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Comparison of Effectiveness of Calcipotriol Versus Steroids In The Treatment of Chronic Hand Eczema

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ABSTRACT

Objective: To evaluate efficacy of calcipotriol versus topical corticosteroids ointment in treatment of chronic hand eczema (CHE).

Study Design: Quasi-experimental.

Place and Duration of Study: Department of Dermatology, Pakistan Naval Ship (PNS) Shifa, Karachi, Pakistan, from May to Nov 2023.

Methodology: Patients with CHE, who met the inclusion criteria, were recruited and divided into two groups, with one group receiving calcipotriol and the other was given topical corticosteroids twice daily, for 2 months. Hand Eczema and Severity Index (HECSI) scores and patient self-assessment conducted at baseline, second, sixth, and eighth week after enrollment, were used to measure efficacy. During the treatment, adverse reactions were also assessed.

Results: A statistically significant improvement was noted in HECSI compared to baseline, beginning in second week of therapy ($p<0.001$) and reaching 75.00% reduction at the end of the treatment period with no significant difference noted between the two regimens ($p>0.05$). Almost all individuals improved by more than 50.00% by the end of the study duration. Moderate scaling was the most frequent side effect of calcipotriol, whereas moderate dryness was the most frequent negative effect of topical corticosteroids.

Conclusion: Calcipotriol ointment was noted to have the same therapeutic efficacy as topical corticosteroids in the treatment of CHE.

Keywords: Calcipotriol, chronic hand eczema, steroid, topical vitamin D analogues

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INTRODUCTION

Chronic Hand Eczema (HE) refers to all skin-related inflammatory illnesses of the hand, which affects 14.50% of individuals globally, with occurrence of 7.30 cases per 1000 people-years [1]. Females were noted to present at an earlier age than males, with onset in early 20s, with no effect on mortality, however, a considerable influence on individual's quality of life (QoL) and increased morbidity was reported with approximately 30.00% patients reporting work impairment and loss of productivity [2]. Pathogenesis follows a multifactorial pattern due to variable etiologies and prognoses, making management difficult [3]. Exogenous variables such as irritation, contact with allergens or endogenous reasons like psoriasis are implicated in the typical etiologies. 4 Many treatment modalities have been used to treat CHE, such as skin protection strategies, topical treatment and even systemic treatment and physical modalities.[5,6] Calcipotriol, a topical vitamin D analogue, binds to vitamin D receptors (VDR), modulating epidermal proliferation, influencing keratinocyte differentiation, and inhibiting inflammatory impact.[7] Previous studies have found that using topical vitamin D analogues twice daily has an excellent therapeutic effect on chronic hyperkeratotic hand eczema, but more research is needed to provide stronger statistical proof. [8] Recently, investigations showed successful management of chronic palmoplantar dermatitis with topical vitamin D derivative only.[9] and in conjunction with topical corticosteroids.[10] Comparative trials using topical vitamin D analogues in management of CHE, on the other hand, are scarce. As a result, the purpose of this study is to determine if topical calcipotriol solely is as efficient as normal topical corticosteroid monotherapy in management of CHE.

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METHODOLOGY

This quasi-experimental study was conducted in the Department of Dermatology, PNS Shifa, Karachi, Pakistan, from June to December, 2023 after gaining approval from Ethics Review Committee (ERC/2023/DERMA/17 dated May 29, 2023), where

sample size was calculated using Open Epi online sample size calculator for two groups, where Group I had a clinical improvement of 77.00% while Group II had a clinical improvement of 70.00%.[11], after which sample size enrolled was 60 patients through non-probability convenient sampling technique.

Inclusion Criteria: Patients between the ages of 20 to 70 years, belonging to either gender, with symmetrical CHE of more than 3 months duration and having recurrent (more than or equal to 2 episodes per year) CHE were included.

Exclusion Criteria: Patient who were pregnant or lactating, suffered from another dermatologic condition of the hand, known allergy to calcipotriol or topical corticosteroids ointment, use of topical corticosteroid within the last 2 weeks, use of systemic treatment within the last 4 weeks were excluded.

Patients were explained in detail regarding the treatment duration, the need for regular follow-up, probable side effects, such as scaling, stinging, redness, edema, during the study treatment and the voluntary nature of the study and then signed the inform consent form. Patients were randomly assigned to one of two groups: Group A received calcipotriol ointment, whereas Group B received topical corticosteroids. Before beginning treatment, pre-treatment pictures are obtained, and patients' clinical severity scores are analyzed by dermatologists using Hand Eczema Severity Index (HECSI) scores. The HECSI was calculated based on the severity of clinical signs, which included six different clinical presentations (redness, scaling, infiltration, edema, fissures, and vesicles) and total area involvement, which was divided into five locations (fingers, palms, back of hands, and wrists) while the severity of six clinical symptoms is rated using the following scale: 0 means no skin changes; 1 means mild disease; 2 means moderate disease; and 3 is severe disease with affected area of each hand scored from 0 to 4 for the severity of clinical symptoms as follows: 0, 0%; 1, 1-25%; 2, 26-50%; 3, 51-75%; 4, 76-100% with the total sum of the extent scores for each area multiplied by the total sum of the intensity scores for each clinical indicator, yielding the HECSI total score, which ranges from 0 to 360.[11,12] Patients were also questioned and asked to rate the severity of their hands using a Visual Analogue Scale (VAS) before treatment and a Quartile grading score at each visit during the second, sixth, and eighth weeks. The improvement was based on the quartile grading score. All patients were instructed to apply the ointment (calcipotriol and topical corticosteroids) twice to the lesion on each hand using a cotton tip which was then discarded. All patients were told to avoid using any additional topical treatments or cosmetics on their hands. Statistical Package for the Social Sciences (SPSS) version 26.00 was used for data analysis. Mean + SD was calculated for quantitative variables while frequency and percentage was calculated for qualitative data. Median interquartile range (IQR) was calculated for HESCI and HESCI score between groups was compared using Kruskal-Wallis test with intra-group comparison made using Wilcoxon rank test. Chi-square test was used to compare the qualitative data between two groups where p-value < 0.05 was considered as significant.

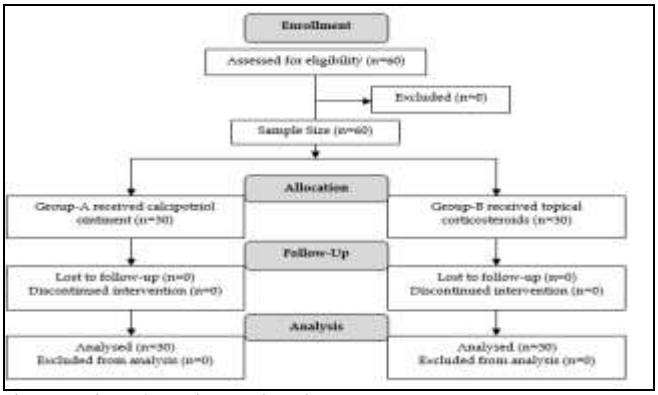

Figure: Patient Flow Diagram (n=60)

RESULTS

The age range in this study was 20 to 70 years with mean age being 36.2 + 4.1 years in Group A and 35.6+ 13.7 years in Group B. Most of the patients were male in both groups with the most common clinical variant in both groups being hyperkeratotic palmer eczema. No statistically significant difference was noted among the baseline and clinical characteristics of both groups, as shown in Table-I.

The HECSI of the two regimens was evaluated at baseline to see if there was any difference in clinical severity between the two groups before starting treatment. The HECSI scores at baseline in Group A were 35.00 (36.25-33.75) and 35.00 (36.25-30.00) in Group B, with no statistical difference in HECSI (p value > 0.05). The overall outcome at the end of the treatment period demonstrated an improvement in HECSI in both groups, as shown in Table-II.

There was no significant difference in clinical improvement from the patients' viewpoints between the two groups in terms of subjective assessment. The

results showed that all individuals in Group A reported at least 100.00% improvement in clinical severity by the end of treatment, compared to 83.30% in Group B, however, when we examined the outcomes of the two therapies at the end of the follow-up period, there was no statistical difference, as shown in Table-III.

Table-I: Baseline and Clinical Characteristics of Patients (n=60)

Baseline Characteristics (Mean+SD)	Group-A (n=30)	Group-B (n=30)	*p*-value
Age (years)	36.20+4.10	35.60+ 13.70	0.56
Duration of Disease (months)	10.00+2.60	9.00+3.00	0.16
BMI (kg/m2)	27.10+5.40	27.40+5.30	0.83
Gender Male Female	n (%) 18.00 (60.00%) 12.00 (40.00%)	n (%) 19.00 (63.00%) 11 (37.00%)	1.00
Clinical Variants Hyperkeratotic palmar eczema Hyperkeratotic concomitant with chronic fissured hand Eczema Pulpitis Recurrent vesicular hand eczema	n (%) 18.00 (60.00%) 5.00 (17.00%) 5.00 (17.00%) 3.00 (10.00%)	n (%) 19.00 (63.00%) 6.00 (20.00%) 5.00 (17.00%) 2.00 (7.00%)	0.96

**SD: Standard Deviation, BMI: Body Mass Index*

DISCUSSION

Calcipotriol is a vitamin D3 derivate which has corticosteroid sparing effects and studies have shown its efficacy in inflammatory disorders.[13,14] A previous study found that applying topical vitamin D analogues twice daily had an excellent therapeutic effect in a clinical case report of 5 individuals with hyperkeratotic palmoplantar eczema.[15] The lesions almost disappeared in four patients after 2 to 8 weeks of application, while one patient saw significant improvement after 7 weeks of treatment with no negative effects, and when relapses occurred, the patients responded well to treatment.[15] Another study 16 indicated that calcipotriol in conjunction with betamethasone ointment was effective in treating refractory CHE, where two patients' lesions were fully healed, and one patient improved by 90.00% after therapy. Both calcipotriol and steroid had a similar efficient therapeutic impact in the treatment of CHE in our study, similar to published literature. The reduction in mean HECSI in the calcipotriol-treated group compared to the topical corticosteroids-treated group exhibited no statistical difference (p>0.05) at any visit but statistically significant difference was observed at the 6th and 8th week of post treatment with very little side effects. Furthermore, there were no significant variations in clinical improvement from patients' views between the two groups in terms of subjective rating. These findings were comparable to those of a previous study in which it has been found that calcipotriol had a distinct effect in hyperkeratotic

Table-II: Comparison of Hand Eczema Severity Index (HECSI) Between Groups (n= 60)

Treatment Response					*p*-value
HECSI					
Groups	Baseline Median (IQR)	2nd Week Median (IQR)	6th Week Median (IQR)	8th Week Median (IQR)	
Group-A (n=30)	35.00 (36.25-33.75)	26.00 (30.00-20.00)	20.00 (25.00-20.00)	12.0 (12.75-10.00)	< 0.001
Group-B (n=30)	35.00 (36.25-30.00)	26.00 (30.00-20.00)	22.00 (25.20)	16.00 (18.5-15.75)	< 0.001
p-value	0.54	0.74	0.01	< 0.00	

Table-III: Participants' self-assessment among two groups (n= 60)

Degree of Improvement	1.00-25.00%	26.00-50.00%	51.00-75.00%	76.00-100.00%	*p*-value
Week-2 Group A (n=30) Group B (n=30)	 10.00(33.30%) 7.00(23.30%)	 15.00(50.00%) 15.00(50.00%)	 0.00(0.00%) 7.00(23.00%)	 5.00(16.60%) 1.00(3.40%)	0.02
Week-6 Group A (n=30) Group B (n=30)	 2.00(6.60%) 2.00(6.60%)	 9.00(30.50%) 6.00(20.00%)	 16.00(53.50%) 17.00(56.60%)	 3.00(8.00%) 5.00(16.60%)	0.77
Week-8 Group A (n=30) Group B (n=30)	 0.00 0.00	 0.00 3.00(10.00%)	 9.00(31.00%) 5.00(16.60%)	 21.00(69.00%) 12.00(73.40%)	0.09
Week-12 Group A (n=30) Group B (n=30)	 0.00 0.00	 0.00 5.00(16.60%)	 21.00(69.00%) 16.00(53.30%)	 9.00(31.00%) 9.00(31.00%)	0.05

Adverse effects of the treatment were reported by both groups, but these symptoms gradually resolved spontaneously between the sixth and eighth weeks of treatment, as did the cessation of localized scaling, as shown in Table-IV.

palmoplantar eczema but this study differs from earlier ones in that it was the first to use both established objective and subjective assessment methods in the evaluation of clinical severity and to compare the outcome with the standard treatment of CHE, unlike an earlier study which proved the efficacy of combination medicine (Calcipotriol 50 microgram/g. Betamethasone 500 microgram/g) [16], this study demonstrated the efficacy of calcipotriol ointment alone. In terms of adverse effects, there were no significant or systemic side effects discovered in this trial. Skin atrophy, telangiectasia, or any skin discoloration, which are serious adverse reactions from chronic corticosteroid use, as well as other contact reactions such as acneiform eruption from accidentally touching other parts of the body, particularly the face, were not reported in this study. Both treatment groups experienced a few localized adverse effects, similar to other studies.[17,18] The most common negative effect in people treated with topical corticosteroids was skin dryness, which is likely due to prolonged corticosteroid use. Scaling was frequently noted in the calcipotriol-treated group and decreased or resolved spontaneously during the treatment period. This reaction could be described by the regulated keratinocyte differentiation and the increased terminal differentiation effect, which are the primary mechanisms of vitamin D derivatives [18].

Table-IV: Comparison of Adverse Effects Between Both Groups (n=60)

Adverse effects	Group A n=30	Group B n=30
Mid scaling	23.00(76.60%)	0.00(0.00%)
Moderate scaling	7.00(23.30%)	0.00(0.00%)
Mid dryness	2.00(6.60%)	3.00(10.00%)
Moderate dryness	2.00(6.60%)	0.00(0.00%)
Mid stinging	2.00(6.60%)	2.00(6.60%)
Mid crackle	2.00(6.60%)	1.00(3.30%)
Moderated crackle	2.00(6.60%)	0.00(0%)
Mid erythema	0.00(0.00%)	1.00(3.30%)

LIMITATIONS OF STUDY

The main limitations of this study included a small number of participants and a short period of follow-up time to determine relapses. Participants may have lost compliance due to their working hours, however, by improving the doctor-patient interaction and providing proper treatment information, the participants appeared to be more cooperative and adhered to the treatment.

CONCLUSION

Calcipotriol ointment yielded similar therapeutic efficacy as topical corticosteroids ointment in the treatment of CHE, with statistically significant improvement in clinical severity in terms of a reduction in mean HECSI from baseline and also from patient self-assessment perspective, increasing its potential to be an alternate therapy option.

Conflict of Interest: None.

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Authors' Contribution

Following authors have made substantial contributions to the manuscript as under:

S & SK: Data acquisition, data analysis, critical review, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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