An occlusive dressing containing betamethasone valerate 0.1% for the treatment of prurigo nodularis

ROSITA SARACENO¹, ANDREA CHIRICOZZI¹, STEVEN PAUL NISTICÒ¹, SERGIO TIBERTI² & SERGIO CHIMENTI¹

¹Department of Dermatology, University of Rome Tor Vergata, Rome, Italy and ²Department of Public Health, University of L’Aquila, L’Aquila, Italy

Abstract

Introduction: Prurigo nodularis is a distressing condition characterized by the presence of multiple nodules associated with intense pruritus. Objective: To assess the clinical efficacy and safety of betamethasone valerate 0.1% tape and a moisturizing itch-relief cream in prurigo nodularis. Methods: Twelve patients were enrolled in this pilot comparison of betamethasone valerate 0.1% tape versus a moisturizing itch-relief cream containing feverfew. The study period was 4 weeks. Clinical evaluation was performed weekly. Results: Eleven subjects completed the 4 weeks of therapy. The mean visual analogue scale (VAS) for pruritus at baseline was 8.75 for both sides of the body. The side treated with betamethasone valerate 0.1% tape showed a higher clinical response (VAS score at week 4: 3.9; p < 0.005) compared with the side treated with moisturizing itch-relief cream (VAS score at week 4: 5.6; p < 0.005). Conclusion: Both treatments were effective. However, the occlusive dressing enhanced the efficacy of the treatment, preventing scratching.

Key words: betamethasone valerate 0.1%, itch-relief cream, occlusion, prurigo nodulare, tape

Introduction

Prurigo nodularis (PN) is a chronic skin condition characterized by symmetric pruriginous nodules (1). A variety of systemic conditions have been reported to be associated with PN (2,3). The treatment of PN is often unsatisfactory. Conventional therapies such as capsaicin, glucocorticoids, ultraviolet therapy and antihistamines have not been particularly successful (4–6). Topical antipruritic and moisturizing agents containing menthol and phenol or anaesthetics might help alleviate the sensation of itching. Healing of the lesions may be achieved by the use of occlusive dressings. Among the occlusive dressings, betamethasone valerate (BMV) is a medium-potency steroid that is available as a tape at 0.1% concentration. We compared, in a half-side manner, the clinical efficacy, safety and tolerability of BMV 0.1% tape and a moisturizing itch-relief cream in patients with PN.

Report

A pilot, bilateral-paired comparison of BMV 0.1% tape with a moisturizing itch-relief cream containing feverfew was performed in 12 patients (mean age 57 years; 10 females and two males) suffering from severe PN which was unresponsive to topical and systemic therapies (Table I). The study was conducted at the Department of Dermatology of the University of Rome Tor Vergata. Ethical approval was granted by the local health authority and informed consent was obtained from all patients.

Subjects with an established clinical diagnosis of PN and bilaterally symmetric lesions were eligible to participate in the study. Subjects who were pregnant or nursing, who had known hypersensitivity to the test medication, or who had shown signs of skin atrophy, telangiectasia or striae in the target region were not included in the study. Enrolled patients were
discontinued from previous topical or systemic treatment for at least 4 weeks prior to the start of the study.

BMV 0.1% tape (Betesil®; Ibsa Farmaceutici Italia S.r.l.) was a 75 cm² (75 × 1000 mm) transparent medical plaster, with the adhesive layer containing 2.25 mg of BMV at the concentration of 0.1%, and was applied to PN lesions on the left side of the body (Figure 1). The plasters were cut according with the size of the nodular lesions, applied once a day for 24 hours and changed every morning after skin cleansing. A maximum of 10 pruritic lesions were selected from the patient and treated. The moisturizing itch-relief cream (ultra-calming cream, Aveeno®), containing a natural ingredient (i.e. feverfew), was used for comparison and applied to PN lesions on the right side of the body twice a day for 4 weeks.

Two blinded physicians assessed clinical improvement using a six-grade clinical evaluation scale
A visual analogue scale (VAS) from 0 to 10 was also used weekly for 4 weeks to assess patient pruritic symptoms.

At the end of the 4-week period, patients were asked to complete a questionnaire evaluating the two treatments in terms of ease of application, effects on cutaneous symptoms, tolerability, adverse events and preference for future use. In addition, patients were asked to evaluate the cost of the treatment and the adhesion of the tape. Blood tests including plasma cortisol levels were measured at the beginning of the treatment and at the end of the study.

Changes in lesion score were evaluated using Student’s t-test for paired values. A p-value < 0.05 was considered statistically significant.

Eleven subjects completed the 4 weeks of therapy; one subject dropped out after the second visit. After reaching a non-pruritic state (mean of 7 days), the skin lesions were noted to regress gradually and the nodules flattened and softened within the 4 weeks of treatment in 7/11 (63.6%) patients in both body halves. For the BMV tape side, 18% (2/11) had no changes (score +0), 63.6% (7/11) had a slight improvement (score +1), 27.3% (3/11) had a moderate improvement (+2), while none (0%) achieved a marked improvement (+3), or complete remission (+4) of the skin lesions.

The mean VAS at baseline was 8.75 for both sides of the body. Over the 4-week treatment period, both the BMV tape and the moisturizing itch-relief cream were effective in treating the skin symptoms. However, lesions treated with BMV tape showed a greater reduction of itch (VAS score at week 4: 3.9; p < 0.005), excoriation and infiltration (Figure 1) from baseline compared to lesions treated with moisturizing itch-relief cream (VAS score at week 4: 5.6; p < 0.005).

While there was more improvement in clinical grading and a greater reduction in the mean VAS in the BMV tape group after 4 weeks (Figure 2), the difference between the two groups was not significant (p > 0.005).

After reaching a non-pruritic state, mild hyperpigmentation remained at the lesional sites in all patients, especially on the pre-tibial nodules. The patient’s questionnaire revealed that both treatments had high cosmetic acceptability and tolerability. The result was that 90.9% of patients (10/11) preferred the tape because the occlusive dressing significantly reduced the ability to scratch the lesions. However, 7/11 patients commented that while BMV tapes were easy to apply, there was loss of adhesion within 24 hours; 27.3% (3/11) considered the cost of the tape (15.50 Euros for four tapes) as a deterrent. One patient discontinued the study for this reason. No side effects were noted in either treatment modalities and no patients showed evidence of hypothalamic–pituitary–adrenal-axis suppression.

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While there was more improvement in clinical grading and a greater reduction in the mean VAS in the BMV tape group after 4 weeks (Figure 2), the difference between the two groups was not significant (p > 0.005).

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Discussion

We report that the occlusive dressing with BMV 0.1% is effective in the treatment of PN, representing a valid therapeutic option in this condition. Corticosteroids are helpful in this condition and the occlusion can enhance penetration of the corticosteroid. By preventing scratching, the occlusive dressing can inhibit the repetitive rubbing, scratching and picking of the skin that perpetuates the disease and could stop the vicious itch–scratch cycle. Vehicle features can influence the potency of a topical therapy, and treatment with corticosteroids under occlusive dressings has become a popular approach during the last decade. The efficacy of the medium-potency glucocorticoid BMV tape has been reported in a randomized, bilateral-paired comparison of BMV 0.1% tape with BMV 0.12% cream in subjects with mild to moderate psoriasis and with symmetrical lesions (7).

The clinical improvement observed in the present study might also be explained by the immunosuppressive effect of corticosteroids on T cells and pro-inflammatory cytokine modulation of the release of neuropeptides involved in the pathogenesis of PN such as substance P and calcitonin gene-related peptide (8).

Since the majority of the patients had xerosis cutis or associated conditions (i.e. haemodialysis, hepatitis C virus positivity), the significant improvement observed in the group treated with the itch-relief product was probably due to skin hydration and cutaneous trophism following the twice-daily application of the moisturizing cream.

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References
