



Effect of topical tacrolimus ointment on scorad index in pediatric atopic dermatitis.

Shazia Bano¹, M. Saleh Khaskhili², Munazzah Meraj³, Moti Ram Bhatia⁴, Rao Irfan⁵

1. FCPS (Dermatology)
Assistant Professor
PUMHS Nawab Shah.
2. Professor
PUMHS Nawab Shah.
3. Ph.D Biochemistry
Associate Professor
PUMHS Nawab Shah.
4. Assistant Professor
PUMHS Nawab Shah.
5. Ph.D (Pharmaceutical Sciences)
Associate Professor
PUMHS Nawab Shah.

Correspondence Address:
Dr. Munazzah Meraj
PUMHS Nawab Shah.
munazzahmeraj@yahoo.com

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ABSTRACT... Objectives: To determine topical tacrolimus ointment's efficacy in atopic dermatitis. **Study Design:** Descriptive case series study. **Setting:** Outpatient Department of Dermatology, Liaquat University of Medical and Health Sciences (LUMHS), Civil Hospital, Hyderabad. **Period:** 12 October 2017 to 12 April 2018. **Material & Methods:** Consisted of 106 patients. Detailed History was taken from patients and systemic review was also done to assessed any co-morbidity. Data was analyzed through SPSS version 23.0. **Results:** In this study 71 (66.98%) patients were men and 35 (33.01%) were female; with male to female ratio 2:1. The mean age was 6.1+1.8 years. Clinical signs of patients were erythema 88(83.01%), edema 76(71.69%), Oozing/ crusting 45(42.45%), excoriation 59(55.66%) and lichenification 64(60.37%). Before treatment start the SCORAD index (SCORAD I) mean was 61.8 ± 11.12 (range 7–103): moderate cases were observed in 87(82.07%) patients (SCORAD I 30 – 49) and 19(17.92%) patients had severe AD (SCORAD I ≥50). After treatment, the SCORAD index mean was 35.8 ± 13.15 (range 7–103): 57(53.77%) patients had SCORAD index values ≤30; moderate cases (SCORAD I 30-49) were observed in 42(39.62%) patients and 7(6.60%) patients had severe AD (SCORAD I >50). In 57(53.77%) cases topical tacrolimus ointment (0.1%) showed positive efficacy in atopic dermatitis, while in 49(46.22%) cases observed negative. **Conclusion:** The application of topical tacrolimus ointment (0.1%) is effective in the treatment of atopic dermatitis in children.

Key words: Atopic Dermatitis, Excoriation, Erythema, Topical, Tacrolimus SCORAD.

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INTRODUCTION

Atopic Dermatitis also known as Atopic Eczema; is an itchy, chronic or chronically relapsing inflammatory skin condition.¹ The management of atopic dermatitis comprises of use of bathing oils, emollients and corticosteroids. Sometimes oral sedating antihistamines and antibiotic may be added.² Two topical immunomodulators, pimecrolimus cream and tacrolimus ointment (0.03% & 0.1%) for atopic dermatitis (AD), have been proved to be effective and free of side effects those associated topical corticosteroids.³ Several studies have been done in this context with promising results.^{4,5,6}

In a study after 3-week application of topical tacrolimus in patients of atopic eczema, the outcome variables like erythema, edema/ papulation, oozing/crusting & excoriation in

the case & control groups were 66.7% vs 6.7%, (p<0.001), 40% vs 3.3%(p<0.001), 65.5% vs 17.7% (p<0.001) and 41.1% vs 7.3% (p<0.005), respectively.⁷ The improvements in pruritus, body surface area involved and SCORAD in the cases and controls were 53% vs 18.8% (p<0.001), 49.9% vs 4.7% (p<0.001) and 50.2% vs 15% (p<0.001), respectively.

It was revealed that tacrolimus and pimecrolimus both drugs were significantly more effective than a vehicle.^{8,9} The rationale of proposed study is that various studies confirm efficacy of topical tacrolimus in atopic dermatitis. All studies are from temperate countries i.e Australia, Germany, Hungry & Japan. We are geographically located in tropical belt, also there are racial differences in skin type. Based on previous studies no study has yet been done with topical tacrolimus in

atopic dermatitis in Pakistan. Therefore, this study was conducted to improve our national database so that it can be confidently prescribed in our population and adverse effects of steroids can be minimized as well.

So, this study was planned to determine the topical tacrolimus ointment's (0.1%) efficacy in atopic dermatitis in children.

MATERIAL & METHODS

One hundred six patients were included in this descriptive case series study which was carried out in outpatient Department of Dermatology, LUMHS, Civil Hospital, Hyderabad, from 12 October 2017 to 12 April 2018. Clinical examination and detailed history of all concern patients were recorded. Systemic review was done for any co-morbidity. Patients will be advised to apply topical tacrolimus ointment (0.1%) to their child twice daily for a period of three weeks. A fingertip unit were explained to parents in order to apply accurate quantity of ointment. Parents were advised to have their follow up weekly for two weeks and then for final outcome at the end of third week. Patients were examined clinically and if SCORAD is less than 30, efficacy were labeled as positive.^{7,10} This information was recorded both before and after treatment for each patient. In order to avoid observer bias, SCORAD index were be assessed by medical officers both before and after treatment. All patients diagnosed on the basis of Hannifin and Rajka's diagnostic criteria for with moderate to severe disease¹¹, both gender and age 1 to 10 years were included in this study. Exclusion criteria included children below one year and above ten years, known allergic to tacrolimus, acute or chronic liver disease, subjects unwilling to participate in the study. Patients currently being treated with systemic and/or topical steroids. Results presented in graphs and tables. Data was analyzed through SPSS software version 23.0 (SPSS Inc., Chicago, IL, USA).

RESULTS

In this study, one hundred six patients were included, 71 (66.98%) patients were male and 35 (33.01%) were female; with male to female

ratio 2.02:1. It was observed that there were age ranging from 1 year to 10 years with mean age 6.1+1.8 years (Table-I).

Clinical signs of patients were erythema 88(83.01%), edema 76(71.69%), Oozing/crusting 45(42.45%), excoriation 59(55.66%), lichenification 64(60.37%) and dryness 91(85.84%) (Table-II).

Age of Patients (Years)	No. of patients (n=106)	Percentage (%)
1-5 years	68	64.15
6-10 years	38	35.84

**Table-I. Age distribution.
Means Age 6.1 + 1.8 years**

Clinical signs	Patients (n=106)	Percentage (%)
Erythema	88	83.01
Edema/papule	76	71.69
Oozing/ crusting	45	42.45
Excoriation	59	55.66
Lichenification	64	60.37
Dryness	91	85.84

Table-II. Clinical Signs.

Before the start of treatment, the SCORAD index mean (SCORAD I.m) (\pm SD) was 61.8 \pm 11.12 (range 7–103): moderate cases (SCORAD I 30 – 49) were observed in 87(82.07%) patients and severe AD (SCORAD I >50) in 19(17.92%) patients. After treatment the SCORAD I.m (\pm SD) was 35.8 \pm 13.15 (range 7–103): 57(53.77%) patients had SCORAD index values below 30; moderate cases (SCORAD I 30-49) were observed in 42(39.62%) patients and 7(6.60%) patients with severe AE (SCORAD I >50) (Table-IV).

After statistical investigation (mild AE: 1st quintile the study group; severe AE: 5th quintile of the study group), SCORAD index cut-off points obtained that were simulating by clinical criteria. Each of the three main component of the SCORAD index (intensity, BSA, and subjective symptoms) were in 57(53.77%) cases showed positive efficacy of topical tacrolimus ointment (0.1%) in atopic eczema, while in 49(46.22%) cases observed negative. A positive correlation

was observed between the results of SCORAD Index and its component i.e BSA, intensity and

subjective symptoms (Figure-1).

		SCORAD	BSA	Intensity	Symptoms
SCORAD	Pearson Correlation	1	.941**	.690**	-.075
	Sig. (2-tailed)		.000	.001	.754
	N	20	20	20	20
BSA	Pearson Correlation	.941**	1	.659**	-.119
	Sig. (2-tailed)	.000		.002	.619
	N	20	20	20	20
Intensity	Pearson Correlation	.690**	.659**	1	.044
	Sig. (2-tailed)	.001	.002		.852
	N	20	20	20	20
Symptoms	Pearson Correlation	.875**	-.119	.044	1
	Sig. (2-tailed)	.000	.619	.852	
	N	20	20	20	20

** . Correlation is significant at the 0.01 level (2-tailed).

Table-III. Pearson correlation show r value***

Severity of Atopic Dermatitis	Before treatment SCORAD index		After treatment SCORAD index	
	No: of Patients	% Age	No: of Patients	% Age
SCORAD index < 30	0	0	57	53.77
Moderate	87	82.07	42	39.62
Severe	19	17.92	7	6.60
Total	106	100	106	100
p Value	<0.001			

Table-IV. Severity of atopic dermatitis according to SCORAD index.

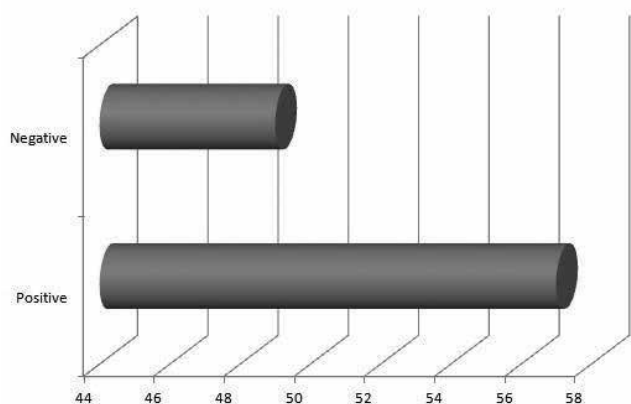


Figure-1. Efficacy of topical tacrolimus ointment (0.1%) in atopic dermatitis.

DISCUSSION

Atopic eczema is an itchy chronic inflammatory condition that start in early childhood. Around 50% of those effected, develop this illness within the 1st year of life, while 30% have it by the age of

1-5 years. Development of AE within four months of age is a risk for airborne allergens sensitization, and so asthma as well.^{12,13,14} Topically applied tacrolimus penetrate the skin sufficiently to have local immunosuppression effects. Topical tacrolimus found to inhibits experimentally induced allergic contact dermatitis and many studies demonstrated its efficacy and absence of cutaneous side effect of skin atrophy, strict telangiectasia and bruising seen with prolong use off corticosteroids.^{7,15}

In our study male is dominant so out of 106 patients, 71 were men (66.98%) and 35 patients were female (33.01%); M:F of 2.02:1, However study of N. Pucci¹⁶ reported that 63 children evaluated in which 37(58.73%) were males and 26(41.26%) females. In our study age varied ranging from a of 1 year to 10 year. While in study of Rahman MF⁷ reported all the age categories were

almost alike between the groups. The median ages of the case and control were 7.0 ± 1.83 and 8.5 ± 1.44 years, respectively. There are many studies having different methods for scoring AD severity.¹⁵⁻¹⁸ It was found that the SCORAD index is one of the most evaluated one for AE. Our results are coincident with the results of other researchers.^{7,19} In our study, 57(53.77%) cases positive efficacy of topical tacrolimus ointment (0.1%) in atopic dermatitis, while in 49(46.22%) cases observed negative. This consistency prove it, as a reliable criterion for AE scoring,²⁰ it has also been referred to in AD patients not selected for age.²¹ Therefore, this single parameter was used to grade the severity of AD, as it seems to be a crude method, even if applied to single cases in clinical practice.

CONCLUSIONS

Atopic dermatitis is most frequent chronic inflammatory skin disorder which has a high impact on the quality of life of patients. Topical tacrolimus ointment is more effective therapy in atopic dermatitis. In our study we observed the efficacy of 57(53.77%) cases positive.





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AUTHORSHIP AND CONTRIBUTION DECLARATION

Sr. #	Author(s) Full Name	Contribution to the paper	Author(s) Signature
1	Shazia Bano	Conduction of study.	
2	M. Saleh Khaskhili	Manuscript editing.	
3	Munazzah Meraj	Manuscript writing.	
4	Moti Ram Bhatia	Statistical analysis.	
5	Rao Irfan	Manuscript editing.	