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The Therapeutic Efficacy of Mometasone Furoate Cream 0.1% Applied Once Daily vs Clobetasol Propionate Cream 0.05% Applied Twice Daily in Chronic Eczema

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ABSTRACT

Background: Mometasone furoate [9a, 21-dichloro-11b, 17dihydroxy-16a-methyl-pregna-14-dione-3, 20-dione-17-(2furoate)] is a synthetic, 17-heterocyclic corticosteroid which has been shown to be highly effective as an anti-inflammatory agent which is approximately half as potent in suppressing hypothalamic-pituitary-adrenal (HPA) axis function as betamethasone valerate.

Method: The present open, randomised, third party blinded, left-right sided study was designed to compare the therapeutic efficacy of mometasone furoate cream 0.1% with clobetasol propionate cream 0.05% applied twice daily in chronic eczema following a 3-week course of therapy.

Patients/Results: Sixty consecutive patients with moderate to severe bilateral chronic eczema on the limbs were recruited into the study. The mean scores of various signs/symptoms including erythema, induration, crusting, scaling, excoriation and pruritus before and after 3 weeks treatment with mometasone furoate (MF) and clobetasol propionate (CP) cream, were compared. The baseline scores for MF and CP treated sites were almost identical. There was significant decrease in the mean scores of all signs/symptoms after 3 weeks treatment with MF and CP. There was also a significant difference in the mean scores between MF and CP treated sites after 3 weeks of treatment. The mean scores were significantly lower for CP treated sites than MF treated sites. More CP treated sites achieved "cleared" or "marked improvement" response than MF treated sites. There were more "excellent" or "good" grades on CP treated sites than MF treated sites at the end of 3 weeks of treatment. None of the patients showed any side-effects after 4 weeks of treatment.

Conclusion: Overall, 53% of patients considered the MF treated sites to be good or excellent vs 88% for CP treated sites.

Keywords: lichen simplex chronicus, topical steroids, therapeutics

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INTRODUCTION

Topical steroid has become the mainstay in the treatment of eczema since the introduction of hydrocortisone 30 years ago. Since then groups of topical steroids of different potency have been introduced. Unfortunately the potency of topical steroids is often directly proportionate to the risk of side-effects. There is always a constant search by pharmaceutical companies for formulations which can offer greater therapeutic benefits yet possess minimum side effects.

Mometasone furoate [9a,21-dichloro-11b, 17dihydroxy-16a-methyl-pregna-14-dione-3, 20-dione-17-(2furoate)] is a synthetic, 17-heterocyclic corticosteroid. It has been shown to be highly effective as an anti-inflammatory agent which is approximately half as potent in suppressing hypothalamic-pituitary-adrenal (HPA) axis function as betamethasone valerate[1,2,3].

Mometasone furoate ointment has been reported to be an effective vasoconstrictive agent on human skin. In one study, lesions of most psoriatic patients treated for two weeks with mometasone furoate ointment exhibited slight or moderate improvement. Results indicated that mometasone furoate may be more potent than betamethasone-17-valerate ointment[1].

Clinical investigations of this drug have been expanded to assess the clinical effects – safety and efficacy – in patients with moderate to severe corticosteroid responsive dermatoses.

The present study was designed to evaluate the therapeutic efficacy of mometasone furoate cream 0.1% in chronic eczema following a 3-week course of therapy. The therapeutic efficacy of mometasone furoate cream applied once daily was also compared with that of clobetasol propionate cream 0.05% applied twice daily.

MATERIALS AND METHODS

This is an open, randomised, third party-blinded, left-right sided patient study conducted in the National Skin Centre (NSC), Singapore between April 1994 and October 1994.

Sixty consecutive patients with moderate to severe bilateral chronic eczema on the limbs were recruited into the study. The study was designed to compare the therapeutic efficacy and safety of mometasone furoate cream 0.1%, applied once daily and clobetasol propionate cream 0.05%, applied twice daily on chronic eczema on the same patient.

In selecting the patients, those with chronic eczema as evidenced by lichenified scaly patches and plaques bilaterally on the limbs for at least 6 months, were included.

Exclusion criteria included pregnancy, known hypersensitivity to corticosteroids, presence of skin atrophy (eg. telangiectasia and/or striae), those on systemic steroids within 28 days of entering the study.

Antihistamines must be discontinued one day prior to Study Day 1. No medication other than the study preparation was to be applied to the study area.

The creams were dispensed to the patients on Days 1, 8 and 15 of the study. One tube each of mometasone furoate cream was dispensed to the patients each week. Patients will be asked to return the used tubes at the next weekly follow-up visit (days 8, 15 and 22).

Patients were instructed to apply a thin layer of cream once or twice daily (when using mometasone furoate and clobetasol propionate respectively) to the study sites.

Mometasone furoate cream was applied on one limb and clobetasol propionate cream on the other limb. The side to be treated with mometasone furoate cream was chosen randomly and the assessor was blinded to this. Patients were treated for 3 weeks and assessed for response to treatment at weekly intervals.

The signs/symptoms of chronic eczema on the treated areas including erythema, induration, crusting, scaling, excoriation and pruritus were scored upon entry into the study (Day 1 or baseline scores) and at follow-up visits on Days 8, 15 and 22 post-treatment using a severity scale which ranges from 0 = none to 3 = severe.

The physician's overall evaluation of the severity of eczema to the 2 creams was recorded during each visit. Each patient was followed up and assess during each follow-up by the same dermatologist who examined the patient during the first visit. Patients' response to the treatment was also recorded during each visit.

Individual sign/symptom scores, the total sign/symptom score, the percentage improvement in the total score and the physician's overall evaluation of change in disease was analysed statistically.

The therapeutic efficacy (based on visual scoring of individual signs/symptoms and overall scores) of mometasone furoate and clobetasol propionate were studied individually after 3 weeks of treatment. We also compared the therapeutic efficacy of the two creams after 3 weeks of treatment.

Examinations for signs of skin atrophy in the target areas were made at each visit. Cosmetic acceptability on each treated site was also recorded during each visit.

Non-parametric statistical analysis using the Rank Sign tests was used to assess statistical significance, p values of < 0.05 were considered statistically significant.

RESULTS

Fifty-eight out of the 60 patients recruited completed the study. The mean age was 45.7 years (range 16 years to 85 years). There were 25 (43.1%) males and 33 (56.9%) females. Equal number of patients were treated with mometasone furoate cream on the left and right side of the body.

All patients studied had endogenous eczema presenting with lichenified patches and plaques including patients diagnosed with lichen simplex chronicus 86.2% (50/58), hands and feet eczema 6.8% (4/58), discoid eczema 1.7% (1/58), prurigo nodularis 1.7% (1/58) and unclassifiable eczema 1.7%(1/58). Mean duration of eczema was 7.5 years (range: 3 years – 30 years).

Location of treatment sites included the arms 17.2% (10/58), hands 13.8%(8/58), feet 31% (18/58) and legs 37.9% (22/58).

Table I shows the mean scores of various signs/symptoms including erythema, induration, crusting, scaling, excoriation and pruritus before and after 3 weeks of treatment with mometasone furoate (MF) and clobetasol propionate (CP) cream. The baseline scores for MF and CP treated sites were almost identical. There was significant decrease in the mean scores of all signs/symptoms after 3 weeks of treatment with MF and CP. There was also a significant difference in the mean scores between MF and CP treated sites after 3 weeks of treatment. The mean scores were significantly lower for CP treated sites than MF treated sites.

Table II shows the dermatologists' assessment of patients' response to MF and CP treatment. More CP treated sites achieved "cleared" or "marked improvement" response compared to MF treated sites; CP appeared to be more effective than MF. Table III shows patients' assessment of their own response to treatment. There were more "excellent" or "good" grades on CP treated sites than MF treated sites at the end of the treatment. None of the patients showed any side-effects after 4 weeks treatment.

DISCUSSION

The results showed that mometasone furoate and clobetasol propionate were both effective in treating chronic eczema. There was progressive reductions in all signs/symptoms scores (including erythema, crusting, excoriation, induration, scaliness and pruritus) from baseline (before starting treatment) to the end of the third week of treatment on both MF and CP treated sites. There was significant reduction in the signs/symptoms scores in all parameters at the end of third week when compared to baseline values before treatment commenced. The overall scores were also significantly lower at the end of the third week compared to baseline.

Table I – Mean scores of various parameters before and during treatment with mometasone furoate (MF) and clobetasol propionate (CP) cream

		Mean scores (SD) Week 1	Week 2	Week 3	Week 4	p value (week 1 vs week 4)
Erythema :	MF	1.5 (0.7)	1.0 (0.6)	0.8 (0.5)	0.6 (0.4)	0.000
	CP	1.5 (0.7)	1.1 (0.6)	0.7 (0.5)	0.4 (0.4)	0.000
Crusts :	MF	0.9 (0.9)	0.5 (0.6)	0.3 (0.5)	0.2 (0.4)	0.000
	CP	0.9 (0.8)	0.4 (0.5)	0.2 (0.4)	0.1 (0.2)	0.000
Excoriation :	MF	1.1 (0.8)	0.4 (0.6)	0.2 (0.5)	0.2 (0.3)	0.000
	CP	1.1 (0.8)	0.4 (0.5)	0.1 (0.2)	0.0 (0.1)	0.000
Induration :	MF	1.9 (0.7)	1.5 (0.7)	1.1 (0.7)	0.9 (0.6)	0.000
	CP	1.9 (0.8)	1.3 (0.8)	0.8 (0.6)	0.4 (0.4)	0.000
Pruritus :	MF	1.6 (0.8)	0.7 (0.8)	0.4 (0.6)	0.3 (0.4)	0.000
	CP	1.7 (0.8)	0.6 (0.7)	0.2 (0.3)	0.1 (0.2)	0.000
Scaliness :	MF	1.7 (0.7)	1.0 (0.6)	0.9 (0.6)	0.6 (0.5)	0.000
	CP	1.7 (0.7)	0.9 (0.5)	0.6 (0.5)	0.2 (0.3)	0.000
Overall total scores	MF	8.8 (3.1)	5.1 (2.8)	3.7 (2.4)	2.7 (1.7)	0.000
	CP	8.9 (3.2)	4.7 (2.7)	2.5 (1.9)	1.3 (1.3)	0.000
Overall response MF vs CP p values		0.900	0.081	0.001	0.000	

Table II – Dermatologists' assessment of response to treatment

		Number (percentage) Week 2	Week 3	Week 4
Cleared :	MF	0	1 (1.7)	4 (6.9)
(100%)	CP	0	1 (1.7)	11 (19.0)
Marked :	MF	5 (8.6)	6 (10.3)	12 (20.7)
(> 75%)	CP	9 (15.0)	21 (36.2)	30 (51.7)
Moderate :	MF	14 (24.1)	21 (36.2)	17 (29.3)
(50% – 75%)	CP	15 (25.9)	22 (37.9)	11 (19.0)
Slight :	MF	37 (63.8)	24 (41.4)	14 (24.1)
(< 50%)	CP	32 (55.2)	11 (19.0)	4 (6.9)
No change :	MF	2 (3.4)	6 (10.3)	11 (19.0)
	CP	2 (3.4)	3 (5.2)	2 (3.4)

MF = mometasone furoate, CP = clobetasol propionate
Percentage of total clearance at week 4 was significantly higher on clobetasol propionate than mometasone furoate treated sites. Chi square = 7.53, p = 0.006

Table III – Patients' assessment of response to treatment

		Number (percentage) Week 2	Week 3	Week 4
Excellent :	MF	3 (5.2)	3 (5.2)	6 (10.3)
	CP	9 (15.5)	11 (19.0)	25 (43.1)
Good :	MF	19 (32.8)	22 (37.9)	25 (43.1)
	CP	22 (37.9)	38 (65.5)	26 (44.8)
Fair :	MF	32 (55.2)	29 (50.1)	21 (36.2)
	CP	25 (43.1)	9 (15.5)	7 (12.1)
Poor :	MF	4 (6.9)	4 (6.9)	6 (10.3)
	CP	2 (3.4)	0	0

MF = mometasone furoate, CP = clobetasol propionate
Percentage of "excellent" response at week 4 was significantly higher on clobetasol propionate than mometasone furoate treated sites. Chi square = 10.45, p = 0.001.

No side effects were observed on any of the treated sites. This is probably due to the short duration of treatment. Potent topical steroids including CP are known to cause skin atrophy, telangiectasia, striae, and hypothalamo-pituitary axis suppression.

The improvements in the signs/symptoms scores were significantly greater on CP treated sites than MF treated sites. It would appear that CP was more effective in clearing chronic eczema than MF. The overall improvement based on visual scoring was significantly better for CP treated sites than MF treated sites.

Our study also indicated that the dermatologists and patients found CP to give better response than MF in chronic eczema. Total clearance was observed in 19% of CP treated sites compared to 7% on MF treated sites.

Forty-three sites of patients graded CP treated sites to be excellent after 3 weeks of treatment compared to 10% for MF treated sites. None of the patients indicated "no change" after treatment on CP sites compared to 10% on MF treated sites.

Overall, 53% of patients considered MF treated sites to be good or excellent vs 88% for CP treated sites.

According to the manufacturers' treatment guidelines, MF was to be applied only once daily whereas CP should be applied twice daily. In our study, MF treated sites were treated once daily and CP treated sites were treated twice daily. MF and CP treated sites might not be comparable as a result. Response to MF treatment might be better if applied twice daily. Alternatively, application of emollient in between MF treatment might also improve eczema.

MF applied once daily and CP applied twice daily appeared to be effective in treating chronic eczema. CP appeared to be more effective than MF. However, MF has the advantage of single daily application.

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