CLINICAL EFFICACY OF A NEW TOPICAL CORTICOSTEROID - FLUOCORTOLONE CREAM

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Summary

Thirtyone patients with various eczematous dermatoses were treated with a twice daily non-occlusive application of a combination of 0.25% each of Fluocortolone Caproate and 0.25% Fluocortolone Trimethylacetate in a cream base. The cases selected were of eczematous dermatitis, contact dermatitis, neurodermatitis, nummular eczema, dyshydrotic eczema, discoid lupus erythematosus and perioral dermatitis of both acute and chronic types. In 15 cases of subacute eczemas, there was relief from the subjective symptoms within 2 weeks and all the cases healed totally within one month. There were 14 cases of chronic eczema all of which had relief from pruritus within 18 days and got complete healing in 28 days. Sensitisation to the cream was not observed.

Ultralan Cream is an absorptive oil-in-water emulsion base containing 0.25% Fluocortolone Caproate (Fluocortolone Hexanoate-British Pharmacopoeia) and 0.25% Fluocortolone Trimethylacetate (Fluocortolone Pivalate-British Pharmacopoeia). Their parent compound is a derivative of corticosterone[1] unlike all other available corticoids which are derived from hydrocorticosterone. Its chemical name is 6 α - Fluoro - 16 α - methyl - 1 - dehydrocorticosterone with the chemical structure as follows.

The trimethyl ester is a quick acting compound while Fluocortolone Caproate is slow and long acting. The combination of the two offers a 'biphasic' action i.e. quick onset of action and at the same time sustained effect; a distinct advantage in topical therapy. The non-greasy cream leaves no unsightly shine on the skin and is thus well suited for application in a humid atmosphere. On the basis of data available from clinical studies in Europe, it has been claimed[2],[3]&[4] that Fluocortolone and its caproic acid esters exert good therapeutic action. We have tried this newly developed steroid cream for treatment of various types of dermatoses.

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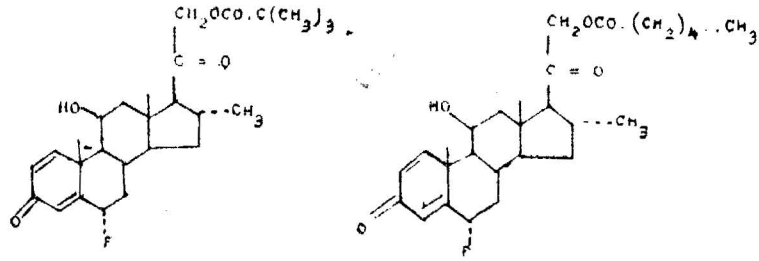
Material and methods

A total of 31 patients were studied of whom 16 were treated as inpatients, so that a daily assessment of their progress could be ascertained. The 15 outdoor patients consisted of hospital staff and others who could conveniently call over for a weekly follow-up. 15 of these cases were of sub-acute on chronic, 14 of chronic and 2 of other types of dermatoses.

The patients that underwent the trial had by and large eczemas for varying lengths of time.

Formula:



FLUOCORTOLONE TRIMETHYL-ACETATE

FLUOCORTOLONE CAPROATE

Fig.

Mode of Application

A thin film of the cream was gently massaged into the diseased area twice a day. During the course of therapy the patients were not given any other drug.

Assessment

The patients were assessed both subjectively and also by objective parameters viz, erythema, oedema, oozing, vesiculation, crusting, scaling and lichenification. We have classified our cases for assessment into various categories, to enable us to determine the efficacy of the application in each group of diseases. The cases of dermatitis have also been categorized into sub-acute and chronic types on the basis of their clinical symptomatology.

Observations

Types of dermatoses selected for the study are given in Table 1. Of the 31 patients, 18 were males and 13 females. There were 14 cases of eczematous dermatitis, 9 of contact dermatitis, 3 of Neurodermatitis, 1 each of nummular eczema, dyshydrotic eczema, seborrheic dermatitis, discoid lupus erythematosus and perioral dermatitis. The cases were classified again as 15 cases of sub-acute eczemas, 14 cases of chronic eczemas and 2 belong to miscellaneous group.

TABLE 1
Types of Dermatoses

Diseases	Sex M	Sex F	No of cases
Eczematous Dermatitis	7	7	14
Nummular Eczema	—	1	1
Dyshydrotic Eczema	—	1	1
Contact Dermatitis	7	2	9
Seborrheic Dermatitis	1	—	1
Neurodermatitis	2	1	3
Discoid Lupus Erythematosus (DLE)	—	1	1
Perioral Dermatitis	1	—	1
Total	18	13	31

The ages of patients (Table 2) varied from 2 to 60 years. The majority were between 11 to 40 years, and only one below 10 years.

TABLE 2
Age Group

Below 10 years	...	1
11—20 years	...	6
21—30 years	...	10
31—40 years	...	6
41—50 years	...	5
51—60 years	...	3
	Total	31

Clinical improvement profile is given in Table 3. Within 10 days of treatment 9 patients showed improvement and 9 others responded well with 15

TABLE 3
Clinical Improvement

Diagnosis	No.	Below 10 days	11-15 days	16-20 days	21-25 days	25-30 days	No Response	Poor Response
Eczematous Dermatitis	14	1	7	3	1	2	—	—
Contact Dermatitis	9	5	2	2	—	—	—	—
Nummular Eczema	1	1	—	—	—	—	—	—
Seborrheic Eczema	1	1	—	—	—	—	—	—
Neurodermatitis	3	1	—	—	—	—	1	1
Dyshydrotic Eczema	1	—	—	—	—	—	1	—
Discoid Lupus Erythematosus	1	—	—	—	—	—	—	1
Perioral Dermatitis	1	—	—	—	—	—	—	1
Total Cases	31	9	9	5	1	2	2	3

TABLE 4
Contact Dermatitis

Total Duration	Present Flare Up	Relief of subjective symptoms—days	Disappearance of lesions in objective days
1 year	3 months	8	16
4 months	2 months	7	16
2½ years	15 days	18	28
6 months	2 weeks	16	24
1 year	1 week	14	21
3 months	1 month	14	18
10 days	2 days	8	15
1 year	2 months	8	20
3 months	1 month	7	20

days of treament. Eight cases took 16 to 30 days for disappearance of the lesions. Three patients showed poor response and two showed no response at all.

There were 9 patients with contact dermatitis (Table 4). These were assessed as in the other cases on the basis of a change in the subjective symptoms and clinical improvement indicated by disappearance of the initial lesions. The duration of the contact varied from 10 days to 2½ years with varying periods of a flare up. Four out of the nine patients had a duration of over one year. Five of these patients had relief from itching within 8 days and the rest within 10 to 18 days. The lesions took 15 to 30 days to disappear completely.

Results of the 3 cases of neurodermatitis (Table 5) were of particular interest to us because of the chronic nature of the disease. In the first case where the disease was of 5 years duration there was partial relief from itching with 12 days of treatment. However, there was only minimal effect on the lichenification till the 32nd day, after which the patient was given a once daily application with saran wrap. There was considerable relief of itching and lichenification decreased. The patient however developed a folliculitis by the 52nd day. The second case showed no improvement even after 54 days of application. In the third case where the disease was of 1 year duration, there was subjective improvement in 8 days and lesions healed in 20 days.

TABLE 5
Neurodermatitis

Total Duration	Flare Up	Days taken for subjective improvement	Total days taken for objective clinical improvement	Comments
5 years	1 year	10 days	54th day	Itching and lichenification persisted although reduced to a certain amount; Folliculitis developed on the 54th day.
4 years	2 months	8 days	54th day	Even after 54 days treatment clinical improvement is slight.
1 year	1 month	8 days	20th day	Absolutely clear.

TABLE 6
Sub-Acute Eczema

Diagnosis	Duration	Number of days taken for clinical improvement	Number of days taken for healing
Contact Dermatitis	1 week	14	21
Contact Dermatitis	2 days	7	15
Contact Dermatitis	1 month	14	18
Eczematous dermatitis	1 month	6	13
Eczematous dermatitis	2 weeks	15	23
Eczematous dermatitis	1 week	6	25
Eczematous dermatitis	8 days	12	20
Eczematous dermatitis	3 weeks	12	20
Eczematous dermatitis	4 days	10	27
Eczematous dermatitis	1 month	8	20
Eczematous dermatitis	10 days	10	20
Eczematous dermatitis	3 days	6	13
Seborrheic Eczema	1 week	8	22
Contact dermatitis	15 days	18	28
Dyshydrotic Eczema	10 days	No response	—

There were 15 cases of subacute eczema (Table 6). Nine of these were of eczematous dermatitis, four of contact dermatitis and one each of seborrheic dermatitis, and dyshydrotic eczema. Clinical improvement took between 6 to 18 days while complete healing occurred between 13 to 28 days. In the single case of dyshydrotic eczema the patient was given concomitant systemic steroids as the clinical condition was severe. However, when the dermatitis was controlled, and the oral steroid withdrawn gradually, local use of the cream was unable to check the relapse.

There were 14 cases of chronic eczema (Table 7), 5 of which were eczematoid dermatitis, 5 of contact dermatitis and 3 of neurodermatitis and 1 of nummular eczema. The 4 cases of eczematoid dermatitis took from 11 to 18 days to be relieved of the itching and 20 to 28 days for complete clinical recovery. Minimal lichenification persisted in two patients.

TABLE 7
Chronic Eczema

Diagnosis	Total Duration	Number of days taken for clinical improvement	Number of days taken for complete cure
Contact Dermatatis	3 months	7	20
,, ,,	6 months	16	24
,, ,,	4 months	7	16
,, ,,	1 year	8	16
,, ,,	1 year	8	20
Eczematous Dermatitis	2 years	11	20
Eczematous Dermatitis	1 year	12	24
Eczematous Dermatitis	1 year	18	27
Neurodermatitis	4 years	Clinical improvement is slight even after 54 days 1 week slight.	
Neurodermatitis	5 years	12	Folliculitis on 54th day. Itching & Lichenification present.
Neurodermatitis	1 year	8	20
Nummular Eczema	1 year	6	27
Eczematous Dermatitis	1 year	16	28
Eczematous Dermatitis	1 year	12	24

TABLE 8
Miscellaneous

Disease	Total Duration	Flare Up	Number of days taken for subjective improvements	Total number of days taken for objective healing
Perioral Dermatitis	2 months	1 month	7 days	Treated upto 74th day
Discoid Lupus Erythematosus	6 months	4 months	Patient did not turn up after 18th day	

There was one patient each with perioral dermatitis and discoid lupus erythematosus (Table 8). The former showed improvement in 1 week after which the progress remained static upto the 74th day. In the latter case, there was initial improvement in that, the oedema and erythema decreased slightly but remained unchanged thereafter upto the 18th day after which the patient was lost to follow-up.

Conclusion

Topical steroids are now an essential tool in a dermatologists' therapeutic armamentarium. Steroids have been used mainly for their anti-inflammatory and anti-pruritic properties. Ultralan cream used in the various dermatoses by us, has shown good therapeutic results showing subjective and objective improvement in a short duration in most of our cases. There was no evidence of any untoward local reaction in spite of prolonged application. It may be used in all eczematous skin conditions requiring local corticosteroid therapy. Although topical steroids have a good therapeutic effect in cases of neurodermatitis, sudden unexplained bouts of frenzied itches may offset any clinical recovery that may have been obtained with local steroids.

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