

## BECLOMETHASONE DIPROPIONATE — A NEW TOPICAL CORTICOSTEROID

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### Summary

30 patients with chronic Eczema of various types were selected to compare the efficacy of Beclomethasone dipropionate 0.025% + Chinoform and Betamethasone 17 valerate 0.12% + chinoform in a single blind study. Good to excellent response was obtained in 73% with beclomethasone dipropionate & 80% with betamethasone 17 valerate ointment. Overall results showed that both preparations were very effective in achieving satisfactory response. No side effects were noted.

The major dermatological advance during last decade has been the development of powerful anti-inflammatory topical corticosteroids for the treatment of various dermatological disorders. Triamcinolone, Fluocinolone acetonide, Flurandrenol and Flumethasone pivalate are fluorinated corticosteroids of powerful topical activity. The non-fluorinated corticosteroids are Betamethasone 17-valerate and the newer one Beclomethasone dipropionate. The activity of different topical corticosteroids can be judged by vaso constrictive tests. In these tests on human beings Beclomethasone dipropionate is exceptionally active as can be seen from the following table, suggesting that Beclomethasone is 5000 times more powerful than Hydrocortisone.

The effect of systematically administered Beclomethasone has not been studied in man but Raffle & Friar-Bell (1967)

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were unable to demonstrate any adrenal suppression in patients undergoing treatment with topical Beclomethasone. In another communication the same authors were unable to find adrenal suppression even after the use of a new ointment base containing Beclomethasone in 5% propylene glycol.

TABLE I

Hydrocortisone	1
Betamethasone alcohol	8
Fluocinolone 16, 17 acetonide	1000
Betamethasone 17 valerate	3600
Beclomethasone 17, 21 dipropionate	5000

An extensive clinical evaluation in hospital patients has been reported by Caldwell and his colleagues (1968) who showed that Beclomethasone was atleast as effective as Fluocinolone acetonide. The same workers also concluded that preparations containing 0.025% of the drug was as effective as 0.1% and that the new base in which Beclomethasone was dissolved in 5% propylene glycol was markedly effective than the micocrystalline suspension of the drug in white paraffin. Properties of steroids by itself

have important influence on the effectiveness of steroid preparation but the nature of ointment or cream base is also important. Portnoy (1965) showed that in different topical steroids the use of ointment base containing propylene glycol significantly increased therapeutic activity.

The present study was undertaken to compare the efficacy of Beclomethasone dipropionate and Betamethasone 17 valerate in patients suffering from various types of Eczemas. The trial was designed as a single blind between the patients.

**Materials and Methods**

30 patients took part in trial who received either Beclomethasone or Betamethasone ointment. The patients selected had chronic eczematous lesions and many of them had not derived any improvement from the routine hospital treatment. None of the patients received systemic corticosteroid therapy. Many patients also had a superadded bacterial infection.

The patients selected had their history taken and clinical examination recorded on a proforma. Beclomethasone and Betamethasone were supplied in identical looking cartons marked A and B and were given to the patient in a randomised fashion by a junior doctor. The investigator did not know which ointment patients were receiving till the data on all 30 patients was completed. The ointment was to be applied twice daily and the patient reported after one week and two weeks when final assessment was done. Clinical effects were recorded at 1 or 2 weeks of treatment by using a five point scales from 5 to 1, with 5 representing the initial status and 1 indicating no visible signs of lesions. Side effects were also recorded.

The formula of the ointments used were:

1. Beclomethasone dipropionate 0.025% + chionoform 3% in cream base.
2. Betamethasone 17 valerate 0.12% + chionoform 3% in arachis oil.

None of the above two ointments were presuspended in propylene glycol.

**Results**

30 patients completed the trial (20 females & 10 males). Equal number of patients received either beclomethasone or betamethasone ointment.

TABLE II

Disease	Number of patients
Eczema	16
Neurodermatitis	8
Seborrhoeic Eczema	2
Contact Dermatitis	3
Nummular eczema	1
Total	30

**Discussion**

From the results it is clearly evident that both beclomethasone dipropionate and betamethasone 17 valerate are highly effective ointments available for treatment of eczema. Good to excellent response was obtained in 73% patients treated with beclomethasone and 80% of patients treated with betamethasone ointments. Overall results show that betamethasone is slightly superior to that of beclomethasone although statistically this was not significant. However, initial improvement with betamethasone is indicated from Table-2 which shows that 4 patients cleared in one week while none with beclomethasone cleared after one week of treatment. The response rate at the end of two weeks trial period was almost equal with both ointments.

From Table-4 it is clear that Beclomethasone showed better improvement to the tune of 77% in severe cases, as against 71% with Betnovate. This suggests that Beclomethasone showed

TABLE III

Preparation	Week	Cleared	Much improved	Improved	Slightly improved	No change
Beclomethasone	1st	0	8	6	1	—
Dipropionate	2nd	4	7	3	1	—
Betamethasone	1st	4	7	4	—	—
17 valerate	2nd	8	4	3	—	—

The initial degree of severity of eczema may influence the effectiveness of a preparation. The following table indicated the type of response to the severity of the condition.

TABLE IV

Initial severity	Type of ointment	No. of patients	(after two weeks)				
			cleared	much improved	improved	slightly improved	no change
Severe	Beclomethasone dipropio	9	3	4	1	1	—
	Betamethasone 17 valerate	7	2	3	2	—	—
Moderate	Beclomethasone dipropio	6	1	3	2	—	—
	Betamethasone 17 valerate	8	6	1	1	—	—
Total		30	12	11	6	1	—

TABLE V

The degree of improvement can be judged from the following table.

Degree of response	Beclomethosone dipropionate		Betamethasone 17 valerate	
	No. of patients	%	No. of patients	%
Excellent (Scale 1)	4	27	8	53
Good (Scale 2)	7	46	4	27
Moderate (Scale 3 & 4)	4	27	3	20
Unchanged (Scale 5)	—	—	—	—

better improvement in patients having severe lesions as compared to Betnovate which showed better improvement in patients having moderate degree of lesions. However, the difference in improvement, with both the treatment in either of the groups was not statistically significant.

None of the preparations tried was dissolved in propylene glycol a procedure which increases the efficacy of the ointment. The incorporation of a steroid in this way enhances the effect probably due to increased availability. Beclomethasone is almost insoluble at normal temperature in liquid and white

paraffin and it may be difficult for the steroid to diffuse out of the base consisting of these constituents. Since propylene glycol is hydrophilic solvent a possible explanation for its enhanced effect is that the passage of steroids into the skin is facilitated.

In our study, single blind trial was designed each patient acting as his own control. The standard double blind trial has its own disadvantages. Not all patients have bilateral lesions of equal severity and there is no guarantee that those who have, will diligently apply a preparation from one tube to one side of the body and the preparation from the other tube to opposite side for the trial period of 2 to 3 weeks. This can only be achieved effectively by hospitalisation and under the supervision of nursing staff. Results obtained from comparisons that are not double blind may not be significant in a statistical analysis, nevertheless are quite meaningful and realistic. The results indicate that overall effectiveness of both preparations is about 70-80% in achieving a satisfactory response. There were no side effects noted during the study.

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