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Evaluation of the efficacy and safety of topical corticosteroids in the treatment of atopic dermatitis

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Abstract
Background and Objectives: Topical corticosteroids (TCS) continue to be a cornerstone in the treatment of atopic dermatitis (AD), although apprehensions regarding their optimal potency, effectiveness, and localized adverse effects endure. This study assessed the clinical efficacy and safety of two frequently utilized topical corticosteroid regimens in adult and adolescent patients with mild atopic dermatitis.
Materials and Methods: A prospective, randomized, double-blind, parallel-group trial was conducted with 70 individuals with mild atopic dermatitis (age ≥12 years). Patients were randomized 1:1 to receive either a low-potency TCS (hydrocortisone 1% cream; Group A, n=35) or a medium-potency TCS (betamethasone valerate 0.1% cream; Group B, n=35) applied twice daily to affected areas for 4 weeks, followed by an 8-week follow-up during which tapering/maintenance was per protocol. The primary outcome was the change in the Eczema Area and Severity Index (EASI) score from baseline to Week 4.
Results: All 70 patients who were randomly chosen finished the 4-week therapy phase. The groups had similar baseline demographics and illness severity (mean age 29.4±11.2 years; mean baseline EASI 12.8±4.1). At Week 4, the mean EASI fell significantly in both groups: Group A (low-potency) from 12.6±4.0 to 6.0±3.1 (mean change −6.6±3.2), and Group B (medium-potency) from 13.0±4.2 to 4.0±2.9 (mean change −9.0±3.5). DLQI scores improved significantly in both groups, with a more pronounced mean improvement in Group B ($p = 0.04$). The median time to a clinically significant response (≥50% EASI decrease) was 3 weeks for Group B and 4 weeks for Group A ($p = 0.02$). Local adverse effects were mostly modest and included temporary burning or irritation (Group A: 4/35, 11.4%; Group B: 7/35, 20.0%) and telangiectasia or skin thinning (0/35 in Group A vs. 2/35, 5.7% in Group B).
Conclusion: Topical corticosteroids led to significant clinical enhancement in mild atopic dermatitis. Medium-potency TCS resulted in a more significant and rapid alleviation of illness severity and symptoms in comparison to low-potency TCS, but with a minor elevation in local cutaneous side effects. These results support using the lowest effective potency for the shortest amount of time that is appropriate for the severity of the disease, with strict monitoring for any adverse effects that may occur.

Keywords: Atopic dermatitis, topical corticosteroids, efficacy, safety, EASI, pruritus, randomized trial

Introduction
Intense pruritus, redness, lichenification, and xerosis are symptoms of atopic dermatitis (AD), which is a chronic, recurrent inflammatory skin condition. The condition impacts individuals of all ages and is linked to intense bodily pain, emotional anguish, and a decline in overall well-being. Because of environmental, immunological, and genetic factors, the prevalence of Alzheimer's disease (AD) has been rising worldwide in recent decades, especially in metropolitan populations [1-3].
An excessive Th2 immune response and increased vulnerability to irritants, allergens, and microbial colonization are the pathophysiologic outcomes of atopic dermatitis, which is caused by a complex interaction between skin barrier dysfunction, immunological dysregulation, and genetic predisposition. The main goal of treatment is to reduce inflammation and repair the skin's protective barrier using emollients, topical corticosteroids (TCS), and topical calcineurin inhibitors. Patients should also be educated on how to properly care for their skin and avoid certain triggers [4-6].
The anti-inflammatory treatment for Alzheimer's disease has primarily relied on topical

corticosteroids for over 50 years. By lowering cytokine-mediated inflammation, they alleviate itching, redness, and swelling. To balance efficacy against the possibility of side effects, such as skin atrophy, telangiectasia, striae, and hypothalamic-pituitary-adrenal (HPA) axis suppression with extended or inappropriate administration, it is crucial to choose the proper corticosteroid potency, vehicle, and treatment duration. Poor adherence and unsatisfactory disease control are common outcomes of steroid treatment because patients continue to worry about steroid phobia and incorrect administration [7-9].

Topical corticosteroids have been shown to be effective in treating atopic dermatitis in a number of studies; however, there is a lack of evidence comparing the safety profiles and potencies of these medications in actual clinical settings. In order to facilitate reasonable prescribing and patient counseling, it is vital to determine the best potency that delivers maximal therapeutic benefit with minimal side effects [10-12].

Because of this, we set out to see how well and safely mild atopic dermatitis patients responded to topical corticosteroids of varying potencies. In addition to determining the frequency and kind of systemic or local side effects linked with their usage, the study sought to evaluate the improvement in disease severity, symptom alleviation, and quality of life.

Material and Methods

This was a prospective, randomized, double-blind, comparative clinical trial undertaken in the Department of Dermatology at a tertiary care teaching hospital over a period of 12 months. A total of 70 individuals aged 12 years and older, clinically diagnosed with moderate atopic dermatitis based on the Hanifin and Rajka criteria, were recruited and randomly allocated into two therapy groups, each including 35 patients. This study was conducted at department of Dermatology, I Care Institute of Medical Sciences and Research, Banbishnupur, Haldia, West Bengal, from May 2018 to April 2019. The study sought to assess the efficacy and safety of low- and medium-potency topical corticosteroids in individuals with mild atopic dermatitis.

Inclusion Criteria

- Patients aged 12 years and above of either sex.
- Clinically diagnosed cases of moderate atopic dermatitis.
- Willingness to comply with study protocol and provide written informed consent.

Exclusion Criteria

- Patients with severe or generalized atopic dermatitis
- Use of topical corticosteroids or immunomodulators within the past 2 weeks.
- Presence of secondary bacterial, viral, or fungal skin infection.
- Known hypersensitivity or allergy to corticosteroids.
- Pregnant or lactating women.
- Patients with systemic diseases such as diabetes mellitus, liver, or renal disorders.
- Patients unwilling or unable to complete the follow-up period.

Safety Assessment

Local side effects including burning, redness, irritation, telangiectasia, striae, and hypopigmentation were recorded at each visit. Comprehensive blood counts, liver and kidney function tests, and fasting blood glucose levels were among the usual laboratory investigations used to evaluate systemic safety both at baseline and 4 weeks later.

Randomization and Blinding

A computer-generated randomization schedule was used to assign patients to one of the two groups. Nobody knew which patients were getting which treatments because the researcher and patients were both blinded. For the purpose of blinding, we utilized identical tubes that were coded.

Statistical Analysis

We used SPSS version 20.0 to examine the data. Mean ± standard deviation (SD) was used to express continuous variables, and Student's t-test was employed for comparison. The Chi-square test or Fisher's exact test was used to compare the categorical variables. A statistically significant result was defined as a p-value less than 0.05.

Results

In the study, 70 patients with moderate atopic dermatitis participated and finished it; 35 patients were assigned to the hydrocortisone (1% group) and betamethasone valerate (0.1%) therapy groups. There was a considerable improvement in clinical outcomes for both groups, although those in Group B who received medium-potency corticosteroids had even more improvement.

Table 1: Baseline Demographic and Clinical Characteristics of Study Participants

Parameter	Group A (Hydrocortisone 1%) (n=35)	Group B (Betamethasone valerate 0.1%) (n=35)	p-value
Mean Age (years)	29.1±10.8	29.8±11.6	0.81
Male: Female ratio	20: 15	18: 17	0.62
Mean duration of disease (years)	4.8±2.5	5.0±2.1	0.74
Mean baseline EASI score	12.6±4.0	13.0±4.2	0.68
Mean baseline DLQI score	12.4±3.2	12.8±3.5	0.72

Both research groups' baseline characteristics are shown in Table 1. The results showed that the groups were comparable and that the randomization process was successful in terms of age, gender distribution, disease duration, and baseline EASI and DLQI scores.

Table 2: Changes in Eczema Area and Severity Index (EASI) Scores

Assessment Time	Group A (Mean ± SD)	Group B (Mean ± SD)	p-value
Baseline	12.6±4.0	13.0±4.2	0.68
Week 2	8.5±3.4	6.3±3.0	0.01
Week 4	6.0±3.1	4.0±2.9	0.001
% Reduction from baseline	52.4%	69.2%	—

Table 2 shows that following therapy, both groups' EASI ratings decreased significantly. The better clinical efficacy of the medium-potency corticosteroid was demonstrated by the faster and more significant improvement in Group B (69.2% reduction compared to 52.4% in Group A, $p<0.05$).

Table 3: Investigator's Global Assessment (IGA) and Pruritus (VAS) Scores

Parameter	Group A (Mean ± SD / %)	Group B (Mean ± SD / %)	p-value
IGA Success (clear/almost clear) at Week 4	18 (51.4%)	26 (74.3%)	0.03
Mean Pruritus VAS (Baseline)	4.1±1.2	4.0±1.3	0.82
Mean Pruritus VAS (Week 4)	1.8±0.9	1.2±0.8	0.02
Mean Improvement in VAS	2.3±0.7	2.8±0.6	0.04

According to Table 3, there was a notable improvement in pruritus and overall clinical presentation in both groups. Patients in Group B were more likely to have "clear" or "almost clear" skin after using IGA ($p=0.03$). A medium-potency corticosteroid produced a more pronounced improvement in mean pruritus scores.

Table 4: Change in Dermatology Life Quality Index (DLQI) Scores

Time Point	Group A (Mean±SD)	Group B (Mean±SD)	p-value
Baseline	12.4±3.2	12.8±3.5	0.72
Week 4	6.2±2.8	4.4±2.5	0.04*
Mean Change	−6.2±2.4	−8.4±2.9	0.03*

There was a considerable improvement in both groups' DLQI levels after treatment, suggesting a higher quality of life overall. On the other hand, Group B showed a more significant improvement ($p<0.05$), indicating that patients felt a better benefit from medium-potency corticosteroid treatment.

Table 5: Adverse Effects Observed During Study

Adverse Effect	Group A (n=35)	Group B (n=35)	p-value
Burning/irritation	4 (11.4%)	7 (20.0%)	0.31
Erythema	2 (5.7%)	3 (8.6%)	0.64
Telangiectasia	0 (0%)	2 (5.7%)	0.15
Skin thinning	0 (0%)	1 (2.9%)	0.31
Striae	0 (0%)	0 (0%)	—
Total adverse events	6 (17.1%)	13 (37.1%)	0.08

Both groups experienced modest and transient local adverse effects, as detailed in Table 5. Brief burning and moderate erythema were the most common symptoms in Group B, which had a slightly higher prevalence. Neither regimen was associated with any major or systemic adverse effects throughout the course of the four weeks of treatment, demonstrating their general safety.

Discussion

The physical and mental health of people with atopic dermatitis (AD) is greatly impacted by this inflammatory skin condition, which is chronic and relapsing. As the gold standard anti-inflammatory medication for managing acute flares and sustaining remission, topical corticosteroids (TCS) form the backbone of treatment. In order to determine the ideal dosage that provides sufficient disease management with few side effects, this study assessed the safety and effectiveness of two different corticosteroids hydrocortisone 1% and betamethasone valerate 0.1% in 70 individuals with moderate AD [13-15].

Reductions in pruritus Visual Analogue Scale (VAS) ratings and Eczema Area and Severity Index (EASI) scores showed that both therapy groups significantly improved clinically. In contrast to hydrocortisone, which has a lower anti-inflammatory effectiveness, betamethasone valerate reduced illness severity more quickly and to a larger extent in patients treated with it. The medium-potency corticosteroid showed greater clinical efficacy at Week 4, with a mean percentage reduction of 69.2% in the betamethasone group compared to 52.4% in the hydrocortisone group ($p<0.05$) [16-18].

Consistent with previous research, these results show that moderate-potency corticosteroids alleviate symptoms faster and increase lesion clearance in moderate AD than low-potency drugs. The investigations were conducted by Hanifin *et al.* (2002) and Luger *et al.* (2009). Similarly, betamethasone valerate was more effective in treating moderate disease, as 74.3% of patients in the medium-potency group reached "clear" or "almost clear" status on the Investigator's Global Assessment (IGA) compared to 51.4% in the low-potency group. Reflecting the high psychological burden of AD and the benefit of effective

medication, there was a significant increase in quality of life in both groups as measured by the Dermatology Life Quality Index (DLQI). Patient satisfaction and daily functioning are both improved by speedier disease control, according to the larger drop in DLQI ratings in the medium-potency group [19-21].

No serious side effects or abnormalities in laboratory testing were found during the research, and both formulations were well-tolerated. Although they were short-lived and resolved on their own, the betamethasone group did experience a significantly higher incidence of local adverse responses such burning, erythema, and mild irritation. This study highlights the safety of short-term use of medium-potency corticosteroids when properly suggested and monitored, as no significant problems such as substantial skin atrophy, striae, or telangiectasia were observed over the 4-week treatment period.

Leung *et al*. (2004) and Wollenberg *et al*. (2008), among others, have previously shown that short, regulated courses of TCS are not as likely to cause deleterious effects as longer or improper use. These findings are in line with these findings. This is why it's so important to teach patients the right way to apply it, how much to take, and for how long so they may get the most out of their treatment with the least amount of side effects [22-24].

The current study highlights the importance of tailoring the selection of topical corticosteroid to each patient by taking into account factors such as skin sensitivity, age, disease severity, lesion location, and lesion location. For milder diseases or delicate skin areas, such as the face or intertriginous regions, low-potency agents like hydrocortisone are OK. However, when it comes to moderate lesions on the trunk and limbs, medium-potency corticosteroids like betamethasone valerate work better. Assessment of long-term safety and relapse rates is not possible due to the study's limitations, which include its tiny sample size and very short length. To assess the possible advantages of intermittent maintenance regimens and the chronic use of varying corticosteroid potencies, future research should involve bigger populations and longer follow-up periods [25, 26].

Conclusion

Results showed that moderate atopic dermatitis patients' clinical symptoms and quality of life were improved by both low- and medium-potency topical corticosteroids. Hydrocortisone 1% (low potency) reduced illness severity and pruritus more quickly than betamethasone valerate 0.1% (medium potency). The medium-potency corticosteroid was generally safe for short-term usage, with the exception of a few mild local adverse effects including burning and erythema. No significant or systemic side effects were noted. Based on disease severity, lesion site, and individual patient response, it is crucial to determine the potency of topical corticosteroids according to these results, while following the principle of utilizing the lowest effective potency for the shortest duration. Optimizing therapeutic efficacy and minimizing potential hazards associated with corticosteroid medication requires proper patient education, regular monitoring, and adherence to treatment guidelines.

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Conflict of Interest

None

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