Journal of Dermatological Treatment (1990), 1, 203 - 206

A comparative study of betamethasone dipropionate with salicylic acid and betamethasone valerate for the treatment of steroid-responsive dermatoses of the scalp

RK Curley[1], CFH Vickers[2], T Norris[3] & DR Glover[3]

[1]*Department of Dermatology, St Georges Hospital, London;* [2]*Department of Dermatology, Royal Liverpool Hospital, Liverpool;* [3]*Medical Department Schering Plough Ltd, Mildenhall, Suffolk, UK*

Betamethasone dipropionate (0.05%) with salicylic acid (2%) lotion and betamethasone valerate (0.1%) lotion were compared in a double-blind randomized study in 56 patients with steroid-responsive dermatoses of the scalp (39 had psoriasis and 17 had eczema). Scaling and pruritis were the most common presenting features. Forty-seven patients completed the 3-week course of treatment. Both lotions resolved scaling, although the betamethasone dipropionate with salicylic acid was significantly better than the betamethasone valerate for scaling in psoriasis patients ($p = 0.009$). Virtually all patients had pruritus at baseline, and both treatments had a rapid onset of action, with a trend towards a higher proportion of complete symptom resolution in the betamethasone dipropionate patients after 2 weeks of treatment. Excoriation and inflammation were alleviated by both applications, especially for the psoriasis patients. This trend was reflected in the investigators' evaluation in the 'much improved' category, where a significant difference was found in psoriasis treated with the betamethasone dipropionate ($p = 0.037$). Two adverse events occurred, both in the betamethasone dipropionate group. Three patients withdrew because of failure of treatment, two from the betamethasone valerate group and one from the betamethasone dipropionate group. We conclude that both lotions were effective, but that there were clinically relevant differences between them.
(*J Dermatol Treat* (1990) 1: 203–206)

Introduction

Betamethasone valerate (0.1%) has long been recognized as a useful therapy for psoriasis and other steroid-responsive dermatoses of the scalp. Betamethasone dipropionate (0.05%) falls into the same class of steroid potency and is combined with salicylic acid (2%) in lotion form as a scalp application. The salicylic acid acts as a bacteriostatic, keratolytic, and penetration enhancer for the steroid,[1,2] the latter effect being reported as important in the treatment of hyperkeratotic dermatoses.[3,4] The inclusion of salicylic acid thus allows a lower concentration of the steroid to be included in the formulation. It is of relevance, therefore, to compare and contrast the efficacy, onset of action and tolerability of betamethasone dipropionate (0.05%) with salicylic acid (2%) with that of betamethasone valerate (0.1%) scalp application.

Correspondence: Dr T Norris, Medical Department, Schering Plough Ltd, Mildenhall, Suffolk IP28 7AX, UK

Patients and methods

Patients were considered for entry to the study if they had psoriasis or other steroid-responsive dermatoses of a dry nature affecting the scalp, with or without involvement of other hairy and non-hairy areas of the body. Patients were allocated at random to one or the other treatment group, and the treatments were applied in a double-blind manner. Patients were excluded if they had received any topical corticosteroids within the preceding month. Patients with clinically obvious skin infection, and pregnant or lactating women, were also excluded. The concomitant use of any other anti-inflammatory agent was prohibited, or any other medication that could affect the course of the disease. Occlusive dressings were not permitted, due to excessive betamethasone absorption via the salicylic component, and patients with moist lesions were also excluded.

The treatment regimen was a twice-daily application for three weeks to the affected scalp area, with assessments after 7, 14 and 21 days of treatment. A baseline visit was used to obtain patient history and for clinical assessments of the conditions in terms of the following symptoms: induration, lichenification, excoriation, erythema, crusting, scaling, pruritus, pain and exudate. These were graded on a four-point scale ranging from 'none' to 'severe'. A diagram of the treated area(s) was made and shaded in to approximate the size of the area(s). The percentage area of involvement of the lesion was stated approximately.

All these steps were repeated and recorded at each visit. Patients were also asked when improvement of their symptoms had first been noted and if they had suffered any side-effects. At the final visit the clinician graded the response in an overall evaluation on a five-point scale from 'cured' to 'worse' and the patients graded the cosmetic acceptability of the treatment.

The study received approval from the local ethical committees and informed patient consent was obtained in each case. Statistical analysis of continuous data was by the Mann-Whitney U test for independent samples. Disease parameters and overall evaluation were compared by the chi-squared test. Where there were too few patients in some categories, groups were combined and Fisher's Exact test was used.

Results

Of the 59 patients who entered the trial, 3 were excluded from the analysis because of protocol violations. The remaining 56 patients comprised 22 males and 34 females

aged between 14 and 81 years with moderate to severe steroid responsive dermatoses (39 had psoriasis and 17 had eczema). With respect to age, weight and height the treatment groups were well matched. However, the sex ratio differed somewhat between groups, with two thirds of patients in the betamethasone dipropionate being female compared to an approximately equal ratio in the betamethasone valerate group. Table I shows the duration of the condition of the patients at presentation, the time since primary diagnosis and the disease status for each of the treatment groups.

Disease symptom grading showed that all but one patient (betamethasone valerate) had moderate or severe scaling at baseline, and both groups improved in the first 2 weeks. By week 3 the difference in improvement in the two groups was highly significantly in favour of the betamethasone dipropionate, psoriasis group (chi-squared = 6.84, p = 0.009) (Figure 1). In each group, 37 patients had pruritus at baseline and by the first week nearly 50% in each group had complete relief. This symptom resolution trend continued to week 3 at which time only seven patients reported pruritus (3 dipropionate, 4 valerate; Figure 2).

Excoriation and inflammation were present at baseline in 19 patients and improved over the 3-week regime in both groups. The other symptoms of crusting, induration, lichenification and exudation were not widespread enough at baseline to warrant evaluation. Pain was reported in four patients at baseline, disappearing during treatment in the three betamethasone dipropionate patients but remaining severe in the betamethasone valerate patient. For both groups onset of action of improvement was noted in the majority of patients within the first week, especially for scaling and pruritus. Overall both scalp applications were cosmetically acceptable.

The investigators' comments indicated that, overall,

Table I Disease history

	Duration of present condition (months)		*Time since primary diagnosis (months)*		*Disease status*		
Group	*Median*	*Range*	*Median*	*Range*	*Exacerbating rapidly*	*Exacerbating slowly*	*Stable*
Betamethasone dipropionate (0.5%) + salicylic acid (2%) (n = 28)	24.0	0.7–528.0	66.0	3.0–660.0	2	7	18
Betamethasone valerate (1%) (n = 28)	18.0	0.7–456.0	72.0	3.0–456.0	1	14	13

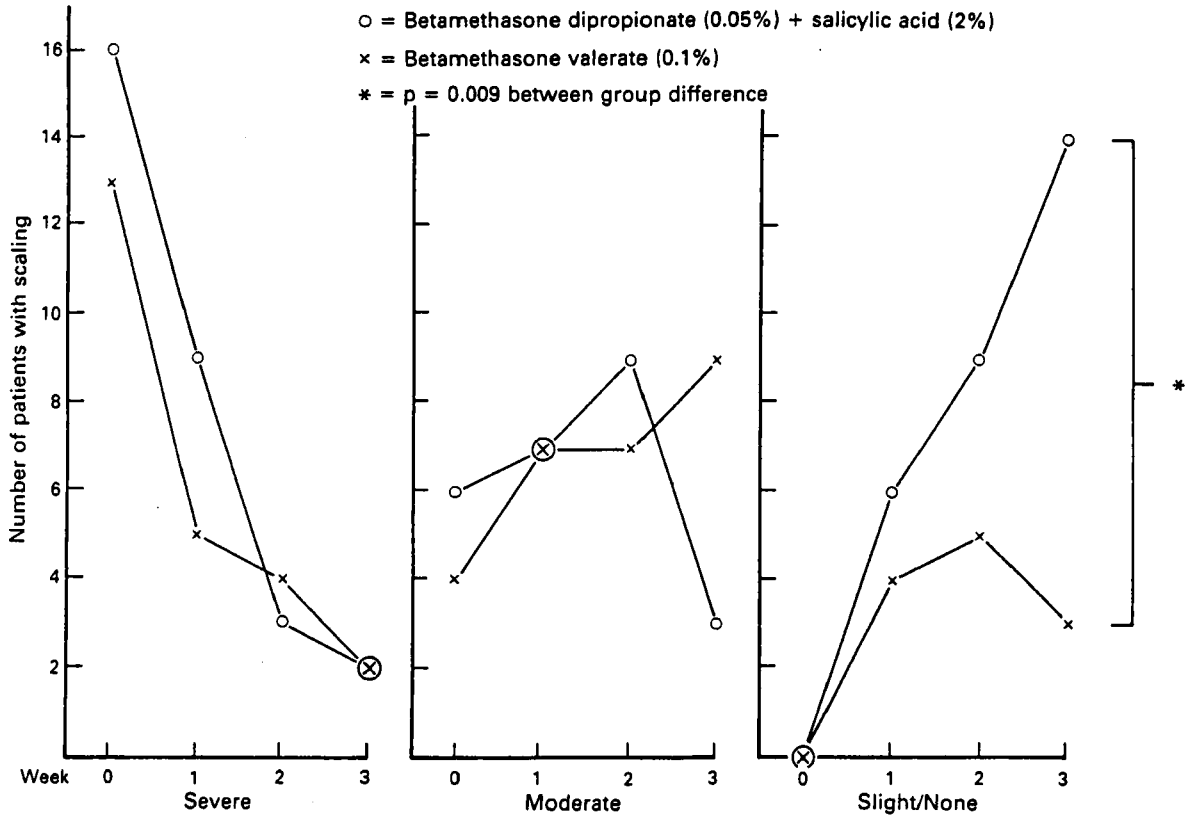

Figure 1 Severity of scaling in psoriasis patients.

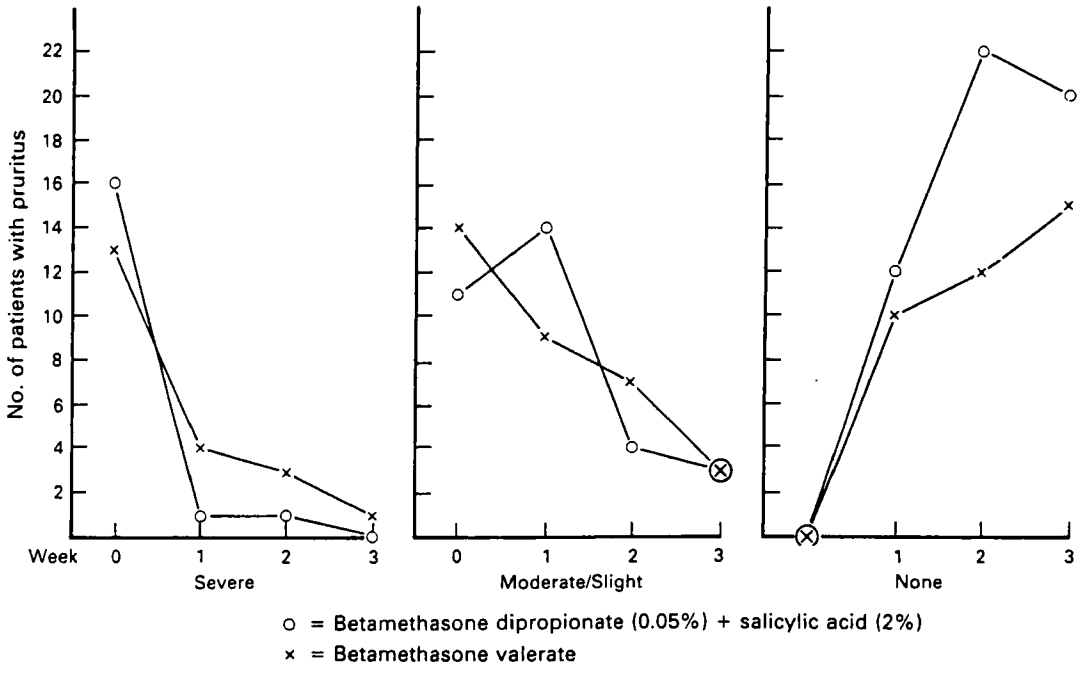

Figure 2 Severity of pruritus.

25% of conditions were resolved within the 3-week period, with 11% showing no change. Betamethasone dipropionate resolved more symptoms in patients with psoriasis (five of seven) whereas more symptoms of eczema were resolved with betamethasone valerate (five of six). Examination of the category data for betamethasone dipropionate patients with psoriasis in the marked improvement/resolution groups demonstrated a significant difference ($p = 0.037$) compared with betamethasone valerate. The investigator evaluations are shown in Figure 3.

Of the 56 patients included in the study, 47 completed the 3-week treatment regime, and nine were regarded as treatment failures, three from the betamethasone dipropionate group and six from the betamethasone valerate group. Treatment failures comprised: three withdrawals (two betamethasone valerate; one dipropionate); four betamethasone valerate patients who failed to return to clinic and were lost to follow-up; and two betamethasone dipropionate patients who reported possible adverse events. The adverse events were in a patient who stated that his scalp was lumpy and sore so he stopped his medication (but 2 days later at clinic no problems were apparent), and in a patient who was admitted to hospital after 7 days because of an exacerbation of symptoms. However, it was unclear whether the betamethasone dipropionate was the cause of the symptom exacerbation.

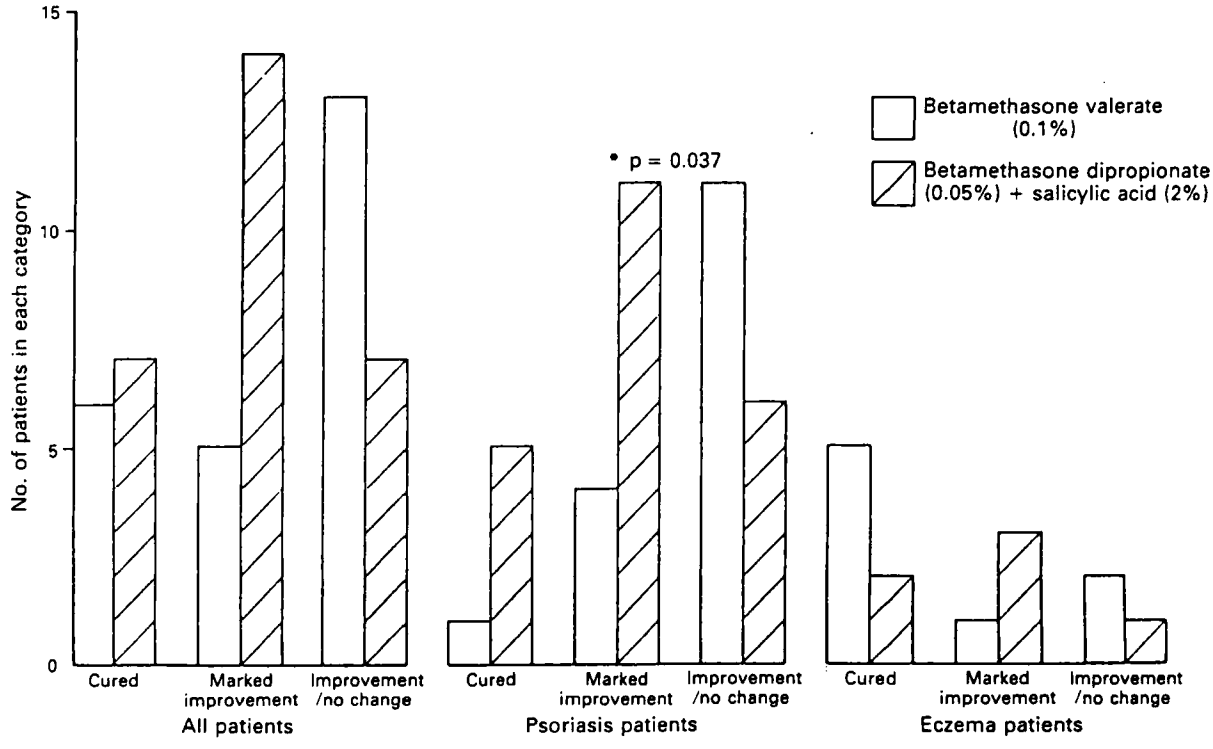

Figure 3 Investigators' overall evaluation.

Discussion

In this study both scalp applications were well tolerated and resolved the majority of symptoms of psoriasis and eczema. The different concentrations of steroid with or without salicylic acid did, however, lead to some clinically relevant differences. There was a trend towards the symptoms of psoriasis patients improving more quickly on betamethasone dipropionate than on betamethasone valerate in the investigators' overall evaluation, with a statistically significant difference between treatments. For the symptom of excoriation the betamethasone dipropionate patients tended to respond better, whereas betamethasone valerate relieved inflammation more swiftly.

The results of this study are similar to the findings in a previous study which compared betamethasone dipropionate with salicylic acid and clobetasol propionate in patients with psoriasis of the scalp. Both treatments were similar in response, but the betamethasone dipropionate had a statistically greater anti-pruritic effect. The authors of that study noted that clobetasol was the more potent of the two steroids, but that the equal efficacy of response may have been due to the salicylic acid component with the betamethasone dipropionate. In contrast studies of betamethasone dipropionate with salicylic acid versus flumethasone 21-pivalate and salicylic acid alone in psoriasis have shown the same statistical outcome for pruritus and overall evaluation.[6,7] A further study which compared triamcinolone and betamethasone found that betamethasone was the more effective steroid.[8]

In conclusion the results obtained in this study appear to reflect the different active moieties in the betamethasone dipropionate and betamethasone valerate. The salicylic acid in the former could be expected to relieve scaling and excoriation more effectively while the higher concentration of betamethasone in the valerate preparation could be expected to have more anti-inflammatory effect.

Acknowledgment

This work was supported by a grant from Schering-Plough Ltd. We thank Mrs Susan Miller for her assistance in preparing the manuscript.

References

1. Chambers WC, Cash WS, Marinaccio A, Diprosone (betamethasone dipropionate) cream 0.05%. Review and report of a multicentric study. *J Int Med Res* (1976) **4** (suppl 3): 1–26.
2. Charney P, Betamethasone dipropionate cream for the treatment of psoriasis. *Arch Dermatol* (1976) **112:** 681.
3. Mattelaer G, Treatment of psoriasis and other chronic dermatoses. Reports on the use of betamethasone dipropionate-with-salicylic acid-alcohol solution (Diprosalic Scalp Lotion) and ointment (Diprosalic Ointment). *Clin Trials J* (1979) **16:** 154.
4. Zirnbach C, Drug portrait – betamethasone dipropionate plus salicylic acid. *Selecta* (1981) **12:** 3–10.
5. Hillstrom L, Pettersson L, Svensson L, Comparison of betamethasone dipropionate lotion with salicylic acid (Diprosalic) and clobetasol propionate lotion (Dermovate) in the treatment of psoriasis of the scalp. *J Int Med Res* (1982) **10:** 419–22.
6. Eriksson G, Betamethasone-17,21-dipropionate with salicylic acid, a double-blind comparative evaluation with flumethasone-21-pivalate with salicylic acid in the treatment of psoriasis. *J Int Med Res* (1975) **3:** 368–70.
7. Henningsen SJ, Midtgaard K, Betamethasone dipropionate with salicylic acid (Diprosalic) in the treatment of psoriasis. A double-blind comparison with flumethasone-21-pivalate with salicylic acid. *Clin Trials J* (1978) **15:** 97–101.
8. Fredriksson T, A clinical comparison of three corticosteroid alcoholic solutions in the treatment of psoriasis of the scalp. *Pharmatherapeutica* (1976) **1:** 252–6.