A Hydrocolloid Occlusive Dressing Plus Triamcinolone Acetonide Cream is Superior to Clobetasol Cream in Palmo-Plantar Pustulosis

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The purpose of this study was to compare the therapeutic efficacy of a hydrocolloid dressing (Actiderm^R) over a medium strength corticosteroid (triamcinolone acetonide (TAA) 0.1% cream) with that of a highly potent corticosteroid (clobetasol propionate 0.05% cream) in palmo-plantar pustulosis and localized pustular psoriasis. It was a randomized, open, prospective, right-left comparative trial in 19 patients. The Actiderm dressing and the TAA cream were applied every third day, whereas the clobetasol cream was applied twice daily for 4 weeks. Both treatments resulted in a significant improvement. On completion of treatment, complete clearance was found in 13 patients (63%) with Actiderm plus TAA, but in only 3 patients (21%) with clobetasol ($p = 0.001$). Four weeks after stopping therapy, the clinical parameters had returned to their pre-treatment level, except for erythema on the Actiderm plus TAA treated lesions ($p < 0.05$). No clinically important adverse effects were reported or observed; in particular there was no sign of skin atrophy at the end of study. The results of this study demonstrate that Actiderm applied over a medium strength corticosteroid every third day is highly effective against palmo-plantar pustulosis and localized pustular psoriasis. However, it is necessary to develop treatment regimens to maintain the improvement achieved. ***Key words: Hydrocolloid occlusion; Corticosteroid; Palmo-plantar pustulosis.***

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Persistent palmo-plantar pustulosis (PPP) is a term applied to a palmo-plantar eruption displaying sterile pustules appearing in erythematous and scaly plaques. Similar lesions occur in pustular psoriasis (PP) localized to palms and feet. These two clinical disorders run a recurrent course and are notably refractory to treatment. Topical corticosteroids, dithranol and coal tar may be tried as local monotherapies. However, the nature of these diseases may demand photochemotherapy (PUVA) or systemic therapy such as aromatic retinoids, methotrexate or cyclosporin A.

Hydrocolloid occlusive dressings such as DuoDerm^R are well-established for the treatment of wounds. Recently a thinner and more flexible variant of DuoDerm (Actiderm^R) has been introduced for the treatment of various dermatoses. Occlusion with Actiderm alone has been shown to improve psoriasis vulgaris (1, 2). However, the combination of Actiderm with a topical corticosteroid is much more effective (3). Administered in this way, a medium strength topical corticosteroid appears to have the same clinical efficacy in psoriasis vulgaris as potent and highly potent corticosteroids (3).

The present study was conducted to determine the efficacy and safety of Actiderm over a medium strength corticosteroid applied every third day, versus that of a highly potent corticosteroid applied twice daily.

MATERIALS AND METHODS

Study design

This was a randomized, open, prospective right-left comparison of Actiderm plus triamcinolone acetonide (TAA) 0.1% cream applied every third day, versus clobetasol 0.1% cream applied twice daily. The study was divided into three phases: 1) a wash-out qualification phase lasting 2 weeks (during this phase, patients received an emollient to be used as required); 2) a treatment phase lasting 4 weeks; and 3) a 4-week follow-up phase during which patients used an emollient as required. Visits were at weeks –2, 0, 2, 4 and 8.

Patients

Out-patients (16 men, 3 women) aged 18–71 years with PPP or localized PP for 0.5–40 years (mean 12 years). Patients were required to have symmetrically located lesions on either palms ($n = 3$), soles ($n = 14$) or both ($n = 2$). Those excluded were patients whose skin lesions were unstable during the 2-week wash-out period, patients who had been using systemic anti-psoriatic treatment or UV radiation within 2 months prior to study entry, patients with infected skin lesions or with a known allergy to any of the treatment materials. All patients gave their informed consent to join the study. The study was approved by the local medical ethics committee.

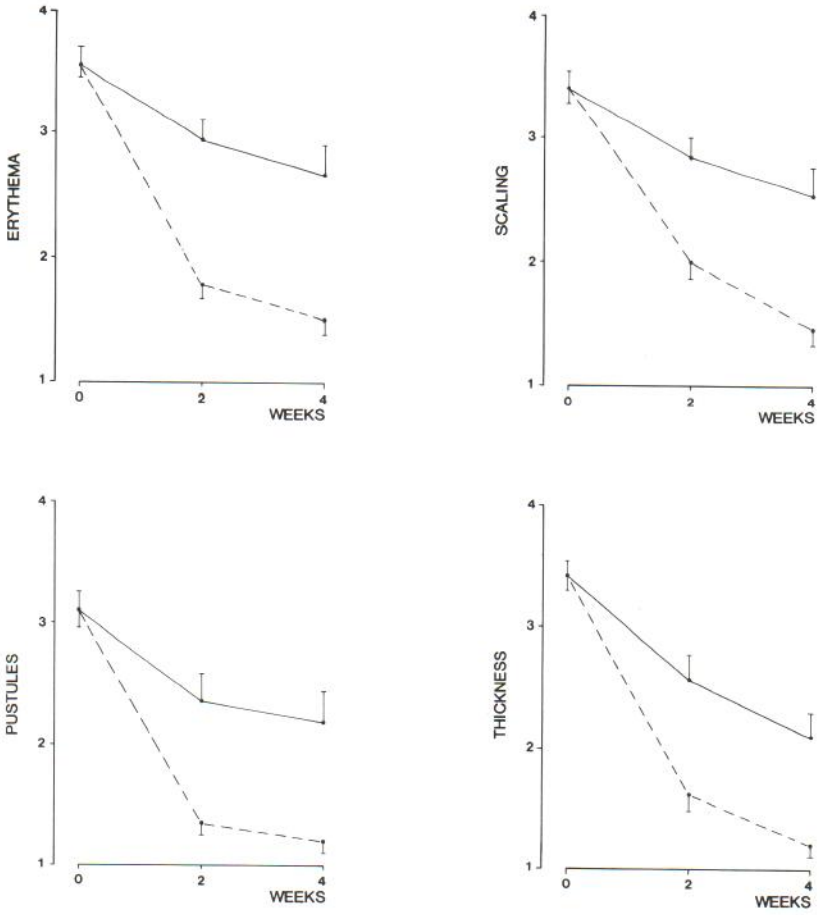

Fig. 1. Changes in erythema, pustules, scaling and thickness during treatment with Actiderm plus triamcinolone acetonide 0.1% cream (----) and with clobetasol propionate 0.05% cream (——). Values are means and SEM.

Study drugs

Actiderm dressings (thickness: 0.5 mm) were kindly provided by ConvaTec, Copenhagen, Denmark; triamcinolone acetonide (TAA) 0.1% cream by Novo Nordisk, Copenhagen; and clobetasol propionate 0.5% cream by Glaxo, Copenhagen. For those lesions covered by Actiderm, the dressing extended approximately 1.5 cm beyond the margin of the lesions (i.e. the area to which TAA 0.1% cream was applied). Actiderm plus TAA 0.1% cream was replaced every third day. If the dressing became detached sooner, a new dressing was applied, but without reapplying the TAA cream. Clobetasol 0.05% cream was applied twice daily. Both treatments continued for 4 weeks or until complete resolution.

At each visit the investigator recorded for each side the severity of the eruption on a 4-point scala (1: absent; 4: severest) for each of the clinical signs: erythema, thickness, scaling, pustules. The degree of itch was recorded on a similar scale. At each post-randomization visit the investigator made an assessment of the overall response to therapy (separately for each side) compared with baseline on a 5-point scale (−1: worse; +4: cleared). In addition, the presence of skin atrophy was assessed on a 4-point scale (0: absent; 3: severest) at the follow-up visit (4 weeks post-therapy). Adverse events were evaluated at each post-randomization visit.

Statistical analysis

The comparison of efficacy of treatments was based on intra-patient differences in respect of changes in symptom scores and investigator's overall assessments. The Wilcoxon test for matched pairs (signed rank test) was used for these comparisons. All *p*-values reported are two-sided. *P*-values below 0.05 were considered significant.

RESULTS

During the 4-week treatment period both Actiderm + TAA and clobetasol improved the skin lesions (Fig. 1). For each of the severity parameters there was a significantly greater improvement with Actiderm + TAA than with clobetasol at both the interim visit (erythema, $p = 0.001$; scaling, $p = 0.004$; pustules, $p = 0.002$; thickness, $p = 0.003$) and at the end of treatment (erythema, $p = 002$; scaling, $p = 0.001$; pustules, $p = 0.002$; thickness, $p = 0.003$).

The investigator's overall assessment of improvement after treatment for 2 weeks showed a moderate improvement in 95% of the lesions treated with Actiderm + TAA, but only in 21% of the lesions treated with clobetasol ($p = 0.001$). At the end of treatment, the lesions had cleared in 63% with Actiderm + TAA and in 16% with clobetasol ($p = 0.001$).

Moreover, the improvement in the pruritus as assessed by the patient was significantly greater following Actiderm + TAA treatment than following clobetasol, both at the interim visit ($p < 0.01$) and at the end of treatment ($p < 0.002$).

Four weeks after stopping treatment, most of the lesions had reverted to their pre-treatment level. However, the Actiderm + TAA-treated lesions still showed a slight improvement for erythema ($p = 0.031$).

Adverse events were reported on the Actiderm-treated side in a few patients: loose dressing ($n = 2$) hydrocolloid material outside the margins of the dressing ($n = 2$), and accumulation of sweat under the dressing ($n = 1$). These adverse events were mild and transient. The degree of skin atrophy was assessed clinically 4 weeks after stopping therapy. Atrophy was not detected in any patient.

DISCUSSION

This study clearly demonstrates that topical monotherapy of PPP is usually inadequate. Even with clobetasol, the most potent topical steroid currently available, applied twice daily, many patients failed to respond satisfactory. In contrast, treatment with Actiderm over TAA cream changed twice weekly proved very effective. Although the bioavailability of topical corticosteroid is increased under Actiderm, this combination can be regarded as a dual therapy, because the dressing can itself exert a therapeutic effect in reducing hyperplasia and erythema (1, 4).

It is possible that occlusion under plastic-like Saran wrap can be used as an alternative to Actiderm. However, these plastic dressings have to be changed daily, may cause maceration and are often found unpleasant. In contrast, the rather thin, skin-coloured hydrocolloid occlusive dressing Actiderm can be left on for up to one week, and even when taking a shower, and has therefore improved the acceptability of occlusive therapy.

Despite the marked therapeutic effect of Actiderm over a medium potent corticosteroid, the cessation of therapy was followed by a gradual recurrence of the disease. This indicates that continued treatment is required to maintain the improvement induced. This could take the form of intermittent therapy with Actiderm over TAA 0.1% cream. A potentially more effective approach might be to combine Actiderm with more potent topicals, either potent corticosteroids or the novel vitamin D analogues.

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