dressings may enhance infant comfort, reduce caregiver workload, and improve parental satisfaction, while potentially decreasing the frequency of repeated applications. However, future multicenter

randomized controlled, blinded trials with longer follow-up are needed to confirm their long-term efficacy, safety, and cost-effectiveness.

Disclosures and acknowledgments

The authors declare no conflicts of interest with respect to the research, authorship, and/or publication of this article.

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

The study was approved by the Research Ethics Committee of Bakırköy Dr. Sadi Konuk Training and Research Hospital (Approval No. 2017-15-12, date: November 6th, 2017). Institutional approval was also obtained from the hospital administration. Written informed consent was obtained from all the parents or legal guardians prior to participation. The permission to use the “Clinical Evaluation Scale for Characterization of the Severity of DD” was obtained from the original author. The study was conducted in accordance with the principles of the Declaration of Helsinki. Clinical trial registration: ClinicalTrials.gov ID – NCT07186907.

Artificial intelligence (AI) was not used in the creation of the manuscript.

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