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Original Article

Efficacy, safety and tolerability of mometasone furoate 0.1% cream, ointment and lotion in childhood eczema

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Abstract

Background Topical corticosteroids have been the first line treatment in children with eczema. Efforts to develop new topical glucocorticoids with reduce systemic bioactivity help to treat them. Mometasone furoate 0.1% has been found to be efficacious in children with atopic dermatitis.

Objective To evaluate the therapeutic efficacy, safety and tolerability of mometasone furoate 0.1% cream, ointment and lotion in childhood eczema.

Patients and methods The study was conducted from Oct 2007 to Jan 2008 at the outpatient department of dermatology at Abbasi Shaheed Hospital, Karachi. A total of 50 children, aged ≥12 years, of either sex with all types of childhood eczema were included in the study and those with infection, complication like scars, atrophy, striae, etc, known hypersensitivity to corticosteroids and on any other medicaments were excluded. Parents of children were instructed to apply a thin layer with gentle rubbing twice daily for three weeks. Fingertip unit (FTU) was demonstrated to parents. Tubes of mometasone furoate 0.1% cream, ointment and lotion were given to parents according to the need. Emollient was applied twice daily. Children were followed up at 3, 6 & 12 weeks. SPSS – 13.0 was used for statistical analysis. Friedman test was applied to compare the significance of results at $p<0.05$.

Results Out of 50 patients enrolled, at 3 weeks of follow-up only 43 reported. 29 (67% showed improvement and 14 (32%) fully resolved. At 6 weeks 32 (74.4%) had complete resolution and 7 (16.2%) had improved, but at 12 weeks only 25 patients (58%) had resolved and 6 patients (13.9%) relapsed, while 2 patients were gradually improving. Efficacy in resolution of sign/symptoms on 12 weeks was ($p<0.001$). No cutaneous or systemic side effects were seen.

Conclusion Mometasone furoate 0.1% cream, ointment and lotion are found to be effective, safe and highly tolerable in childhood eczema and the compound was found equally safe in infants.

Keywords
Childhood eczema, mometasone furoate

Introduction

Glucocorticoids have a wide range of anti-inflammatory effects and their use in eczema is established.[1] However in addition to cutaneous adverse effects like atrophy, systemic effects such as growth suppression in children also bring fear to parents for the use of corticosteroids.

Now and then, clinical trials are done to prove the safety and tolerability of new compounds. Mometasone furoate has been found to be efficacious in children with

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atopic dermatitis and have been associated with a low risk of adverse effects.[2,3]

Mometasone furoate is a potent topical glucocorticoid. Its affinity to human glucocorticoid receptor is approximately 22 times that of dexamethasone.[4] Side effects of such compounds depend on degree of inflammation, skin perfusion, and thickness of epithelial layer, dose, application, occlusive dressing and potency of compound.[5]

The study was designed to evaluate the safety, efficacy and tolerability of mometasone furoate 0.1% cream, ointment and lotion twice daily in childhood eczema.

Patients and methods

It was an open-labeled, single centre non-comparative study conducted at Abbasi Shaheed Hospital, Karachi, from October 2007 to January 2008. 50 children of either sex, aged ≤12 yrs, infants with different types of eczema **(Table 1)** were selected. Children with infection, complication like scars, atrophy, striae, etc, known hypersensitivity to corticosteroids and on any other medicaments were excluded.

Mometasone furoate 0.1% cream, ointment and lotion were given to the parents on first visit for three weeks. Fingertip unit (FTU) method was demonstrated, 1.5 FTU (one arm), 3 FTU (one leg), 3 FTU (front/back of trunk), 1 FTU (scalp). Instructions were given to apply a thin layer of ointment/cream/lotion with gentle rubbing only on affected skin twice daily for three weeks. Emollient was applied twice to the desired area. Patients signs and symptoms e.g. pruritus, scaling, erythema, induration, lichenification were recorded on day one and on follow up visits 3rd, 6th and 12th weeks, using a severity scale from 0=none to 3=severe. Each patient was assessed during the Follow-up visits by same two dermatologists. Individual signs and symptoms scores, total signs and symptoms scores, the percentage improvement in total score and physician overall evaluation was analyzed statistically. Adverse effects sign of skin irritability, atrophy etc. were specifically looked.

Table 1 Different types of eczemas (n=50).

Types of eczema	*n (%)*
Atopic dermatitis	21 (42)
Seborrhoeic dermatitis	18 (36)
Discoid eczema	3 (6)
Pityriasis alba	2 (4)
Prurigo	4 (8)
Contact dermatitis	2 (4)

Institutional Ethical Committee approval was obtained and all efforts were made to stay true to the Declaration of Helsinki.

Data analysis

SPSS-13.0 (software) was used for statistical analysis. Friedman test for repeated qualitative data was applied to compare the significance of clinical outcome, relief in signs and symptoms and patients comfort at $p<0.05$.

Results

Among 50 children of variable eczema 27 (54%) were male and 23 (46%) were female. Aged ≤12 years among them 24 were infants. Presenting complaints were pruritus, erythema, scaling, irritability and lichenification. Pruritus was present in 44 (88%), irritability in 38 (76%), erythema in 44 (88%), scaling in 47 (94%) and lichenification in 2 (4%). Out of 50 patients, 43 returned for first follow up on 3rd week. Later 39 patients were recorded

Table 2 Overall effectiveness in the relief of signs and symptoms

Signs & symptoms	*N*	*3rd week*	*6th week*	*12th week*
Pruritus	44			
Mild		17	7	6
Moderate		7	-	1
Severe		-	-	-
Resolved		15	28	22
Irritability	38			
Mild		11	3	6
Moderate		3	-	-
Severe		-	-	-
Resolved		20	29	21
Erythema	44			
Mild		26	7	7
Moderate		5	-	1
Severe		-	-	-
Resolved		14	32	25
Scaling	47			
Mild		26	8	6
Moderate		2	-	-
Severe		-	-	-
Resolved		13	29	25
Lichenification	2			
Improved		2	2	1
Resolved		-	-	1

Table 3 Follow up findings

Clinical outcome	*Total no.*	*Cured*	*Improved*	*No change*	*Worse*	*Relapse*
3rd week	43	14	29	---	---	---
6th week	39	32	7	---	---	---
12th week	33	25	2	---	---	6

on 6th week follow up visit. On 12th week, 33 patients came for follow up.

Table 2 shows overall effectiveness in relief of signs and symptoms and **Table 3** shows the clinical outcome on each week follow up. After 3 weeks, 14 (32%) fully resolved and 29 (67.4%) showed improvement. After 6 weeks 32 (82%) had complete resolution, 7 (17.9%) had improvement, but after 12 weeks only 25 (75.7%) had resolution, 2 (6%) showed improvement while 6 relapsed (18%). Those who relapsed were the patients of atopic dermatitis. On 6th and 12th week, patients' resolution was significant (p<0.001).

None of the patients reported any local or systemic side effects. Overall patients' comfort was evaluated. It was significant (p<0.001).

Discussion

Patients always prefer not to use corticosteroids in their children even when their eczema is severe. Previous research also shows that many patients fail to adhere to treatment regiments because of fear of corticosteroids.[6]

Although topical corticosteroids are the treatment of choice in all types of eczema, numerous studies and clinical trials have focused to obtain excellent results on efficacy and tolerability while minimizing adverse effects of corticosteroids.[7] But so far none of the studies can point to one ideal topical steroid with virtually no side effects.

In our study 0.1% mometasone furoate applied twice for 3 weeks proved to be as effective as 0.005% fluticasone propionate ointment in moderate to severe atopic dermatitis.[8] Majority of our patients were infants and the compound was applied on face and scalp area for 3 weeks. The safety and efficacy are comparable with the study by Lebwohl *et al*.[9] Regarding the safety and efficacy of mometasone furoate numerous studies have been conducted in atopic children,[10] which proved its effectiveness in minimizing and resolving acute flares with limited side effects. Single application is far better than frequent application of same potency corticosteroid which reduces the cost and side effects.

Mometasone furoate 0.1% cream, ointment and lotion applied once/twice is more effective than flucinolone acetonide or triamcinolone acetonide applied three times daily in psoriasis. The incidence of adverse reactions was minimal.[11] Thus the conclusion drawn by many authors was that use of mometasone furoate in psoriasis, as well as in chronic eczema was statistically more significant. More trials non-comparative/comparative are needed to further focus on clinical effectiveness, cost-effectiveness, local and systemic side effects of once daily or more frequent use of various corticosteroids and other drugs like tacrolimus and pimecrolimus etc. in childhood eczema with large sample size.

References

1. Gradman J, Wolthers OD. Short term growth in children with eczema during treatment with topical mometasone furoate and tacrolimus. *Acta Paediatr* 2007; **96**: 1233-7.
2. Breverk T, Werfel T, Kapp A. Safety and efficacy of topical calcineurin inhibitors in the treatment of childhood atopic dermatitis. *Am J Clin Dermatol* 2005; **6**: 65-77.
3. Prakash A, Benfield P. Topical mometasone. A review of its pharmacological properties and therapeutic uses in the treatment of dermatological disorders. *Drugs* 1998; **55**: 145-63.
4. Valotis A, Neukam K, Elert O, Hogger P. Human receptor kinetics, tissue binding affinity and stability of mometasone furoate. *J Pharm Sci* 2004; **93**: 1337-50.
5. Turpeinen M. Influence of age and severity of dermatitis on the percutaneous absorption of hydrocortisone in children. *Br J Dermatol* 1988; **118**: 517-22.
6. Fischer G. Compliance problems in pediatric atopic eczema. *Aust J Dermatol* 1996; **37** (Suppl 1): S10-S13.
7. Sahasranaman S, Issar M, Hochhaus G. Metabolism of mometasone furoate and biological activity of metabolites. *Drug Metab Dispos* 2006; **34**: 225-33.
8. Pei AY, Chan HH, Ho KM. The effectiveness of wet wrap dressing using 0.1% mometasone furoate and 0.005% fluticasone propionate ointments in the treatment of moderate to severe atopic dermatitis in children. *Pediatr Dermatol* 2001; **18**: 343-8.
9. Lebwohl M, Peets E, Chen V. Limited application of mometasone furoate on the face and intertriginous areas: analysis of safety and efficacy. *Int J Dermatol* 1993; **32**: 830-1.
10. Green C, Colquitt JL, Kirby J *et al.* Clinical and cost effectiveness of once daily verses more frequent use of same potency topical steroids for topical eczema: a systemic review and economic evaluation. *Health Technol Assess* 2004; **8**: 101-20.
11. Medansky RS, Bressinck R, Cole GW *et al*. Mometasone furoate ointment and cream 0.1% in treatment of psoriasis: comparison with ointment and cream formulation of flucinolone acetonide 0.025% and triamcinolone acetonide 0.1%. *Cutis* 1988; **42**: 480-6.