Accepted: 16 March 2021

DOI: 10.1111/jocd.14091

ORIGINAL ARTICLE

JCD Journal of Cosmetic Dermatology WILEY

A novel treatment of diaper dermatitis in children and adults

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Funding information
None

Abstract

Background: Diaper dermatitis (DD) is an acute inflammatory reaction, regardless of the cause, of the diaper-covered area. Topical skin barrier repair cosmetic products are the mainstay treatment to cure and/or prevent DD.

Aims: To assess the efficacy/tolerability of a zinc gluconate-taurine/zinc oxide and panthenol/ glycerin/ *Butyrospermum parkii* butter barrier cream using clinical evaluation.

Methods: In this prospective, open-label trial, 20 patients (10 infants/10 adults), with mild/moderate DD enrolled at the Dermatology University Clinic of Catania (Italy) were instructed to apply the cream twice daily for 30 days. Degree of erythema was performed clinically by a 5-point severity scale (from 0 = no erythema to 4 = severe erythema), at baseline, at 15 and 30 days. An Investigator Global Assessment (IGA) using a 6-point scale (from −1 = worsening to 4 = complete response/clear) along with product tolerability was also performed at 15 and 30 days. Statistical analysis was performed using SAS version 9.

Results: At 15 days, a reduction of clinical erythema assessment (CEA) from baseline was observed (mean from 3.2 ± 0.8 to 2.5 ± 0.3; $p < 0.06$), that although nonsignificant, showed a significant progressive improvement at 30 days (mean from 3.2 ± 0.8 to 1.1 ± 0.9; $p < 0.0001$) without any age differences.

Conclusions: Our preliminary results indicate that the tested barrier cream may represent a promising approach in DD rash. It may be used in mild-to-moderate forms in monotherapy without significant side effects or, where required, in association with pharmacological agents. Its long-term use is likely safe.

KEYWORDS
barrier cream, diaper dermatitis, topical treatments

1 | INTRODUCTION

Diaper dermatitis (DD), also known as diaper rash, is an acute inflammatory reaction, regardless of the cause, of the diaper-covered area, such as buttocks, perianal areas, genitals, inner thighs, and waistline.[1,2] DD usually occurs in neonates and infants, with a prevalence between 7 and 50% of the general population, with no substantial variability between different ethnic groups. It may be also observed in 5.6–50% of elderly adults affected by urinary incontinence or in bedridden.[3]

Its pathophysiology is complex and multifactorial. Although prolonged contact between the skin and urine and/or feces is likely to

promote its development through irritation by ammonia and bacterial enzymes (ie, fecal proteases and lipases) release, other factors, such as modifications of skin microbiota due to local humidity increase and/or overgrowth of pathogenic strains (ie, *Candida albicans*, *Staphylococcus* spp. *Streptococcus* spp.), have been considered.[1,2] DD is rarely long lasting, but when present it may cause considerable discomfort to both infants and adults.[4]

Topical skin barrier repair cosmetic products are the mainstay treatment to cure and/or prevent DD. A pharmacological approach is generally indicated in more severe forms of DD, especially when secondary infections occur.[4]

The aim of this open-label prospective clinical trial was to evaluate by clinical evaluation the efficacy and tolerability of a new barrier cream based on zinc gluconate and taurine complex, zinc oxide combined with panthenol, glycerin, and *Butyrospermum parkii* butter in the treatment of mild-to-moderate irritant DD.

2 | MATERIALS AND METHODS

From September 2018 and May 2019, twenty subjects of both genders, 10 aged from 1 day to 4 years and 10 adults affected by mild-to-moderate DD were enrolled at the Dermatology Clinic of Catania, Italy. Study duration was up to 30 days. The study was performed in accordance with the ethical principles from the Declaration of Helsinki 1996 and Good Clinical Practices.

Parent's or patient's written consent was obtained before the treatment was begun. Inclusion criteria were as follows: infants or adult subjects, of either gender, with mild-to-moderate DD, who underwent a wash-out period of at least 2 weeks for topical antifungals and/or corticosteroid treatments, and of at least 1 month for oral antifungals or corticosteroids. No other topical products or drugs were allowed, except for mild cleansers (fragrances and allergy-free) and super-adsorbent diaper to be changed several times a day.

At baseline, all enrolled patients underwent microbiological evaluation by cultures of cotton swabs from diaper-affected areas. If negative, patients' parents or adult subjects were instructed to apply the barrier cream in the affected area twice daily for 30 days. In order to reduce potential evaluator bias, all subjects were evaluated by an investigator not directly involved in the study at baseline (T0), at 15 (T1) and 30 days (T2).

Primary endpoint for efficacy was the evaluation of a clinical parameter score (erythema) at day 30; secondary endpoint was the evaluation of tolerability at the end of the study.

Clinical efficacy evaluation was performed by (1) clinical erythema assessment (CEA) by a 5-point severity scale (0 = no erythema; 1 = very mild erythema: light pink; 2 = mild erythema: pink; 3 = moderate: red; and 4 = severe: severe red) at all time points, and by (2) Investigator Global Assessment (IGA) based on a 6-point scale (−1 = worsening; 0 = no response; 1 = mild response: 50% improvement; 2 = moderate: 50–80% improvement; 3 = excellent: >80% improvement; and 4 = complete response: clear) at 30 days. Digital photography was performed at all time points.

Evaluation of tolerability and cosmetic acceptability by a 3-point severity scale (0 = poor; 1 = good; and 2 = excellent) at 15 and 30 days were also obtained.

The quantitative data are reported as mean ± standard deviation (SD), while the qualitative ones are expressed in number and percentage. The statistical significance was set at $p \leq 0.05$. Data were evaluated using SAS version 9.

3 | RESULTS

All enrolled cases (10 children/10 adults) completed the study. Subject demographic and clinical data are shown in Table 1.

At 15 days, a nonsignificant reduction of CEA from baseline was observed (mean from 3.2 ± 0.8 to 2.5 ± 0.3; $p<0.06$) in all patients. In addition, IGA showed excellent response in 2 cases (10%), moderate in 7 cases (35%), and mild in 11 cases (55%).

At 30 days, a significant decrease of CEA severity was found when comparing clinical scores at baseline (3.2 ± 0.8) to those obtained at the final evaluation (1.1 ± 0.9) ($p < 0.0001$) (Figures 1 and 2) without any age differences. At the end of treatment, IGA showed additional clinical improvement from baseline both in infants than in adults (Figures 1–3). In detail, in infants a complete response was obtained in 6 cases (60%), excellent in 2 (20%), moderate in 1 (10%),

TABLE 1 Demographic and clinical history data at baseline of enrolled patients (20 cases)

	Children	Adults
Sex	6 M/4F	7F/3 M
Mean age (months/years)	18±10.5 months	84±6.2 years
DD severity	4 mild/6 moderate	5 mild/5 moderate
Previous topical treatments	Steroids: 2 Antifungals: 3 Steroids in combination with antifungals: 1 Talcum powder: 1 Zinc oxide paste: 3	Steroids: 3 Antifungals: 3 Steroids in combination with antifungals: 3 Zinc oxide paste: 1

and mild in 1 case (10%), while in adults a complete response was observed in 4 cases (40%), excellent in 3 (30%), moderate in 2 (20%), and mild in 1 case (10%). No worsening or no response was recorded in any case. No signs of local intolerance were documented, and product tolerability was rated as excellent in 90% of patients.

4 | DISCUSSION

This open-label, prospective trial based on clinical evaluation of DD indicates that this new barrier cream is an effective treatment for infants and adult patients with mild-to-moderate DD.

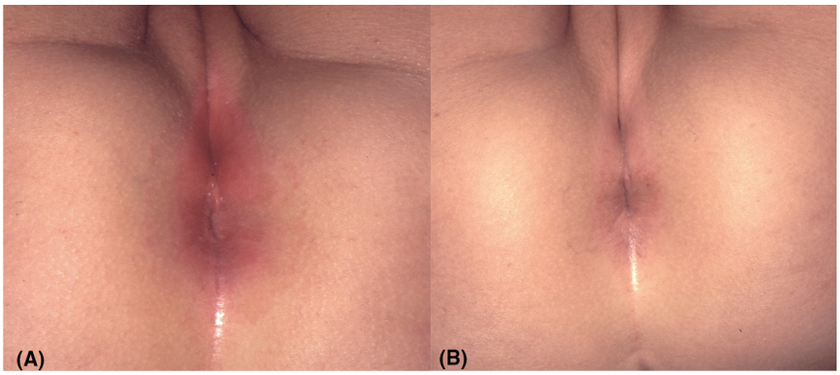

FIGURE 1 An 8-month baby girl with a 2-month history of mild perianal DD extending to the vulvar area had been treated with zinc oxide paste, but her mother refused to continue this treatment due to poor improvement. At clinical examination, on the perianal area a moderate erythema was observed (A). After 15 days of treatment with the tested barrier cream used twice daily, an excellent response was obtained, with the persistence of very mild erythema (B)

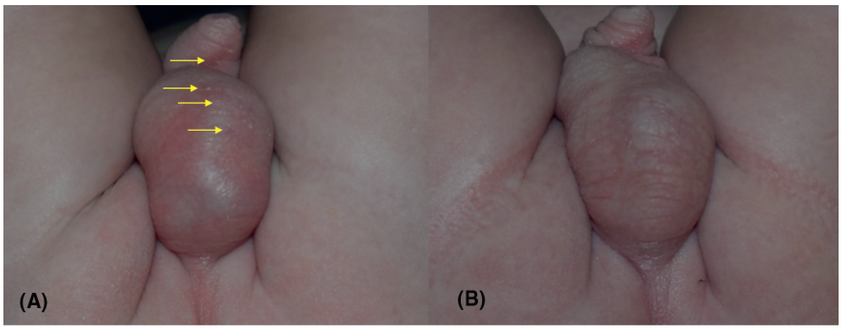

FIGURE 2 An 11-month baby boy with a 1-month history of mild DD on the scrotal skin area treated with a topical steroid agent was admitted for parents' concern regarding side effects from prolonged treatment. At clinical examination, on the scrotal area a moderate erythema was observed along with mild skin atrophy likely resulting from the steroid treatment. Few pustular lesions were also present (arrows) (A). A complete clearing after 30 days of treatment with the tested barrier cream used twice daily (B) was obtained

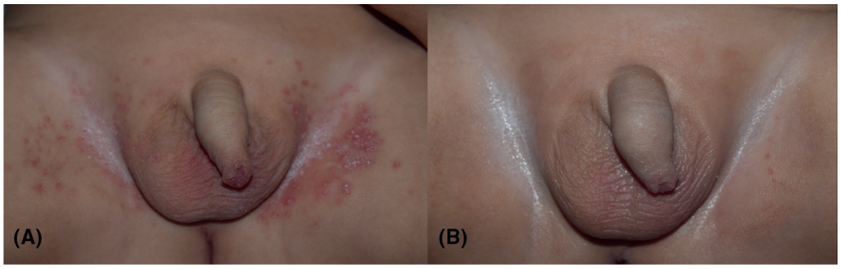

FIGURE 3 A 12-month infant with a 2-month history of moderate scrotal DD extending to inguinal fold areas underwent evaluation for a clinical worsening despite treatment with a topical steroid agent and negative skin swabs. At clinical examination, on the scrotum and the inguinal folds, a moderate erythema was observed (A). A complete clearing after 30 days of treatment with the tested barrier cream used twice daily (B) was obtained

The effect of the tested cream may be related to multiple mechanisms of action of its ingredients, including zinc gluconate-taurine complex, zinc oxide, panthenol, glycerin, and *Butyrospermum parkii* butter.

In detail, *zinc gluconate*, the zinc salt of gluconic acid, has antiseptic and anti-inflammatory properties, likely through a balancing effect between bad and good skin microbiota, and through a reduction of the production of inflammatory mediators like nitric oxide, respectively.[5,6] *Taurine* (2-aminoethansulfonic acid), a free amino acid present at high concentration in tissues exposed to damage of reactive oxygen species (ROS), is supposed to play a protective role in inflammation associated with oxidative stress.[7] Moreover, taurine present in the zinc gluconate-taurine complex (patent pending) formulation may also act as a zinc carrier capable of strengthening the anti-inflammatory properties of both agents. *Zinc oxide* (ZnO) is an inorganic agent with well-known anti-irritant, anti-inflammatory, and antiseptic properties.[8] The study cream is also formulated with humectants, such as *panthenol*, a pro-vitamin of the B-complex, and *glycerin*, as well as with *Butyrospermum parkii* butter, a waxy agent extracted from the nut of *Vitellaria paradoxa* tree that acts through emollient and anti-inflammatory effects.[9–11]

5 | CONCLUSIONS

Our preliminary results indicate that the tested barrier cream may represent a promising approach in DD rash. It may be used in mild-to-moderate forms as monotherapy or, where required, in association with pharmacological agents. The product has shown to be safe and well tolerated. Further studies on larger series of DD patients are necessary to confirm our finding and results.

CONFLICT OF INTEREST

None to declare.

ETHICAL STATEMENT

This study received approval by the local ethical committee.

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How to cite this article: Dall'Oglio F, Musumeci ML, Puglisi DF, Micali G. A novel treatment of diaper dermatitis in children and adults. *J Cosmet Dermatol*. 2021;20(Suppl. 1): 1–4. https://doi.org/10.1111/jocd.14091