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Comparison of Topical Treatment with Desoxymethasone Solution 0·25% with Salicylic Acid 1% and Betamethasone Valerate Solution 0·1% in Patients with Psoriasis of the Scalp

Lars Hillström, MD, *Department of Dermatology, District General Hospital, S-801 17 Gävle, Sweden*

A new preparation for treatment of psoriasis of the scalp, containing desoxymethasone 0·25%, salicylic acid 1% and polyol-fatty esters in ethanolic solution (Ibaril®) was tested in patients with psoriasis of the scalp. In a double-blind study comprising forty patients there was a significant difference in favour of this solution in comparison with betamethasone valerate solution, 0·1% (Betnovat®) after 2 weeks of treatment.

Introduction

Desoxymethasone is one of the most widely used compounds in the group of fluorinated corticosteroids. When used in a cream or fatty ointment vehicle, it has proved to be a very useful and efficacious drug in the treatment of psoriasis and other dermatoses (Bossong & Grimmer 1975, Björnberg & Hellgren 1975, Fredriksson 1979, Kuokkanen 1977, Lassus 1977, Lundell 1975, Nair & Nair 1975, Savin 1978).

Notable is a fast onset of action, mostly a short treatment period needed for improvement or cure and a tolerability very well accepted by the patient.

Recently a new formulation of this steroid has been developed, desoxymethasone 0·25% with salicylic acid 1% in ethanolic solution (Ibaril®)* intended for the treatment of psoriasis and seborrhoeic eczema of the scalp or other hairy areas.

*Kindly supplied by Hoechst Aktiengesellschaft. Also marketed as Topisolon®.

The present study was undertaken to assess the efficacy and tolerance of desoxymethasone solution 0·25% with salicylic acid 1% (Ibaril®) in comparison with betamethasone valerate solution 0·1% (Betnovat®) in the treatment of psoriasis of the scalp.

Material and Methods

Patient population and treatment

Forty patients, sixteen males and twenty-four females, with psoriasis of the scalp were selected for the study. Only patients who had not been treated with other steroids for at least 1 week were allowed to enter the study. However, other medications than steroids were permitted in the treatment of psoriasis or other dermatoses if they occurred on other parts of the body than the scalp (e.g. dithranol). This therapy was allowed to be continued concomitantly during the study. No patients with skin infections were selected. Neither pregnant or lactating patients nor patients taking interfering medication were included.

The patients were randomly divided into two groups, each consisting of twenty patients.

The randomization was done in advance by the manufacturer with the aid of a table with random digits and kept secret from the doctor during the study. The patients in one of the groups were treated with Ibaril® and the patients in the other group with Betnovat® solution. There were no significant differences between the two groups with regard to sex and age distribution, initial disease severity, total duration of the disease, duration of the present condition or the area to be treated.

Concomitant diseases existed in a small number in both groups but they did not interfere with the dermatological disease.

The two preparations were packed in 50 ml bottles with identical appearances except for the patient numbers on the labels.

The doctor was informed that the two solutions differed in odour and that he was not allowed to sniff them. Thus, all the samples given to the patients looked the same and neither the patient nor the doctor knew who was given Ibaril® and who was given Betnovat®.

Two bottles of 50 ml solution were supplied to each of the patients initially and also after 1 week of treatment. The bottles intended for each of the two treatment periods were given back to the doctor on the occasion of the next visit. The patients were instructed to apply a small quantity of the solution once in the morning and once in the evening, completely covering the afflicted area. The disease status was evaluated before and after 7 and 14 days of treatment. Furthermore, the patients were evaluated after another 7 days which were free of treatment. At each of these visits the severity of the symptoms of scaling, erythema, infiltration and pruritus was studied. The classifications were: none, slight, moderate or severe.

Moreover, at the end of each of the 3 weeks an over-all evaluation of the therapeutic result in comparison with the initial status was performed by the doctor and by the patient. The patients were also asked about side-effects and cosmetic acceptability at each visit.

An approximate weekly consumption of the solutions was also estimated.

Statistical methods

The following tests were used in the comparison of the two groups:

Chi-squared test for general data, over-all evaluation and cosmetic acceptability.

Kruskal-Wallis test (Wallis-Roberts 1964) for scaling, erythema, infiltration and pruritus.

Differences at the 5% level were regarded as significant.

Results

Of the forty patients entering the study, seventeen patients in the Ibaril® group and fourteen patients in the Betnovat® group could be followed through the whole test period.

One of the patients in the Ibaril® group changed treatment during Week 3 in spite of a favourable result, one stopped the treatment after 2 weeks because of a too slow healing rate and a third patient stopped the treatment after 2 weeks because of lack of symptoms.

In the Betnovat® group two patients were treatment failures after the first week of treatment. Two more patients proved to be treatment failures after the second week of treatment and two patients changed treatment after 2 weeks because of a too slow healing rate.

The over-all therapeutic result for the two preparations was compared by means of the Chi-squared test with Yates' correction. The categories 'much worse' – 'slightly better' were put together against the category 'much better' in a four-fold table. There was no significant difference between the two preparations after the first week of treatment (Table 1). However, after the second week of treatment Ibaril® proved to be significantly better than Betnovat® as judged both by the doctor and by the patient ($\chi^2 = 5{\cdot}55$; $p < 0{\cdot}05$).

After the third week, during which no treatment was given, there was no significant difference judged by the over-all result between the preparations.

With regard to the different clinical symptoms, a significant difference could be seen in favour of Ibaril® for the erythema status after the second week of treatment (Table 2). However, a difference – although not significant – existed already initially with regard to the erythema status which was enlarged during the treatment. Other differences were not statistically significant.

No adverse reactions were seen and the cosmetic acceptability was somewhat better for the Ibaril® solution although the difference was not significant (Table 3).

Table 1

Over-all therapeutic result judged by the doctor and the patient

	After 1 week		*After 2 weeks*		*After 3 weeks**	
	Doctor	*Patient*	*Doctor*	*Patient*	*Doctor*	*Patient*
IBARIL						
Much better	8	11	18	18	11	12
Slightly better	11	8	2	2	4	2
No change	1	1	–	–	1	2
Slightly worse	–	–	–	–	1	1
Much worse	–	–	–	–	–	–
	20	20	20	20	17	17
BETNOVAT						
Much better	9	10	9	9	6	6
Slightly better	6	5	4	4	3	3
No change	5	4	4	3	5	5
Slightly worse	–	1	–	1	–	–
Much worse	–	–	1	1	–	–
	20	20	18**	18**	14	14

* The last week is without any treatment
** Two patients are not included because they were treatment failures after the first week of treatment.

Table 2

Changes in degree of severity during the therapy

	Initial				*Week 1*				*Week 2*				*Week 3**			
	0	*1*	*2*	*3*	*0*	*1*	*2*	*3*	*0*	*1*	*2*	*3*	*0*	*1*	*2*	*3*
IBARIL																
Scaling		3	10	7	3	10	7		10	9	1		4	8	5	
Erythema	2	6	10	2	9	5	6		13	7			8	6	3	
Infiltration		8	6	6	6	10	4		13	6	1		9	4	4	
Pruritus	7	3	4	6	10	9	1		15	5			11	5	1	
BETNOVAT																
Scaling			16	4	1	11	8		6	5	6	1	4	6	4	
Erythema		5	12	3	3	12	5		6	8	4		6	3	5	
Infiltration		2	15	3	7	7	6		7	7	3	1	6	2	6	
Pruritus	7	7	4	2	13	5	2		13	3	2		11	1	2	

*The last week is without any treatment
0 = none
1 = slight
2 = moderate
3 = severe

Table 3

Cosmetic acceptability

	Number of patients		
	Ibaril	*Betnovat*	
Very good	9	8	
Good	10	7	n.s.
Moderate	1	4	
Poor	–	–	
No answer	–	1	
	20	20	

The mean values of the approximate weekly consumption were between 63 and 64 ml for both preparations.

Discussion

In the present trial the results with both Ibaril® and Betnovat® solutions were very good. However, after 2 weeks of treatment Ibaril® showed a significantly more rapid onset of improvement and healing according to the over-all evaluation.

Several patients in the Ibaril® group stressed that they did not feel so dry in the scalp after treatment with this solution than with other solutions containing ethanol. The reason for that probably is that Ibaril® solution contains polyol-fatty esters.

The addition of salicylic acid to scalp solutions also makes the preparation more efficacious.

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