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A novel treatment of intertrigo in athletes and overweight subjects

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Abstract

Background: Intertrigo is a recurrent inflammatory dermatosis involving large/small body folds. Skin barrier products represent the mainstay of treatment in uncomplicated mild/moderate intertrigo.

Aims: To assess by clinical and instrumental evaluation the efficacy and tolerability of a new barrier spray containing zinc gluconate-taurine complex and zinc oxide combined with panthenol, glycerin, and Shea (Butyrospermum parkii) butter in mild-to-moderate intertrigo in athletes and overweight subjects.

Methods: In this open-label prospective trial, 20 adult patients, with mild/moderate intertrigo enrolled at the Dermatology University Clinic of Catania (Italy), were instructed to apply the spray twice daily for 30 days. Degree of erythema was performed clinically and by polarized dermoscopy using a 5-point severity scale (from 0=no erythema to 4=severe erythema) at baseline, and at 15 and 30 days. The measurement of pruritus was carried out by a subject-completed visual analog scale (VAS) (from 0 mm=no pruritus to 100 mm=severe pruritus), at all time points. An Investigator Global Assessment (IGA) using a 6-point scale (from −1=worsening to 4=complete response/clear) was also conducted at 30 days, along with a self-administered tolerability questionnaire. Statistical analysis was performed using SAS version 9.

Results: At 15 days, a statically significant reduction from baseline in erythema severity (mean from 3.4 ± 0.3 to 2.5 ± 0.2) along with pruritus intensity (mean from 70 ± 15.4 mm to 40 ± 9.5 mm) was observed. At 30 days, all evaluated parameters showed a further progressive statistically significant reduction from baseline. No relevant side effects were recorded.

Conclusions: Our results suggest that the tested spay containing antiseptic/anti-inflammatory and anti-irritation agents may represent a valid therapeutic option for mild/moderate intertrigo.

KEYWORDS
athletes, barrier spray, intertrigo, overweight subjects, topical treatments

1 | INTRODUCTION

Intertrigo is a recurrent inflammatory dermatosis involving large and/or small body folds that may be generally induced by mechanical events, such as friction from skin-to-skin rubbing, or by increased skin heat and humidity causing maceration.[1] Although intertrigo may occur in both gender and all races, it is more common in athletes, such as cyclists or runners, as well as in overweight subjects with or without diabetes.[2,3] Hyperhidrosis, long-term care settings, poor hygiene, occlusive clothing, and use of wool and synthetic fibers are other frequent predisposing factors.[4] In early stages, erythema may range from mild to severe. With time, abrasion and fissuration, with weeping and crusting, may ensue, as well as secondary bacterial or fungal infections. Pruritus, burning, stinging, and pain are common symptoms. Treatment of mild-to-moderate uncomplicated intertrigo primarily includes changing all the above-mentioned environmental factors and use of topical skin barrier products.

The aim of this open-label prospective clinical trial was to assess by clinical and instrumental evaluation the efficacy and tolerability of a new barrier spray containing zinc gluconate-taurine complex and zinc oxide combined with panthenol, glycerin, and Shea (*Butyrospermum parkii*) butter in mild-to-moderate intertrigo in athletes and overweight subjects.

2 | MATERIALS AND METHODS

From September 2018 to May 2019, twenty adult subjects of both genders, affected by mild-to-moderate intertrigo, were enrolled at the Dermatology University Clinic of Catania (Italy). The 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. Patients' written consent was obtained before the treatment was begun. All patients who fulfilled the following inclusion criteria were enrolled: subjects ≥ 18 years of age, of either gender, overweight (Body Mass Index: 25-30) with or without diabetes or engaging in physical activity regularly, affected by mild-to-moderate intertrigo with any concomitant infection and/or other skin disease. Washout was as follows: at least 3 weeks from topical antifungals and/or corticosteroids and/or antiseptics, and at least 1 month from oral antifungals or corticosteroids. No other topical products or drugs were allowed, except for mild cleansers (fragrances and allergy-free).

At baseline, all enrolled patients underwent microbiological evaluation by cultures of cotton swabs from affected fold areas. If negative, patients were instructed to apply the barrier spray on the affected areas twice daily for 30 days. In order to reduce potential bias, all subjects were evaluated by an investigator not directly involved in the study at baseline (T0), and at 15 (T1) and 30 days (T2). Primary endpoints for efficacy were the evaluation of all clinical parameter scores (erythema, pruritus) at day 30; secondary endpoint was the evaluation of tolerability at the end of the study.

TABLE 1 Demographic characteristics and anamnestic data of enrolled patients (20 cases)

Sex
14 M/6 F
Mean age (years)
44 (range: 25-67)
Intertrigo severity
10 mild/10 moderate
Patients' characteristics
Overweight (5 cases)
Athlete (2 cases)
Overweight/diabetes (8 cases)
Overweight/athlete (5 cases)
Previous topical treatments
Corticosteroids (8 cases)
Corticosteroids + antifungals (10 cases)
No treatment (2 cases)

Efficacy was assessed by measuring the degree of erythema and pruritus at 15 and 30 days. Degree of erythema was evaluated clinically and by polarized dermoscopy (×10 magnification; Illuco IDS-1100®, Tre T Medical, Camposano, Italy) using a 5-point severity scale (0=no erythema; 1=very mild erythema; 2=mild erythema; 3=moderate erythema; and 4=severe erythema) at all time points. The measurement of pruritus was carried out by a subject-completed visual analog scale (VAS) from 0 mm=no pruritus to 100 mm=severe pruritus at baseline, and at 15 and 30 days. Additionally, an Investigator Global Assessment (IGA) was conducted at the end of the study using a 6-point scale (−1=worsening; 0=no response; 1=mild response: ≤50% improvement; 2=moderate: 51–80% improvement; 3=excellent: >80% improvement; and 4=complete response: clear). Evaluation of tolerability and cosmetic acceptability by a 3-point severity scale (0=poor; 1=good; and 2=excellent) at 15 and 30 days was also performed. 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 (14/M, 6/F) completed the study. Subject demographic and clinical data are shown in Table 1.

After 15 days, a statically significant reduction from baseline in erythema severity (mean from 3.4 ± 0.3 to 2.5 ± 0.2, $p < 0.01$) along with pruritus intensity (mean from 70 ± 15.4 mm to 40 ± 9.5 mm, $p<0.01$) was observed (Figures 1-2).

At 30 days, all evaluated parameters showed a progressive significant reduction from baseline (erythema severity: mean from 3.4±0.3 to 1.5±0.2 at 30 days, $p < 0.0001$; VAS: mean from 70 ± 15.4 to 7.8 ± 10.5, $p < 0.0001$) (Figures 3-4). IGA showed a complete

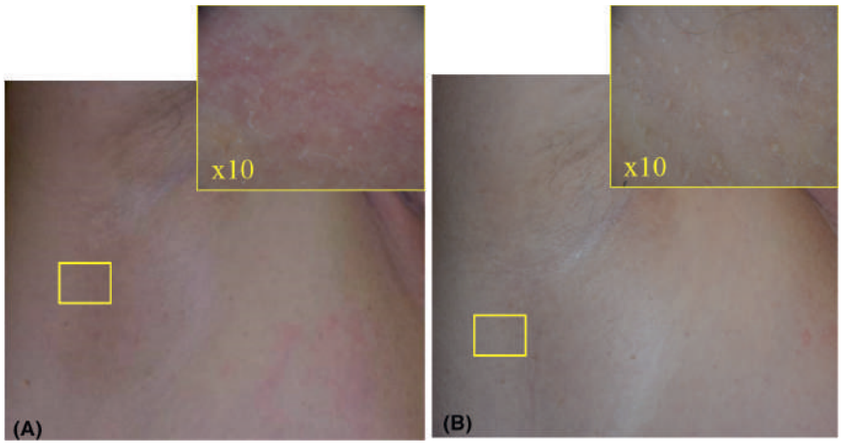

FIGURE 1 A 27-year-old jogger male presented with a 4-month history of mild inflammatory intertrigo in both axillae (A), extending beyond the fold area due to rubbing during intense running activity, and characterized by itch and burning sensation. Treatment with topical corticosteroids was temporarily beneficial, but a main concern was the risk of possible local side effects, including skin atrophy. After 15 days of treatment with the tested barrier spray used twice daily, a complete clinical response was observed (B), along with a significant reduction in pruritus intensity (VAS: from 80 mm to 15 mm). The clinical result was confirmed by dermoscopy evaluation of a target affected area, showing disappearance of erythema at the end of treatment (inserts)

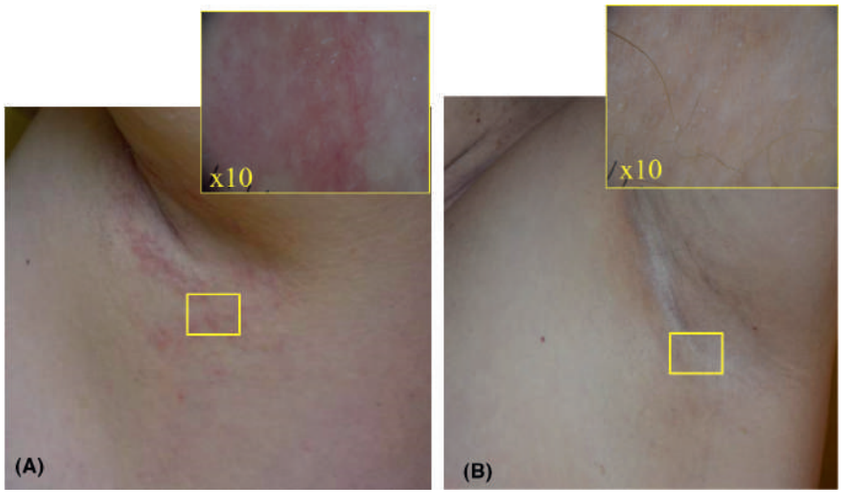

FIGURE 2 A 32-year-old overweight male aerobics instructor with a 2-month history of untreated moderate inflammatory bilateral axillary intertrigo (A) complained of persistent and intense reddening following unavoidable physical activity. After 15 days of treatment (B) with the tested barrier spray used twice daily, a complete clinical response was obtained (B) along with a significant reduction in pruritus intensity (VAS: from 90 mm to 20 mm). The clinical result was confirmed by dermoscopy evaluation of a target affected area showing disappearance of erythema at the end of treatment (inserts)

response in 9 cases (45%), excellent in 6 (30%), moderate in 4 (20%), and mild in 1 case (5%). No patients showed clinical worsening or no response from baseline.

The product tolerability was rated as excellent by all patients, and no local side effects were documented.

4 | DISCUSSION

The results of this open-label prospective trial indicate that the tested barrier spray containing antiseptic, anti-inflammatory, and anti-irritation agents may represent an option to consider when dealing with mild-to-moderate intertrigo, being effective, well tolerated, and free of significant side effects, as confirmed by clinical and instrumental evaluations performed in affected overweight subjects and athletes.

The mechanism of action of the tested spray may be related to multiple synergic mechanisms of action of its ingredients. *Zinc gluconate-taurine* complex (patent pending) is a combination of the zinc salt of gluconic acid and 2-aminoethanesulfonic acid. Both have anti-inflammatory properties. In addition, they also have antiseptic and antioxidant action, respectively. They likely exert a balancing

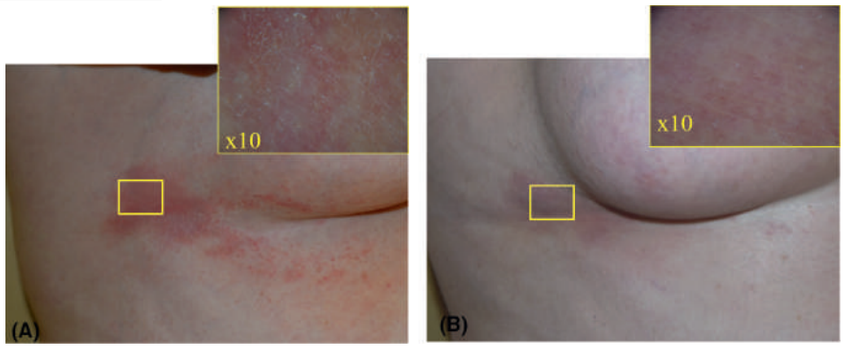

FIGURE 3 A 32-year-old overweight female with a 5-month history of moderate inflammatory submammary intertrigo (A) sought medical advice due to poor response to multiple cycles of topical antifungal treatments. After 30 days of treatment with the tested barrier spray used twice daily, an excellent clinical response was observed (B) along with a significant reduction in pruritus (VAS: from 90 mm to 25 mm). The clinical result was confirmed by dermoscopy of a target area showing a very mild residual erythema after treatment (inserts)

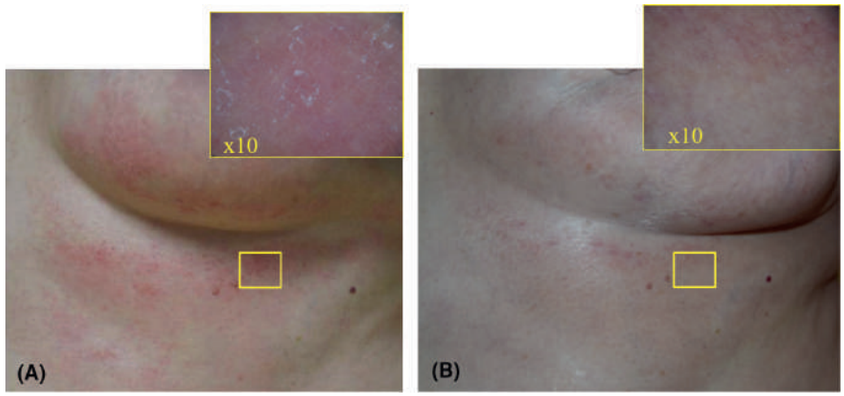

FIGURE 4 A 64-year-old overweight diabetic woman with a 3-month history of moderate inflammatory submammary intertrigo (A) relapsed after a successful treatment with a topical steroid agent. The main reason of consultation was patient refusal to undergo a new cycle of topical steroid therapy. After 30 days of treatment with the tested barrier spray used twice daily, an excellent clinical response was recorded (B) along with a significant reduction in pruritus (VAS: from 75 mm to 15 mm). The clinical result was confirmed by dermoscopy of a target area showing a very mild residual erythema at the end of treatment (inserts)

effect between bad and good skin microbiota, besides a synergic reduction in the release of inflammatory mediators, such as nitric oxide.[5-7] *Zinc oxide* is an inorganic compound with well-known anti-irritant, anti-inflammatory, and antiseptic properties.[8] *Panthenol*, a pro-vitamin of the B complex, and *glycerin* are both humectant molecules that attract water and promote its retention in the stratum corneum of the epidermis.[9,10] Finally, Shea (*Butyrospermum parkii*) butter, a waxy agent extracted from the nut of *Vitellaria paradoxa* tree, acts as an emollient providing a protective film that makes the skin surface smoother, thus preventing skin damage.[11] As a result, the tested product provides moisturizing and anti-inflammatory effects, as confirmed by this clinical and instrumental investigation.

5 | CONCLUSIONS

Our results indicate that the tested barrier spray may represent a valid option to treat and prevent intertrigo. In mild-to-moderate forms of intertrigo, it may be used as monotherapy, whereas in more severe forms, its association with pharmacological agents may provide additional benefits without significant side effects. The main limitations of this study include the relatively small case series with no placebo control group. Further studies on larger series of intertrigo 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.

AUTHOR CONTRIBUTIONS

The manuscript is an original unpublished work, and it is not submitted for publication elsewhere. All writers and contributors who participated in the preparation of the manuscript are listed as authors.

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