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Comparison of the Efficacy of Topical Clobetasol Propionate 0.05% and Emolient versus Topical Clobetasol Propionate 0.05%, Emolient and Oral Vitamin D Supplement in the Treatment of Atopic Dermatitis

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ABSTRACT

Objectives: Atopic dermatitis (AD) is a skin disorder affecting all age groups, but more common in toddlers and older children. This study aims to compare efficacy of topical treatment with oral vit D3 supplements plus standard topical treatment. **Methods:** An open-label comparative study was conducted at dermatology outpatient department of Pak Emirates Military Hospital, Rawalpindi from July 2024 till Dec 2024. Group A Received Topical Clobetasol Propionate 0.05% and Emolient while Group B received Topical Clobetasol Propionate 0.05%, Emolient and Vitamin D3 Supplement 800IU in form of oral drops. Mean SCORAD score before start of treatment and at the end of treatment was compared to measure efficacy of these treatment regimens. Percent decrease in mean score was calculated. **Results:** Vitamin D3 supplemetation yielded significant improvement in symptoms and severity of AD. Group A who received topical treatment only showed 60.2% reduction in mean SCORAD after 8 weeks of treatment while in Group B who received oral Vit D3 along with topical treatment, mean SCORAD was reduced by 72.2%. Difference in efficacy of these two treatment groups came out to be statistically significant. (p-value 0.037) **Conclusion:** Our study suggests that daily dose of oral vitamin D3 supplements might provide clinical improvement in children with AD. It should be considered as a relative adjuvant to the standard regimen of AD along with other oral and topical treatments.

INTRODUCTION

Atopic dermatitis (AD)- also known as eczema is a group of skin disorders characterized by dry and inflammed skin, red and itchy rashes all over the body. It is a chronic relapsing and remitting inflammatory skin disease affecting 1 in 10 people in their lifetime. It can affect all age groups but mostly occurs in young age. Incidence of atopic dermatitis in young children is 10-20%.[1]

Both genetic and environmental factors play a role in development of atopic dermatitis. Common triggers are stress, allergens and family history of the disease. All the environmental factors contribute in severity, intensity and frequency of atopic dermatiis flare ups if the person is genetically predisposed to the skin diseases.[2]

Clinical presentation and distribution of AD depends on patient's age. It presents with erythmatous plaques and patches on face, scalp, trunk and extremeties during first year of life. Older children usually present with papules, plaques and patches on flexural surfaces. Later stages of disease may present as thick and cracked skin, oozing and crusting, scratch marks and superadded infections. Due to the chronicity and severe pruritus, lesions often undergo secondary changes like lichenification.[3]

Atopic dermatitis is a part of atopic triad (atopic dermatitis, allergic rhinoconjunctivitis and asthma) which can occur at the same time or in succession. Patients with atopic triad have a super sensitive immune system flaring up at even minor exposure to the allergens and environmental irritants, and a defective barrier of skin, upper and lower respiratory tract. Children with AD are prone to develop asthma and allergic rhinitis at later stages of life, if not simultaneously.[4]

Diagnosis is made on the basis of specific criteria that

includes personal and family history, and clinical presentation. Therapeutic goal requires multistep approach focusing on trigger avoidance, daily skin care, anti-inflammatory therapy and other complementary approches.[5]

Moisturizers are the cornerstone of all AD treatment regimens. Keeping skin hydration by using moisturizers also helps in prevention of flare ups. First line treatment of acute flares is also use of emolients/moisturizers and topical anti-inflammatory agents (Corticosteroids, Calcineurin inhibitors, PDE4 inhibitors). When atopic dermatitis is not controlled with topical agents, oral therapy with corticosteroids and non selective immunosuppressants like methotrexate, cyclosporine, and azthioprine is started. Phototherapy is also recommended in the treatment of refractory AD, either as monotherapy or in combination.[6]

The role of oral vitamin D3 supplements in emoliaring the effects of AD have been studied over past few years. Systemic reviews and meta analysis suggest a therapeutic role in patients of AD.[7] However no study was found to be conducted in Pakistan where the efficacy of oral vit D was compared with another group receiving topical treatment only. This study aims to compare a group receiving only topical treatment with a group receiving oral vit D3 supplements in addition to the standard topical treatment.

METHODOLOGY

An open-label comparative study was conducted at dermatology outpatient department of Pak Emirates Military Hospital, Rawalpindi. The study was carried out after getting approval by ethical committee of the hospital with ref# A/28/ERC/108/24. The data was collected in the dermatology OPD by the researcher from July 2024 till Dec 2024. Patients fulfilling the inclusion criteria were recruited from the OPD for the study. Male and female children aged between 2-12 years newly diagnosed with atopic dermatitis were included. Patients already taking any topical or oral treatment for atopic dermatitis and patients suffering from any other skin disease or systemic inflammatory illness were excluded from the study.

Sample size was calculated using cochran's formula with population proportion of 10%, 95% confidence interval and 5% margin of error. Written informed consent was taken from parents/ guardians after fully explaining about the disease and drugs being used in study. A total of 140 patients were included initially but 18 were excluded due to loss of follow up. Participants were randomly assigned into two groups.

Group A received Topical Clobetasol Propionate 0.05% and Emolient while Group B received Topical Clobetasol Propionate 0.05%, Emolient and Vitamin D3 Supplement 800IU in form of oral drops (2 drops per day). Daily recommended intake of vit D3 is 600 IU per day for toddlers, older children and adolescents. As our study population also comprised of these age groups, we gave them 800IU per day (2 drops per day of D-max oral drops). Additional intake of 200IU of vitamin D3 was meant to strengthen the damaged skin barrier in the AD patients.[8]

Socio-demographic information and relevant medical history was recorded for each subject. Assessment of efficacy was done before start of treatment and every 2 weeks till 2 months via SCORAD system.[9]

SCORAD is a clinical tool to assess the extent and severity of atopic dermatitis. The tool assesses the area, intensity and subjective symptoms of atopic dermatitis, and a cumulative score is calculated. To determine extent, the sites affected by eczema are shaded on a drawing of a body. The rule of 9 is used to calculate the affected area (A) as a percentage of the whole body. Head and neck 9%, Upper limbs 9% each, Lower limbs 18% each, Anterior trunk 18%, Back 18%, Genitals 1%. The score for each area is added up. The total area is 'A', which has a possible maximum of 100%.

To measure severity, a representative area of eczema is selected. In this area, the intensity of each of the signs (Redness, Swelling, Oozing/crusting, Scratch marks, Skin thickening, Dryness) is assessed as none (0), mild (1), moderate (2) or severe (3). The intensity scores are added together to give 'B' (maximum 18). Subjective symptoms (itch and sleeplessness), are each scored by the patient or relative using a visual analogue scale where 0 is no itch (or no sleeplessness) and 10 is the worst imaginable itch (or sleeplessness). These scores are added to give 'C' (maximum 20).

The total SCORAD is calculated using formula A/5 + 7B/2 + C. The total score range is between 0 to 103. Severity of AD is determined through the total SCORAD score, and classified as mild if score is <25, moderate if 25-50, and severe if >50.[10]

Outcome was determined by reduction in these scores at each follow up in comparison with previous one. Cumulative score before start of treatment and at the end of treatment was compared to measure efficacy of these treatment regimens. The data of 122 patients, who completed the study, was entered and analyzed using SPSS.25 (Statistical Package for Social Sciences). All data is shown as mean ± SD. Relevant statistical tests were applied. A p-value of $\leq$ 0.05 was considered as statistically significant.

RESULTS

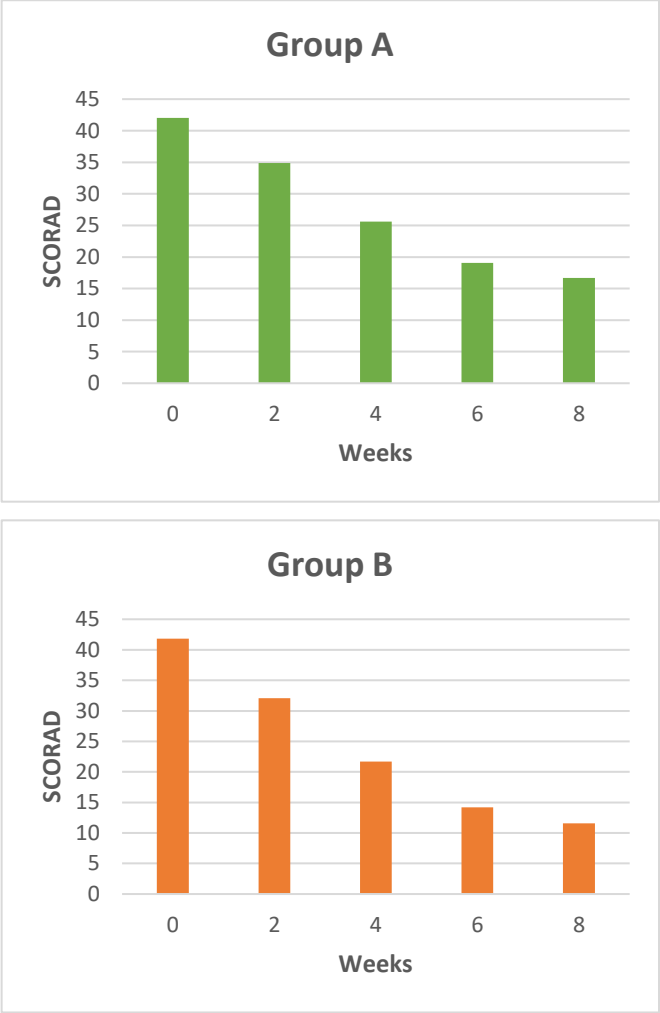
A total of 140 patients were included in the study, 18 were excluded because of loss of follow up. Data of 122 patients was statistically analyzed. Mean age of the patients was 7.5 $\pm$ 3.1. Out of total patients 57% were male and 43% were female.

Mild AD was diagnosed in 57 (46.7%) children, moderate in 42 (34.4%), and severe in 23 (18.8%). Mean

of cumulative score of scorad for both groups was calculated using SCORAD calculator before starting the treatment and it was 42.04 ± 12.05 for group A consisting of 59 patients, and 41.8 ± 9.06 for group B consisting of 63 patients. The score was calculated at every follow up after 2 weeks. The mean score at each visit is shown in the figure 1.

Figure 1

Mean SCORAD of Both Group A & B at Each Follow Up Visit



In group A mean SCORAD reduced from 42.04 ± 12.05 to 16.7 ± 4.02 after the topical treatment. In group B mean SCORAD reduced from 41.8 ± 9.06 to 11.6 ± 3.8 after the topical treatment plus vitamin D3 supplement. To determine the efficacy of each treatment group, paired t-test was applied between the initial and final SCORAD within both groups as shown in table 1.

Table 1

Paired t-test to Compare Mean Values Before and After Treatment in Each Group

	Baseline SCORAD	Final SCORAD	Mean difference	P-value
Group A	42.04 ± 12.05	16.7 ± 4.02	25.34 ± 8.03	<0.001*
Group B	41.8 ± 9.06	11.6 ± 3.8	30.2 ± 5.2	<0.001*

*P-value <0.05 is considered significant

To compare efficacy between both groups, independent sample t-test was applied between the mean final SCORAD values of both groups as shown in table 2.

Table 2

T-test to Compare Mean SCORAD after Treatment between Two Groups

Groups	Mean SCORAD After 8 Weeks of Treatment (Mean ± SD)	% Decrease in Mean SCORAD Score	P-Value
Group A	16.7 ± 4.02	60.2%	0.037*
Group B	11.6 ± 3.8	72.2%	

*P-value <0.05 is considered significant

DISCUSSION

Our study included patients of mild, moderate and severe AD patients. Group of patients receiving topical treatment only showed mean difference of 25.34 ± 8.03 in baseline and final SCORAD. Other group receiving oral vit D along with topical treatment showed mean difference of 30.2 ± 5.2. Percent(%) decrease in SCORAD was 60.2% for group A, and 72.2% for group B. Both groups showed significant improvement after the treatment. However, comparison of the final mean score of both groups showed significant difference when statistically analyzed. Group of patients receiving vitamin D3 showed significant improvement in symptoms and marked reduction in AD severity.

The results of this study showed considerable improvement in AD patients taking vitamin D3 supplements in addition to topical treatment, which is consistent with some previous researches. A study conducted in Iran proved that SCORAD was reduced after treatment of 60 days in patients taking vitamin D3 supplements.[11] Another study showed similar results where the condition of AD patients particularly with moderate to severe disease was improved significantly after taking vitamin D3 supplements.[12] Similarly oral vitamin D3 has been proved to improve symptoms in winter-related AD.[13]

Recent literature suggests the role of vitamin D3 in treatment of AD. However, the exact mechanism of action is uncertain, but UV light has been used in controlled settings as recognized treatment of AD since many years. A study conducted in Norway also shed some light on role of sunlight exposure in improving AD among Norwegian children.[14] In addition, Vitamin D3 is associated well with synthesis of proteins that are necessary to maintain skin barrier function, this mechanism also suggests a role of vitamin D3 in modulating AD severity and symptoms.[15]

One limitation of this study is that the serum vitamin D3 levels should have been measured before and after the treatment to get more comprehensive results. Further studies with multi-center approach and involving laboratory investigations should be done. Another limitation, lack of data for other important domains like

patient reported outcomes and record of any side effects experienced by patients. Moreover, future trials are needed to study role of Vit D3 in other types of AD, considering the possible seasonal fluctuations.

CONCLUSION

Our study suggests that daily dose of oral vitamin D3 supplements provides significant clinical improvement in children with AD. It should be considered as an effective adjuvant to the standard regimen of AD along with other oral and topical treatments.

*Authors' Contribution

Noor ul Wara: Conceived, designed and did statistical analysis & editing of manuscript, is responsible for integrity of research.
Muhammad Waseem Shahid, Mushayada Irshad: Data collection and manuscript writing.
Kaneez Fatima: Review and final approval of manuscript.
Umar Abdul Ali, Iqra Ghaus: Proof Read and Editing

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