The Effect on Psoriasis of Clobetasol Propionate Used Alone or in Combination with UVB

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A study has been carried out to compare the effect of a combination of clobetasol propionate and UVB versus placebo/UVB. No significant reduction in time to healing was observed. However, symptoms abated more rapidly in the steroid/UVB group. Recurrences occurred at an earlier stage following the steroid UVB combination for long periods. A third group, treated solely with clobetasol propionate has also been investigated, but results were poorer than those described above. It is concluded that steroids in combination with UVB should be used only during the initial period in order to achieve a more rapid alleviation of symptoms and to avoid the side effects. *Key words: Potent steroids; UVB; Therapeutic results.* (Received April 5, 1983.)

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UVB has proved to be an effective way of treating psoriasis (1, 2, 3). However, treatment times are long, with poorer patient compliance in consequence. Moreover, when treating psoriasis patients with UVB for long periods of time one must remember the long-term side effects of this therapy, as with potent steroids, since psoriasis is a disease that usually affects the patient for the rest of his life. Steroids have been used since the 'fifties for treating psoriasis. In our experience treatment with steroids leads to a rapid alleviation of symptoms, but complete clearance is rather uncommon.

Thus the question arose whether or not it might be possible to reduce the time to healing by adding a potent steroid to UVB therapy and also if the clearance rate could be improved. The effect of maintenance treatment has been studied too.

MATERIAL AND METHODS

Three groups of patients with plaque psoriasis were studied. In each group 30 patients participated. One group received clobetasol propionate (Dermovat®) and UVB, another placebo/UVB and the third group clobetasol propionate alone. The first two groups were treated double-blind.

Patients were questioned about the duration of the disease and investigated with regard to body surface covered by psoriasis. Patients were allocated to one of the groups in a randomized way.

Patients receiving ultraviolet treatment were treated at a day-care centre in central Gothenburg. They were recommended to come for treatment at least 3 times a week until their psoriasis cleared and after that twice a week for as long as possible in order to study the effect of maintenance therapy. Desquamation in the two groups receiving ultraviolet radiation was achieved by means of *sauna* treatment prior to therapy. Patients received clobetasol proprionate/ placebo according to the protocol in Table I. The initial steroid period lasted for 2 weeks. Subsequently the patients received clobetasol propionate/placebo only twice a week, irrespective of whether or not they were healed after 2 weeks.

A general evaluation of the extent and severity of the psoriasis was made at the beginning of the study, after 1 and 2 weeks and thereafter each forthnight. Skin lesions were considered healed when scaling, infiltration and erythema had disappeared. A slight hyper- or depigmentation was allowed.

No major differences were seen in the different groups with respect to background data such as age, duration of the disease and sex distribution. The group that received clobetasol propionate alone had a slightly less extensive psoriasis.

Statistical evaluation was made using Fisher's permutation test.

Cortisol(s) was analysed in a small number ($n = 13$) of patients before treatment and after 2 weeks of treatment.

RESULTS

There were 7 drop-outs from the placebo/UVB group, 10 from the clobetasol propionate/UVB group and 4 from the clobetasol propionate alone group. The drop-outs either failed to come to the unit for treatment or failed to show up at the regular visits to the doctor. The numbers of patients healed on each therapy are given in Table II. There was no significant difference between the clobetasol propionate/UVB group and placebo/UVB group with respect to percentage of individuals healed. In the group receiving clobetasol propionate only, however, the percentage of healed individuals was lower than in the other two groups. Time to clearing was 4.1 weeks or 14.5 treatments in the clobetasol propionate/UVB group and 4.7 or 15.8 treatments in the placebo/UVB group. In the clobetasol propionate/alone group, time to clearing was 3.4 weeks. These differences are not statistically significant. However, the general severity of psoriasis was clearly lower after one week of treatment in the clobetasol propionate/UVB group (17/20 improved (85%)) compared with the placebo/UVB group (7/23 improved (30.4%)). The corresponding figure for the clobetasol propionate alone group was 13/26 (50%).

The time to relapse is illustrated in Fig. 1 for the patients who continued with maintenance therapy. From this it is evident that the time to recurrence was longest in the placebo/UVB group. Patients receiving clobetasol propionate/UVB had a shorter time in remission than placebo/UVB, while the clobetasol propionate alone group had the shortest time to recurrence. The reason why the line representing placebo/UVB patients does not reach the X-axis is that the last patients were censored, i.e. they wished to stop treatment whilst in a cleared condition.

Regarding plasma-cortisol, no reduction was seen among 6 patients in the placebo/UVB group or in 2 patients in the clobetasol propionate alone group. However, among the 5

Table I. *The protocol used for topical treatment with clobetasol propionate/placebo during the first 14 days*

Day	Treatment
1	Clobetasol propionate/placebo
2	Clobetasol propionate/placebo
3	Clobetasol propionate/placebo
4	Clobetasol propionate/placebo
5	Emollient
6	Emollient
7	Emollient
8	Clobetasol propionate/placebo
9	Clobetasol propionate/placebo
10	Emollient
11	Emollient
12	Clobetasol propionate/placebo
13	Emollient
14	Clobetasol propionate/placebo

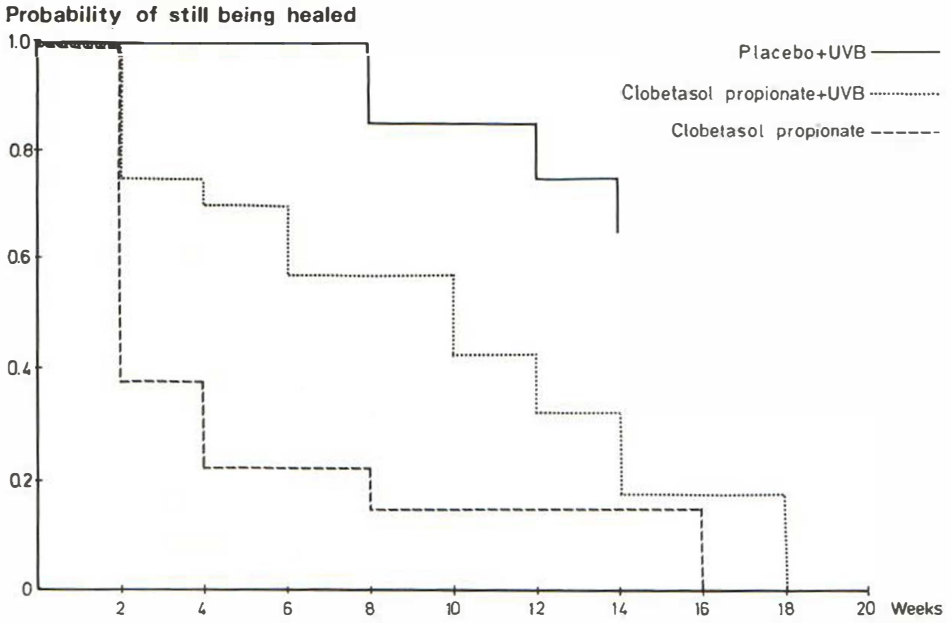

Fig. 1. Probability of still being healed for psoriasis patients treated with placebo/UVB, clobetasol propionate/UVB, and clobetasol propionate alone.

patients in the clobetasol propionate/UVB group who were analysed regarding changes in plasma cortisol, a reduction was seen in 2 patients during therapy.

DISCUSSION

UVB is a well established form of antipsoriatic therapy. However, treatment times are long and it would be worthwhile to reduce the time to healing. In this study the combination of clobetasol propionate and UVB failed to shorten the time to healing, compared with placebo/UVB. This has been shown recently by other investigators using other steroids (4, 5). However, symptoms abated more rapidly when using the combination clobetasol propionate and UVB. For patients with severe psoriasis this could be a way of establishing control over the disease more quickly. One important aspect to point out is that the recurrences seem to occur at an earlier stage with the steroid/UVB combination.

Dermovate alone was not as effective as UVB for the treatment of psoriasis in this

Table II. *Number of patients healed, time to healing, and number of treatments necessary to achieve healing for the three groups*

	Clobetasol propionate/UVB	Placebo/UVB	Clobetasol propionate
Number of patients healed	18/20	20/23	13/26
Time to healing (weeks)	4.1	4.7	3.4
Number of treatments to healing (mean)	14.5	15.8	–

study. The percentage of patients healed in this group was lower than previously reported (6, 7) but in these studies the healing criteria were not the same.

When considering the side effects of a potent steroid one must be careful with the use of such drug among patients with psoriasis. Considering also the relatively poor long-term therapeutic results, steroids should be used intermittently during the initial period and for short periods only. This could minimize the problem of early recurrences.

Compared with other studies on the healing rate and time to healing, the results for both groups receiving UV-irradiation were better than previous data have indicated (3). One explanation could be that the investigation was carried out in a day-care centre where the main treatment is UVB-irradiation. As time goes by we may get a selection of patients who are more responsive to UVB that the general psoriasis population.

Another explanation could be that both the Dermovate and placebo ointments act as emollients, thereby reducing the time to healing. This has been shown by other investigators to be of importance (8). Furthermore, patients referred to the treatment unit probably belong to a group of psoriasis patients who usually have tried corticosteroids for long period of time, but with poor results.

In conclusion, the combination of clobetasol propionate and UVB leads to a more rapid alleviation of symptoms than does UVB alone, whereas time to healing is not significantly shortened.

In order to avoid early recurrences, potent steroids should only be used for short periods in combination with UVB.

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