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Original Article

Comparative efficacy of topical mometasone furoate 0.1% cream vs topical tacrolimus 0.03% ointment in the treatment of atopic dermatitis

Md Alauddin Khan[*], Lubna Khondker[**], Dilshad Afroze[*]

*****Department of Medicine, Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka, Bangladesh
******Department of Dermatology and Venereology, Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka, Bangladesh

Abstract

Objective To compare the efficacy of mometasone furoate and tacrolimus in the treatment of atopic dermatitis.

Methods Sixty patients of atopic dermatitis were treated with mometasone furoate 0.1% (n=30) and tacrolimus 0.03% (n=30). Both treatments were applied twice daily for 12 weeks. Patients were followed up monthly. The disease severity assessed by SCORAD index. A 4-point scale was used to measure the level of response to treatment.

Results Before treatment the respective mean SCORAD was 30.57±13.62 and 30.90±17.17 in group A and B and at the end of treatment decreased to 11.87±12.04 and 11.20±13.85, respectively (p>0.05). Percent reduction of severity from baseline to final follow-up was 69.20±23.41 in group A and 74.77±23.30 in group B (p=0.360). At final follow-up 56.7% of group A and 63.3% of group B achieved excellent response, 13.3% of group A and 16.7% of group B achieved good response.

Conclusion We conclude that both treatments, mometasone furoate and tacrolimus, are effective in the treatment of atopic dermatitis.

Key words
Efficacy, mometasone furoate, tacrolimus, atopic dermatitis.

Introduction

Atopic dermatitis (AD) is an itchy, chronic or chronically relapsing, inflammatory skin condition. The lesion is characterized by itchy papules, occasionally vesicles which become excoriated and lichenified.[1,2] Atopy is a syndrome which may be defined as a genetically determined immune system maturation disorder of unknown origin, in which there is increased liability to form IgE antibodies and is frequently associated with personal or family history of atopic dermatitis, allergic rhinitis or asthma.[3,4] In AD there is activation of the T helper 2 (Th2) immune response, with synthesis of cytokines IL-4, IL-5, IL-10 and IL-13 and inhibition of T helper 1 (Th1) response. IL-4 and IL-5 produces elevated IgE level and eosinophilia in tissue and peripheral blood.[5,6] Pruritus is the hallmark of atopic dermatitis in all stages. 60% infantile AD patients present in first year of life.[7,8] Pruritus is paroxysmal and a constant feature. Skin biopsy for histopathology show spongiosis and edema of the epidermis, hyperkeratosis and acanthosis in chronic stage along with perivascular infiltrate of in upper dermis.[9,10] Topical corticosteroids are very effective in atopic dermatitis but their frequent and long-term use, particularly in children

Address for correspondence
Dr. Lubna Khondker, Assistant Professor,
Department of Dermatology and Venereology
Bangabandhu Sheikh Mujib Medical University (BSMMU)
Dhaka, Bangladesh
Email: lubnaderma@gmail.com

have many side effects.[11] Mometasone furoate is a medium potency corticosteroid, indicated for the relief of the inflammatory and pruritic manifestations of atopic dermatitis.[12] Topical calcineurin inhibitors like tacrolimus may be used as alternate to steroid. Topical tacrolimus suppresses inflammation in a similar way to steroids and is equally as effective as a medium potency steroid.[10] It does not cause skin thinning or other steroid related side-effects.[13] To the best of my knowledge, no study exploring the efficacy and safety of topical mometasone furoate comparing with topical tacrolimus in the treatment of atopic dermatitis has yet been conducted in Bangladesh. So, to know and to treat the patient with atopic dermatitis in an effective way, such kind of study was conducted in Bangladesh.

Methods

A clinical trial was conducted in department of Dermatology and Venereology, Bangabandhu Sheikh Mujib Medical University, Dhaka. The duration of the study was from September 2011 to February 2012. Patients of atopic dermatitis attending outpatient department of Dermatology and Venereology, Bangabandhu Sheikh Mujib Medical University, Dhaka were the study population. Purposive type of non-probability sampling method was followed in this study. Inclusion criteria were patients of atopic dermatitis diagnosed clinically, patient who gave informed written consent, age more than 2 years and patients of either gender. Exclusion criteria were: known hypersensitivity to mometasone or tacrolimus, patients suffering from hepatic, renal, cardiovascular and hematological diseases, patients with co-existing acute infections, neoplasia, uncontrolled hypertension and diabetes mellitus, patients suffering from any food allergy and other skin morbidity causing acute onset of skin rash, skin disorders likely to affect drug absorption or disorders requiring medical treatment within 5 days before the start of the study, pregnancy and lactation.

Procedure of data collection

A total number of 60 patients were primarily selected and they were randomized using computer-generated codes into two groups (group A and group B), each of which included 30 patients. Complete history, general physical and dermatological examinations were done for all enrolled patients. History and physical findings were recorded in a structured proforma. Patients, who matched the inclusion and exclusion criteria and freely gave their informed consent, were selected for the study.

Intervention

Group A was treated with mometasone furoate 0.1% ointment and group B with tacrolimus 0.03% ointment. Both preparations were applied twice daily for a period of 12 weeks. Patients were clinically assessed monthly for three months. Each time the severity of the disease was recorded and clinical photographs were taken. The severity of disease was measured by Scoring of Atopic Dermatitis (SCORAD) index. For calculating SCORAD index, six clinical signs were recorded for each case: erythema, edema/papulation, oozing/crusting, excoriations, lichenification and dryness. Disease extent was measured by using the rule of nine. The average intensity of each clinical sign was graded from 0 to 3 (0=absent, 1=mild, 2=moderate, and 3=severe) at a representative body site, per the SCORAD protocol. Subjective symptoms, pruritus and sleep loss were evaluated with regard to the last 3 days and nights, and all were scored by the patients. Both subjective items were graded on a 10-cm visual analogue scale. The SCORAD index formula is: A/5 + 7B/2 + C. In this formula A is defined as the extent (0–100), B is defined as the intensity (0-18) and C

is defined as the subjective symptoms (0-20). The maximum SCORAD score is 103 (i.e. patients with high score are rated "worse").

A 4-point scale was used to measure the level of response to treatment, if >75% clear - excellent response; if 50-75% clear - good response; if 25-50% clear fair response; if <25% clear - poor response.

Data analysis

Data analysis was performed by Statistical Package for Social Science (SPSS), version-12. Level of significance (*p* value) was set at 0.05 and confidence interval at 95%.

Results

Table 1 shows the clinical characteristics in the two groups. Both groups were comparable in all parameters (p<0.05). Mean age of group A patients was 21.73±4.30 and group B was 19.70±3.44 years. 50% of group A and 58.3% of group B were from the 2 to10 year age group and 50.0% of group A and 33.3% of group B wee older than 10 years. Mean age of onset of disease was 9.37±4.07 years and 7.42±3.12 years in group A and group B, respectively (*p*=0.420). Mean duration of disease was 16.60±17.21 months and 28.20±38.71 months in group A and group B, respectively (*p*=0.139).

All patients of both groups presented with erythema, papules and 16.7% presented with excoriation (*p*=0.999). Lesions on extremities were present in 96.7% of group A and 100.0% of group B, lesions on trunk were present in 6.7% and lesions on face in 3.3% (*p*>0.05).

In **Table 2** effect of both treatments on three cardinal signs of diseases is compared. Both groups showed a comparable improvement (*p*>0.05). At baseline, mean number of erythematous lesions in group A and group B was 12.77±4.01 and 11.80±3.93, respectively (*p*=0.350). At 1st follow-up mean number of erythematous lesions in group A and group B was 7.80±4.11 and 7.77±4.08, respectively, at 2nd follow-up it was 6.10±4.03 and 5.63±4.16 and at final follow-up 4.17±4.02 and

Table 1 Demographic and clinical data of patients.

	Group A (n=30)	*Group B (n=30)*
Age (years)		
2 to10	15 (50.0)#	20 (58.3)*
>10	15 (50.0)	10 (33.3)*
Mean ± SD	21.73±4.30	19.70±3.44*
Age at onset	9.37±4.07	7.42±3.12*
Duration of disease (mo)	16.60±17.21	28.20±38.71*
Erythema	30 (100.0)	30 (100.0)*
Papules	30 (100.0)	30 (100.0)*
Excoriation	5 (16.7)	5 (16.7)*
Affected sites		
Extremities	29 (96.7)	30 (100.0)*
Trunk	2 (6.7)	2 (6.7)*
Face	1(3.3)	1 (3.3)*

* *p*>0.05, Unpaired t test.

Table 2 Extent of score of erythematous lesion, papules and excoriation in different follow-up.

	Group A	*Group B*
Erythematous lesion		
Baseline	12.77±4.01	11.80 ±3.93
1st follow-up	7.80±4.11	7.77 ±4.08
2nd follow-up	6.10±4.03	5.63 ±4.16
Final follow-up	4.17±4.02	3.47 ±4.00
Papules		
Baseline	17.30±10.29	18.57±13.88
1st follow-up	12.40±9.46	13.10± 12.67
2nd follow-up	9.97±8.73	10.10± 11.17
Final follow-up	7.63±8.08	7.73±9.98
Excoriation		
Baseline	0.50±1.33	0.53±1.28
1st follow-up	0.30±0.88	0.30±0.75
2nd follow-up	0.17±0.59	0.10±0.31
Final follow-up	0.07±0.37	0.00

**p>0.05,* Unpaired t test.

Table 3 SCORAD (Mean of total scoring of Atopic dermatitis) in different follow up.

	Group A	*Group B*
Baseline	30.57±13.62	30.90±17.17*
1st follow-up	20.50±13.64	21.17±16.94*
2nd follow-up	16.23±12.74	15.83±15.29*
Final follow-up	11.87±12.04	11.20±13.85*
% reduction from baseline to final follow-up	69.20±23.41	74.77±23.30*

***p*>0.05, Unpaired t test.

Table 4 Clearance level of disease at different follow-ups.

	Group A	*Group B*
1st follow up		
Excellent	1 (3.3)#	1 (3.3)
Good	3 (10.0)	8 (26.7)
Fair	18 (60.0)	12 (40.0)
Poor	8 (26.7)	9 (30.0)
2nd follow up		
Excellent	4 (13.3)	9 (30.0)
Good	14 (46.7)	12 (40.0)
Fair	9 (30.0)	7 (13.3)
Poor	3 (10.0)	2 (6.7)
3rd follow up		
Excellent	17 (56.7)	19 (63.3)
Good	4 (13.3)	5 (16.7)
Fair	7 (23.3)	5 (16.7)
Poor	2 (6.7)	1 (3.3)

*****p>0.05, Chi square test.

3.47±4.00 (p>0.05). At baseline mean number of papules in group A and group B was 17.30±10.29 and 18.57±13.88, respectively (p=0. 690). At 1st follow-up, mean number of papules in group A and group B was 12.40±9.46 and 13.10±12.67, respectively. At 2nd follow up, it was 9.97±8.73and 10.10±11.17 and at final follow-up 7.63±8.08 and 7.73±9.98 (p>0.05). At baseline, mean number of excoriation in group A and group B was 0.50±1.33 and 0.53±1.28, respectively (p=0. 922). At 1st follow up mean number of excoriation in group A and group B was 0.30±0.88 and 0.30 ± 0.75 respectively, at 2nd follow up it was 0.17±0.59 and 0.10±0.31 and at final follow up 0.07±0.37 and 0.00 (p>0.05).

At baseline mean of total score of atopic dermatitis was 30.57±13.62 and 30.90±17.17 in group A and B, at 1st follow up it was 20.50±13.64 and 21.17±16.94, respectively in group A and B, at 2nd follow up it was 16.23±12.74 and 15.83±15.29 and at final follow up it was 11.87±12.04 and 11.20±13.85 respectively in group A and B (p>0.05). Percent reduction of severity from base line to final follow up was 69.20±23.41 in group A and 74.77±23.30 in group B (p=0.360).

At 1st follow up 3.3% of both group got excellent response, 10.0% of group A and 26.7% group B got good response, 60.0% of group A and 40.0% of group B got fair response and 26.7% of group A and 30.0% of group B got poor response (p=0.317).

At 2nd follow up 13.3% of group A and 30.0% of group B got excellent response, 46.7% of group A and 40.0% of group B got good response, 30.0% of group A and 13.3% of group B got fair response and 10.0% of group A and 6.7% of group B got poor response (p=0.470). At final follow up 56.7% of group A and 63.3% of group B achieved excellent response, 13.3% of group A and 16.7% of group B achieved good response, 23.3% of group A and 16.7% of group B achieved fair response and 6.7% of group A and 3.3% of group B achieved poor response (p=0.828).

Discussion

In our study, both treatments showed a significant improvement in mean scores of three important clinical signs of AD, mean SCORAD index and level of clearance in their respective groups (p<0.05). The improvement in all these parameters was similar in two groups (p>0.05), showing that both drugs are equally effective in children as well adults suffering from AD. The efficacy of both drugs is proven in children[9,10] but few studies[14] directly compared these two drugs in AD.

Gradman *et al.*[14] compared the suppressive effects of topical mometasone furoate and tacrolimus on skin prick testing in 12 children with atopic eczema before and after 2 weeks of treatment with topical mometasone furoate and tacrolimus. Both treatments significantly suppressed the allergen wheal size.

Pei *et al.*[15] conducted a study to observe the effectiveness of wet wrap dressings using 0.1% mometasone furoate and 0.005%

fluticasone proprionate ointments in the treatment of moderate to severe atopic dermatitis in children. There was significant improvement in the disease severity from baseline during the first 2 weeks of the open application arm (p=0.043).[15] In another vehicle-controlled trial in AD by Schnopp *et al*.[16] mometasone furoate 0.1% ointment was significantly better than vehicle (p<0.01).

Hoeger *et al.*[17] determined the efficacy of tacrolimus vs. vehicle in children with mild-moderate facial AD dependent on/intolerant of topical corticosteroids. Investigators' global assessment (p=0.004) and median time to clearance was significantly better in favour of tacrolimus treated group.[17]

Zuberbier *et al*.[18] studied whether treatment of patients with AD with tacrolimus can decrease the development of flares necessitating the use of a topical corticosteroid on the face and thus reduce the need for use of topical corticosteroids in this sensitive skin area. Patients in the vehicle group needed prednicarbate treatment on the face on 20.7% of the days vs. 11.7% of the study days in the tacrolimus group (p=0.0024). Fifty per cent of patients in the tacrolimus group had no flare on the face during the treatment period compared with 37.5% of patients in the vehicle group (p=0.012). Long-term intermittent treatment of facial AD in children and adolescents with tacrolimus cream 1% does significantly reduce the need for topical corticosteroids.[18]

Conclusion

In the light of the findings of the study we conclude that each of the treatment of mometasone furoate and tacrolimus is individually effective in the treatment of atopic dermatitis. The efficacy of mometasone furoate 0.1% is almost same as that of tacrolimus in the treatment of atopic dermatitis.

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