

A New Gel Formulation of Miconazole Nitrate 2% for the Treatment of Chronic Intertrigo

Raj Varma, MD; Wendy Cantrell, CRNP; Kelly Werlinger, MD[†]; Boni E. Elewski, MD

We explore the usefulness of a new drying gel containing miconazole nitrate 2% in a unique vehicle for the treatment of chronic intertrigo. Eleven patients with intertrigo were enrolled in the study and instructed to use the gel twice daily. All patients were followed for at least 12 weeks. At follow-up visits, they were asked subjective questions to assess the tolerability and effectiveness of the product. All patients (11/11) reported improvement of their intertrigo and a decrease in new areas of maceration. In addition, all patients were very satisfied with the cosmetic elegance of the product; they had previously used a currently marketed powder containing miconazole 2% but preferred the new gel product. No skin irritation was reported. This regimen is a useful addition to the currently available treatment options for chronic intertrigo.

Intertrigo is a nonspecific inflammation of opposed skin, most commonly found in the inframammary and subpannus areas, crural and gluteal folds, axillae, and interdigital toe webs. Intertrigo is a clinical diagnosis, as there are no characteristic histopathologic features.¹ Symptoms include erythema, pruritus, tenderness, and burning in the absence of infection. The warm, moist environment in the skin fold leads to maceration and erosion, giving a foothold to bacterial and fungal organisms; thus, secondary infections are common.

Although there are several fungal organisms associated with secondary infection of intertrigo, *Candida* is the most likely culprit. However, if the interdigital area is involved, dermatophytes are often the cause. Fungal infections may damage the stratum corneum, making the

patient's skin more vulnerable to bacterial penetration. In fact, it is common for interdigital areas to harbor dermatophytes and bacterial infections concomitantly.¹

Risk factors for the development of intertrigo include high ambient temperature, obesity, diabetes mellitus, exercise and other sweat-provoking activities, immunosuppression, and immobility.¹⁻⁴ Since several of these risk factors cannot be eliminated, intertrigo can be a vexing problem to manage. After treatment of secondary infections, intertrigo is managed by minimizing friction and moisture in body folds. Patients are often instructed to wash with antibacterial soap, then to dry well in between body folds. Individuals with intertrigo should wear nonrestrictive clothing and avoid becoming overheated. In some cases of severe inflammation, steroid creams or topical immunomodulators may be used.² Too often, common strategies fail to relieve patients' symptoms.

Patients are often instructed to use absorptive powders with antibacterial and antifungal activity to both treat and prevent intertrigo. There are no data supporting this recommendation, and patients often report that the powder forms irritating cakes between body folds.³ Thus, the purpose of the current study was to explore the usefulness of a new drying gel containing miconazole nitrate 2% in

Dr. Varma is a Research Fellow, Ms. Cantrell is a Nurse Practitioner, Dr. Werlinger was a Resident, and Dr. Elewski is Professor of Dermatology, all at the Department of Dermatology, University of Alabama, Birmingham.

[†]Deceased.

The authors report no conflict of interest in relation to this article.

a unique vehicle in the treatment of chronic intertrigo. Miconazole is an antifungal agent in the imidazole class of medications. The most commonly used topical forms of miconazole include cream and powder formulations; however, a new drying gel has been developed to absorb and control moisture. In addition to promoting a moisture-free environment, this new gel dries to an elegant powdery finish, thereby preventing irritating cake formation.

METHODS

Eleven subjects (4 men and 7 women) with chronic intertrigo were recruited from dermatology clinics at the University of Alabama, Birmingham. Subjects were selected based on the presence or absence of symptomatic disease. They presented with intertrigo of the groin (5 patients), the breast and axilla (5 patients), and the toe web (1 patient). The study participants were instructed to use the gel twice daily on affected areas and keep follow-up appointments at the clinic. All patients were followed for at least 12 weeks. At follow-up visits, they were asked nonleading subjective questions to assess the tolerability and effectiveness of the product.

RESULTS

One hundred percent (11/11) of patients reported improvement of their intertrigo and a decrease in new areas of maceration. In addition, all patients were very satisfied with the cosmetic elegance of the product. Anatomic location did not seem to affect the efficacy of the medication. All patients had previously used a currently marketed powder containing miconazole 2% but preferred the new gel product. No skin irritation was reported. All patients continued to use the new product after the course of sample medication was completed. For example, after completely clearing with twice-daily use, one patient with groin involvement switched to using the

drying gel 1 to 2 times weekly. On this maintenance regimen, recurrence was prevented.

COMMENT

There is a paucity of data on the treatment of intertrigo.⁵ The treatments that are available do not work for all patients. The new product in this study appears to be a useful addition to current treatment options. Its drying gel formulation keeps areas between body folds dry without caking or irritation. Additionally, its antifungal activity helps treat secondary infection or prevent it altogether. All patients felt the product was effective and preferred it to antifungal powder.

The results here demonstrate the need for a larger evaluative study of this product. Unfortunately, most studies regarding intertrigo often include small sample sizes. We propose a larger, randomized, placebo-controlled clinical trial to fully investigate the efficacy and tolerability of this new product. In the meantime, dermatologists should consider this drying gel when treating the patient with chronic intertrigo.

Acknowledgment—The authors would like to recognize and thank Dr. Kelly Werlinger, who contributed greatly to this study and manuscript prior to her unfortunate passing.

REFERENCES

1. Janniger CK, Schwartz RA, Szepletowski JC, et al. Intertrigo and common secondary skin infections. *Am Fam Physician*. 2005;72:833-838.
2. Chapman MS, Brown JM, Linowski GJ. 0.1% tacrolimus ointment for the treatment of intertrigo [letter]. *Arch Dermatol*. 2005;141:787.
3. Guitart J, Woodley DT. Intertrigo: a practical approach. *Compr Ther*. 1994;20:402-409.
4. Roberts WE. Dermatologic problems of older women. *Dermatol Clin*. 2006;24:271-280.
5. Mistiaen P, Poot E, Hickox S, et al. Preventing and treating intertrigo in the large skin folds of adults: a literature overview. *Dermatol Nurs*. 2004;16:43-46, 49-57. ■