Research Article

A comparative study of topical Mometasone and Tacrolimus ointment in the treatment of atopic dermatitis at Tertiary Care Centre, Telangana

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Abstract

Objective: Atopic dermatitis is a chronic, itchy, inflammatory skin disease. It can significantly impact the quality of life of affected individuals and their families. The aim of this study is to compare and evaluate the efficacy and safety of topical Mometasone Furoate 0.1% ointment versus topical Tacrolimus 0.03% ointment in the treatment of atopic dermatitis. **Material and Methods:** A prospective, open-label, comparative study was conducted at the Osmania General Hospital, Hyderabad, Telangana. Sixty patients clinically diagnosed with atopic dermatitis were simply randomized, of whom Group 1 received topical Mometasone Furoate 0.1% ointment twice daily, and Group 2 received topical Tacrolimus 0.03% ointment twice daily for 12 weeks. The Scoring of Atopic Dermatitis (SCORAD) index was used to assess the severity of the disease. The mean reduction in the SCORAD index was compared with baseline and after 12 weeks. Patients were followed up every month for a period of 3 months. A safety assessment was done according to adverse events reported or noted during the study. **Results:** Out of the 60 patients included in the study, 48.33% were males and 51.66% were females. Before treatment, the respective mean SCORAD was 33.16 ±5.7 & 33.37±5.48 in groups A and B and at the end of treatment it decreased to 15.5 ±3.82 & 14.8 ± 3.40 respectively. There is no statistical significance in the mean SCORAD reduction between the groups [p=0.45]. **Conclusion**: Mometasone Furoate and Tacrolimus are equally effective in the treatment of atopic dermatitis. Serious or new adverse events were not reported.

Keywords: Atopic dermatitis, mometasone furoate, tacrolimus, Telangana

Introduction

Atopic dermatitis (AD) is a chronic inflammatory skin disorder that can impair quality of life, both through its symptoms and through secondary infections. Individuals diagnosed with atopic dermatitis have a profound effect on their quality of life (Hoare et al., 2000). The social stigma of visible skin disease adds to the burden of the disease. It affects up to 2.4% of the world population (Urban et al., 2017). The disease is characterized by acute flare-ups of eczematous pruritic lesions over the dry skin (Nutten, 2015). Atopic dermatitis starts in early childhood, and it is often an indication that the child may develop asthma or allergic rhinitis in the later part of their life. The prevalence of atopic dermatitis has been gradually increasing recently. The pathogenesis of atopic dermatitis is due to an elevated Th2 response reflected by an increased frequency of allergen specific T-cells producing interleukin (IL)-4, 5, and 13 (Kanwar and De, 2011). Atopic Dermatitis can be broadly classified into: The atopic itch, the atopic dry skin, the atopic eczema and the stigmata of Atopic Dermatitis (Thestrup-Pedersen, 2000). The diagnosis is made clinically. A set of diagnostic criteria was developed by Hannifin and Rajka for atopic dermatitis, which encompasses almost all clinical features, and it is found to be more sensitive (De et al., 2006). Various scoring systems are available to determine the severity of atopic dermatitis and one of the best validated systems is the SCORAD INDEX (SCORing Atopic Dermatitis), which is divided into OBJECTIVE and SUBJECTIVE SCORAD (Wolkerstorfer et al., 1999). Objective scoring is based on the assessment of extent and intensity. Extent is scored by using the rule of nine. The intensity is determined by grading each of the 6 items on a scale from 0 to 3 (erythema, oedema/papulation, oozing/crusts, excoriation, lichenication, and dryness-scored on the most representative area). Subjective scoring is done by assessing pruritus and sleep loss on a visual analogue scale (Wolkerstorfer et al., 1999; Kunz et al., 1997).

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The total score is given by the formula: A/5 + 7B/2 + C. A is the extent (0–100), B is the intensity (0–18), and C refers to the subjective symptoms (0–20). The maximum SCORAD score is 103. Objective SCORAD lies between 0 and 83. The severity of atopic dermatitis can be classified into mild (<15), moderate (between 15 and 40) and severe (>40) based on the objective SCORAD. Initial version of the SCORAD index included subjective symptoms also, but the modified version is mainly focused on the objective SCORAD (Kunz et al., 1997)

Topical mometasone furoate 0.1% ointment, a medium potency steroid, has been shown to have a two to fourfold greater anti-inflammatory activity and a longer duration of action (Molin et al., 2013). It has additional antipruritic and vasoconstrictive properties (Molin et al., 2013; Spada et al., 2018). Topical calcineurin inhibitors, that include topical tacrolimus, is an alternative first line therapy used as per treatment guidelines (Cury Martins et al., 2015). and is an alternative to steroids because it suppresses inflammation like that of steroids and is considered equally effective as a medium potency steroid. Also, there is no risk of skin thinning even when it is used for a longer time. The primary objective is to compare the efficacy of topical Mometasone 0.1% and topical Tacrolimus 0.03% based on clinical signs and symptoms in two groups of ATOPIC DERMATITIS patients at baseline and after 12 weeks of treatment using SCORAD INDEX at the Department of Dermatology, Osmania General Hospital, Hyderabad, Telangana.

Materials and methods

This is a prospective, comparative study that was conducted at the Department of Dermatology at Osmania General Hospital, Hyderabad. After obtaining ethics committee approval, 60 patients who were diagnosed with Atopic Dermatitis clinically by dermatologists were enrolled as per eligibility criteria and informed consent was obtained from all participants. The severity of the disease was assessed using the SCORAD index at baseline and after 4 weeks of treatment.

Inclusion and exclusion criteria

Inclusion criteria

- Atopic dermatitis **diagnosed clinically.**
- Age 2-60 years.
- patients of **either gender**
- patient who gave **informed written consent.**
- Patients who can understand and follow dosing and visit schedules.

Exclusion criteria:

- Known case of **hypersensitivity to mometasone or tacrolimus**
- Patients with cardiovascular, renal, and hepatic diseases
- **Immunocompromised** patients
- Patients with co-existing acute infections, uncontrolled hypertension, diabetes mellitus, and neoplastic conditions
- Patients with other skin morbidities that cause an acute onset of skin rash
- Pregnancy
- Lactation

The duration of study was 12 weeks for each group and carried on from August 2021 to January 2022.

The study received ethical approval from Osmania Medical College's Institutional Ethical Committee.

Ethical Approval Number- IEC/OMC/2021 /M. No. (13) Acad-150

Methodology

A detailed history including the present, past, family, and diet, drug history, was taken and a thorough general physical examination and systemic examination were done. Informed consent was obtained from all 60 participants.

Complete history, general physical, and dermatological examinations were done for all enrolled patients. The history of the patients and physical findings were recorded in a structured proforma. Basic investigations were conducted during the first visit.

All the participants were then randomized by simple randomization in a 1:1 ratio into two groups of 30 each:

Group A: topical mometasone furoate 0.1% applied twice daily for a period of 12 weeks. Group B: topical tacrolimus 0.03% applied twice daily for a period of 12 weeks.

Patients were clinically assessed monthly for a period of three months. Each time, the severity of the disease was recorded using the SCORAD index and clinical photographs were taken.

The same dosage of drugs was to be maintained throughout the study, and the patients were advised to apply the drugs at the same time every day as a thin layer over the lesions.

Follow Up: It was done at the end of 4 weeks [first], 8 weeks [second], and 12 weeks [final follow-up].

Evaluation

The severity was assessed using the SCORAD index at pre-treatment baseline (day 0) and then at follow-ups for 12 weeks. The SCORAD index includes the objective symptoms based on the extent and intensity of the disease. The extent was

measured using the rule of nine and the intensity was measured at a representative body area based on 6 clinical signs that included: Erythema, Edema/Population, Oozing/Crusting, Excoriations, Lichenification, and Dryness, which were graded from 0 to 3 (0=absent, 1=mild, 2=moderate, and 3=severe) at a representative body site, per the SCORAD protocol.

The SCORAD index also includes evaluation with subjective symptoms (pruritus **and sleep loss)** with regard to the last 3 days and nights, and these were scored by the patients. Both subjective items grading was done on a 10-cm visual analogue scale.

As per the protocol, the SCORAD index formula is: **A/5 + 7B/2 + C**, where A is extent (0– 100), B is intensity (0–18), and C is subjective symptoms (0–20).

At each visit, the patients were first asked a nonleading question about adverse events and then specifically about

Table 1. Distribution of patients according to Age (n=60)

Age	No. of Patients		Total No. of patients
	Group A	Group B	
10-20	1(3.33%)	1(3.33%)	2(3.33%)
21-30	12(40%)	13(43.33%)	25(41.66%)
31-40	10(33.33%)	11(36.66%)	21(35%)
41-50	4(13.33%)	3(10%)	7(11.66%)
51-60	3(10%)	2(6.66%)	5(8.33%)
Total	30(100%)	30(100%)	60(100%)
Mean ± SD	33.4± 10.48	32.8±9.66	33.1±10.002
p= 0.8185, Insignificant, Student t test			

Table 2. Distribution of patients according to Gender (n=60)

Gender	Group A	Group B	Total
Female	17(56.66%)	14(46.66%)	31(51.66%)
Male	13(43.33%)	16(53.33%)	29(48.33%)
Total	30(100%)	30(100%)	60(100%)
p= 0.4383, Insignificant, Chi-Square test			

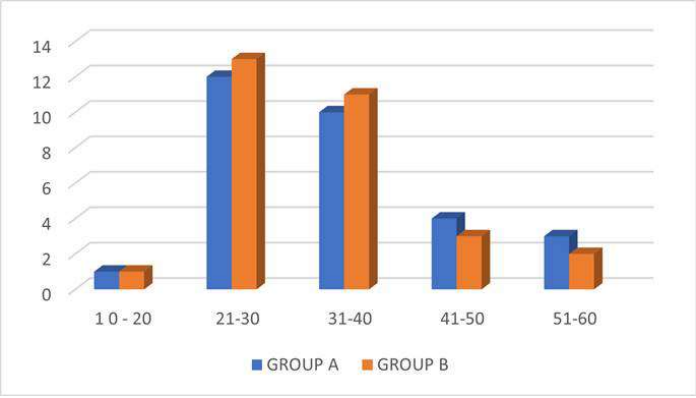

Figure 1. Distribution of patients according to Age (n=60). **Data** shows that out of 60 patients, 2(3.33%) patients were in the age group of 10-20 years, followed by 25 (41.66%) between age 21-30 years, 21 (35%) were between 31-40 years, 7 (11.66%) were between 41-50 years and 5 (8.33%) patients were between 51-60 years. In this study the mean age of subject was 33.1±10.002

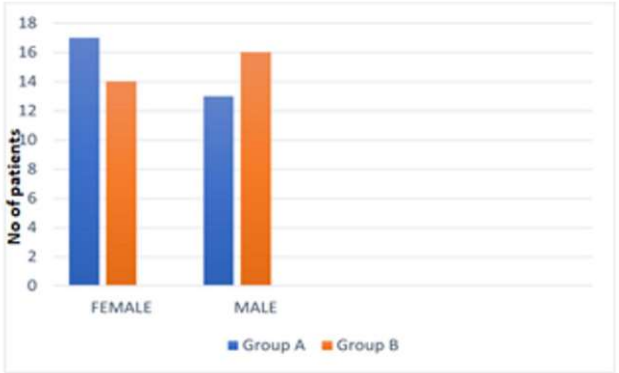

Figure 2. Distribution of patients according to Gender (n=60). **Data** shows out of 60 subjects, females 31(51.66%) outnumbered males 29(48.33%)

Table 3. Distribution of patients according to Duration of Illness (IN YEARS)

Duration of Illness (years)	Group A	Group B	Total
<5	18(60%)	20 (66.66%)	38(63.33%)
5-10	7(23.33%)	5(16.66%)	12 (20%)
11-20	4 (13.33%)	5 (16.66%)	9(15%)
>20	1 (3.33%)	0 (0%)	1 (1.66%)
Total	30(100%)	30(100%)	60(100%)
Mean ± SD	5.73±4.63	5.4±3.73	5.56±4.17
p=0.7622, Insignificant, Student t test			

Table 4. Distribution of patients according to Family history (n=60)

Family History	Group A	Group B	Total
NO	28(93.33%)	29(96.66%)	55(95%)
YES	2(6.66%)	1(3.33%)	3(5%)
Total	30(100%)	30(100%)	60(100%)

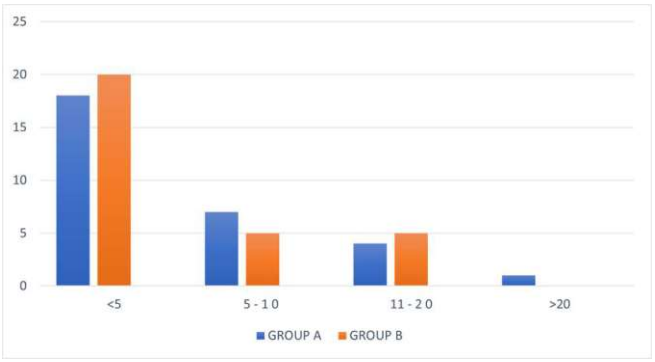

Figure 3. Distribution of patients according to Duration of Illness. **Data** Shows mean duration of disease was 5.56±4.17. Out of 60 patients 38(63.33%) patients had Atopic dermatitis from <5 years, 12 (20%) patients had atopic dermatitis from 5-10years, 9(15%) patients had atopic dermatitis from 11-20 years and 1 (1.66%) patient had atopic dermatitis for more than 20 years

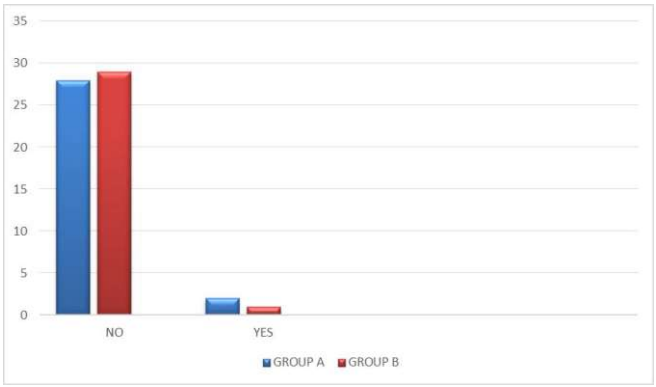

Figure 4. Distribution of patients according to Family history (n=60). Data shows out of 60 patients only 3(5%) patients had positive family history of Atopic Dermatitis

Table 5. SCORAD (Mean of total scoring of Atopic dermatitis) in different follow up

Baseline	Group A	Group B	P-VALUE
	33.16±5.57	**33.37 ± 5.48**	**0.08**
First follow-up (at the end of 4 weeks)	31.2±5.21	30.1±4.39	0.38
Second follow-up (at the end of 8 weeks)	24.4±5.61	23.7±5.77	0.63
Third/Final follow-up (at the end of 12 weeks)	15.5±3.82	14.8±3.40	0.45
p>0.05, Insignificant, Unpaired t test.			

itching or burning sensations in lesional or perilesional skin.

Data entry and Statistical analysis

The data entry was done in MS Excel 2019.Analysis of data was by SPSS Version 23 and Epi info 7.2.0. Microsoft Word and Excel were used to generate graphs, tables, etc. Statistical analysis [descriptive and inferential] was carried out in the study

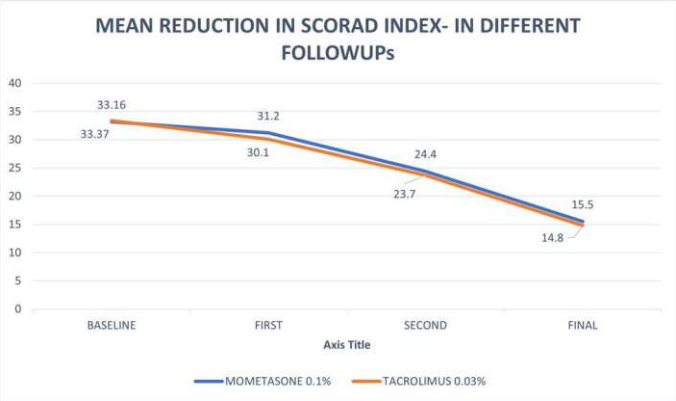

Figure 5. Mean reduction in scorad index. Data shows the mean reduction in the SCORAD index from baseline till the end of 12 weeks. In Group A the SCORAD reduced as follows: 33.16±5.57[baseline], 31.2±5.21[end of 4 weeks], 24.4±5.61[end of 8 weeks],15.5±3.82[end of 12 weeks] and in Group B -the SCORAD reduced as follows: 33.37 ± 5.48 [baseline], 30.1±4.39 [end of 4 weeks], 23.7±5.77 [end of 8 weeks], 14.8±3.40 [end of 12 weeks]. Intra group data comparison shows SCORAD decreased significantly ($p<0.05$) at the end of 4 ,8 and 12 weeks of treatment in comparison with baseline in both groups. Inter group data comparison shows no statistical significance [$p>0.05$].

conducted. Continuous measurements were presented as Mean + SD (Min-Max), and categorical measurements as Number (%).

Student t-test (two-tailed, independent) was used to find the significance of study parameters on a continuous scale between two groups (intergroup analysis) on metric parameters. Student t-test (two-tailed, dependent) was used to find the significance of study parameters on a continuous scale within each group. Significance was assessed at a 5% level of significance.

Discussion

This prospective, open-label, comparative study was undertaken at the Outpatient Dermatology department of Osmania General Hospital to evaluate the efficacy and safety of treatment regimens: topical mometasone furoate 0.1% versus topical tacrolimus 0.03% in patients with Atopic Dermatitis. In the study conducted, the mean age of the subjects was 33.1±10.002 years, and a maximum number of patients was found in the age group of 21-30 years (Table 1 & graph 1). It was observed that females 31 (51.66%) outnumbered males 29 (48.33%) (Table 2 and graph 2). The mean duration of disease in the patients was 5.73±4.63 and 5.4±3.73 in group A and group B, respectively, and almost 38 (63.33%) patients had Atopic dermatitis from <5 years only (Table 3 & graph 3). Out of 60 patients, only 3 (5%) had a positive family history of atopic dermatitis (Table 4 & graph 4).

At baseline mean of total score of atopic dermatitis was 33.16±5.57 and 33.37±5.48 in group A and B, at 1st follow up it was 31.2±5.21 and 30.1±4.39, respectively in group A and B, at 2nd follow up it was 24.4±5.61and 23.7±5.77 and at final follow up it was 15.5±3.82 and 14.8±3.40 respectively in group A and B ($p>0.05$). Intragroup data comparison showed that SCORAD scoring decreased significantly at the end of 4 weeks, 8 weeks, and 12 weeks of treatment in comparison with baseline in both groups (Table 5 & graph 5).

In our study, both treatments showed a significant improvement in mean SCORAD index ($p<0.05$). Gradman and Wolthers, (2008) 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 (Schnopp et al., 2002). in a vehicle-controlled trial in Atopic Dermatitis showed that mometasone furoate 0.1% ointment was significantly better than vehicle ($p<0.01$).

The demographic results in this comparative study show no significant difference, reflecting the homogeneity of study patients in both groups. A comparison of the two groups concerning clinical efficacy was made based on the findings made with the SCORAD index. The efficacy of the drugs was assessed clinically and revealed improvement symptomatically within the groups at the end of the treatment. Reported adverse effects were mild and expected, lasted only for a few days, and did not require intervention. Serious or new adverse events were not reported.

Conclusion

Atopic dermatitis (AD) is a chronic skin condition that is characterized by patches of dry, inflamed, and itchy skin. The causative factor for AD is due to the overproduction of cells in the immune system that promote inflammation. Topical corticosteroids are considered the first line treatment in the treatment of atopic dermatitis. Mometasone furoate 0.1, a medium potency steroid, is indicated for the relief of the inflammatory and pruritic manifestations of atopic dermatitis. Topical calcineurin inhibitors like Tacrolimus is used as an alternate to steroid as it suppresses inflammation in a similar way to steroids. Also, it does not cause skin thinning or other steroid related side effects.

In the study conducted, mometasone furoate and tacrolimus were found to be individually effective in the treatment of atopic dermatitis. No statistical difference was noted between the two groups. Hence, we conclude that the efficacy of mometasone furoate 0.1% and tacrolimus 0.03% ointment is almost the same in the treatment of atopic dermatitis.

Limitations of the study

It is an open-label, prospective study, hence results cannot be

generalized. The sample size and duration of the study are also small. Further studies are required to consider points such as a change in the study population, seasonal variation, sample size, and duration of the study. Also, randomized control trials with larger sample sizes and time periods will provide a better outcome and prove the efficacy of one drug over another.

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All the authors have made significant contributions to the writing, editing, reviewing, and submitting of the manuscript.

Conflict of Interest-**None declared**

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