SYNOPSIS FOR RESEARCH ARTICLE

" COMPARATIVE EFFICACY OF CLOBETASOL 0.05% VERSUS INTRALESIONAL TRIAMCINOLONE IN TREATMENT OF HYPERTROPHIC LICHEN PLANUS IN TERTIARY CARE HOSPITAL"



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INTRODUCTION

Lichen Planus (LP) is an inflammatory dermatosis with immune-mediated pathology involving the skin, nails, hair and mucous membranes with a prevalence rate of 0.22-1.0% in adults globally; more common in individuals aged between 40 to 60 years with a slightly higher incidence among women.[1] There are various sub-types but hypertrophic lichen planus (HLP) occurs in around 10% of cutaneous cases with the former being the most difficult form to treat.[2,3] While classical lichen planus will resolve within 6 to 18 months in up to 85% of cases; untreated HLP lesions can persist for several years, have recognised malignant potential and affect quality of life similarly to psoriasis.[2]

The clinical presentation of HLP comprises thick, hyperkeratotic plaques that occur symmetrically on the extremities, especially the anterior aspect of the shins and ankles. It presents histologically with lichenoid interface dermatitis characterised by prominent acanthosis, hypergranulosis and increased thickness of collagen fibres in the dermis. The diagnosis is confirmed through biopsy with HLP having a 100% histopathological concordance rate, higher than any other LP subtype.[3] The underlying pathology revolves around an abnormal response by CD8+ cytotoxic T-cells that result in interface dermatitis with inflammatory mediators like interferon gamma, tumor necrosis factor alpha and interleukin 17 responsible for inducing keratinocyte apoptosis.[4]

Corticosteroids have always been the backbone of first-line management in HLP with clobetasol propionate 0.05% being the most commonly used product. The use of any individual topical agent showed no advantage over others in a Cochrane systematic review of fifteen randomised control trials.[5] The presence of a thickened and hyperkeratotic epidermis makes transdermal absorption less efficient in HLP thus limiting the role of topical agents to second-line therapy.[6] The use of intralesional triamcinolone acetonide circumvents this problem by injecting high concentrations of the steroid directly into the lesion thereby bypassing the epidermal layer completely.[1] Intralesional triamcinolone is a first-line recommendation for treating hypertrophic and refractory LP according to European S1 guidelines.[1] The available literature reports a good or excellent response in about 55% of cases using clobetasol

propionate and 80% with intralesional triamcinolone acetonide.[1,5] These figures formed the foundation for sample size calculation.

While international literature provides strong recommendations for the treatment of HLP, no prospective comparative study has been conducted in Pakistan to validate these recommendations locally. The disease occurs frequently at tertiary dermatological facilities in the country yet treatment decisions depend upon extrapolated results from international literature. As the Combined Military Hospital Abbottabad caters to a population residing in different parts of the Hazara division, the majority of which do not have easy access to specialized care for their dermatological conditions, the above hospital is a suitable location to produce research results that are applicable to the local setting. The current research work is thus designed using a quasi-experimental comparative approach in a tertiary care facility.

OBJECTIVE

To compare the effectiveness and safety of 0.05% clobetasol propionate cream and triamcinolone acetonide injections in hypertrophic lichen planus.

HYPOTHESIS

NULL HYPOTHESIS

There is no significant difference in the clinical response based on reduction in LP Severity Index Score and Pruritus Visual Analog Scale between topical clobetasol propionate 0.05% and intralesional triamcinolone acetonide 10 mg/mL in hypertrophic lichen planus after 8 weeks of therapy.

ALTERNATIVE HYPOTHESIS

There is a significant difference in the clinical response based on reduction in LP Severity Index Score and Pruritus Visual Analog Scale between topical clobetasol propionate 0.05% and intralesional triamcinolone acetonide 10 mg/mL in hypertrophic lichen planus after 8 weeks of therapy.

OPERATIONAL DEFINITIONS

Hypertrophic Lichen Planus: Confirmed diagnosis with characteristic findings such as thickened, elevated, hyperkeratotic, violaceous papules/patches located on any part of the body along with baseline LP Severity Index (LPSI) score ≥ 2 upon enrollment and Visual Analogue Score ≥ 4 at baseline

Clobetasol propionate 0.05% (Group A): Superpotent topical corticosteroid applied in a thin film to the affected lesion twice daily (morning and night) for 8 weeks without washing for 30 minutes after application.

Triamcinolone acetonide (Group B): 10 mg/mL of triamcinolone acetonide injected intralesionally using a 26-gauge needle, 0.1-0.2 mL per site separated by 1 cm with a maximum volume of 0.5 mL/cm² of lesion size during weeks 0, 2, 4 and 8 (total four sessions over 8 weeks) and lidocaine 2% gel applied 5 minutes before injection for anesthesia.

Clinical Response: Improvement rate from baseline at Week 8; categorized as follows:

- Complete Response (LPSI = 0, total flattening of plaques)
- Good Response (≥ 2-point reduction in LPSI)
- Partial Response (1-point reduction in LPSI)
- No Response (no LPSI reduction or worsening)

Pruritus score: Severity of itching experienced subjectively rated on a 0-10 visual analog scale (VAS; 0 = no itching; 10 = worst possible itching) measured at baseline, week 4, and week 8.

Lesion Area: Surface lesion measurement in cm2 quantified using a measuring tape graduated in centimeters at baseline, week 2, week 4 and week 8.

Adverse Drug Reaction (ADR): Unfavorable medical event temporally related to the treatment assigned specifically skin atrophy, telangiectasias, secondary cutaneous infection, hypopigmentation and systemic corticosteroids effect (Cushingoid manifestations)..

MATERIALS AND METHODS

Study Design

Quasi-Experimental (Non-Randomized Comparative Study).

Study Setting

Department of Dermatology, Combined Military Hospital, Abbottabad.

Study Duration

Minimum of six (6) months following approval of synopsis by CPSP.

Sample Size

Sample size calculation has been done using the formula for difference between two proportions at confidence level 95% (α=0.05) and power 80% (β=0.20). p_1 is estimated as 55% based on Cochrane review data[5], and p_2 as 80% based on European guideline evidence.[1] The calculated sample size was n=52 per group. With an allowance of 10% dropouts, the final sample size will be n=58 per group. Hence, the total sample size is **116** subjects (58 per group).

Sampling Technique

Non-probability Consecutive Sampling.

Sample Selection

Inclusion Criteria:

- Age ≥ 18 years, both genders
- Confirmed clinically as hypertrophic LP with LPSI score ≥ 2 at baseline and VAS score ≥ 4 at baseline
- No use of topical or intralesional treatment of LP within last 4 weeks
- Consent in writing in English or Urdu language

Exclusion Criteria:

- Drug-induced lichenoid lesions
- Pregnant or lactating women
- Having uncontrolled diabetes mellitus or any other active skin infections

- Necessity of systemic corticosteroids or immunosuppressive drugs as the primary treatment
- Previous history of sensitivity to study medicines
- Informed consent refusal

Data Collection Procedure

Following ethical approval by the Ethical Review Committee of the hospital and the Research Evaluation Unit of CPSP, patients visiting the Dermatology OPD of the hospital and clinically suspected to have hypertrophic LP will be screened for inclusion into the study. Following the fulfillment of the inclusion/exclusion criteria, patients will be briefed about the study purpose and written informed consent taken in English/Urdu as per their choice.

During the first visit to the OPD, demographic data and baseline measurements will be collected on a structured proforma. These include name, age, gender, contact no., MR no., address, duration of illness, history of previous treatment, sites involved, characteristics of lesions (number, location), area of lesion measured in cm^2 (with a measuring tape), LPSI (0-4), pruritus VAS score (0-10).

The two groups of eligible participants will be divided in accordance with an odd-even enrollment strategy with odd patients enrolled in Group A and even patients enrolled in Group B. Patients in group A will receive a demonstration of application technique along with instructions to avoid washing for 30 minutes following its application. On the other hand, group B participants will receive pre-injection lidocaine 2% gel topically for 5 minutes prior to each session along with multiple injection sites spaced 1 cm apart with not more than 0.5 mL/cm^2 per session.

Outcome measures will be assessed at weeks 2, 4 and 8 where the assessor will evaluate patients' LPSI scores, pruritus VAS, lesion area in cm^2 and any adverse effects associated with the medication. Treatment outcome at week 8 will be classified on the proforma based on predefined standards as either Complete, Good, Partial or No response.

Data Analysis

Data analysis will be performed using the Statistical Package for the Social Sciences (SPSS) software v.26.0. Mean and standard deviation will be utilized to represent continuous variables such as age, pruritus VAS, lesion area and LPSI score. As for categorical variables like gender, lesion sites, response grade and ADR incidence, the representation will consist of frequencies and percentages. For comparing mean scores between two groups, the independent samples t-test will be adopted. The chi-square test will be used to compare categorical variables such as the response grade and the frequency of ADRs. Intra-group comparisons at different time points will be made using repeated measures ANOVA. A p-value of <0.05 will be considered statistically significant.

REFERENCES

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RESEARCH PROFORMA

COMPARATIVE EFFICACY OF CLOBETASOL 0.05% VERSUS INTRALESIONAL TRIAMCINOLONE IN TREATMENT OF HYPERTROPHIC LICHEN PLANUS

DEMOGRAPHICS

Patient Name:		**MR No.:**	
Age (years):		**Gender:**	☐ M ☐ F
Contact No.:		**Address:**	
Duration of symptoms (months):		**Previous Rx:**	☐ Yes ☐ No

CLINICAL FEATURES AT BASELINE

Lesion Site	☐ Anterior shin ☐ Dorsal foot ☐ Dorsal hand ☐ Ankle ☐ Other: _____
Lesion Character	☐ Hypertrophic plaques ☐ Mixed
No. of lesions	
Lesion Area (cm^2)	
LPSI Score (0–4)	
Pruritus VAS (0–10)	

GROUP ALLOCATION

☐ GROUP A: Clobetasol 0.05% ointment BD

☐ GROUP B: Inj. Triamcinolone 10 mg/mL every 2 weeks

OUTCOME ASSESSMENT

Parameter	Baseline	Week 2	Week 4	Week 8
Pruritus VAS (0–10)				
LPSI Score (0–4)				
Lesion Area (cm^2)				

FINAL RESPONSE GRADE (Week 8)

☐ Complete Response (LPSI = 0)

☐ Good Response (≥2-point reduction)

☐ Partial Response (1-point reduction)

☐ No Response

ADVERSE EFFECTS

Skin atrophy	☐ Yes ☐ No	**Telangiectasia**	☐ Yes ☐ No
Secondary infection	☐ Yes ☐ No	**Hypopigmentation**	☐ Yes ☐ No

Cushingoid features	☐ Yes ☐ No	**Other ADRs**	_____

Investigator Signature: _____ Date: _____

INFORMED CONSENT FORM (ENGLISH)

COMPARATIVE EFFICACY OF CLOBETASOL 0.05% VERSUS INTRALESIONAL TRIAMCINOLONE IN TREATMENT OF HYPERTROPHIC LICHEN PLANUS

I, _____ (name of patient/guardian), hereby give my informed consent to participate in this research study being conducted at the Department of Dermatology, Combined Military Hospital/Abbottabad.
I have been fully informed that:

- The purpose of this study is to compare the effectiveness of two standard treatments for hypertrophic lichen planus; a topical steroid cream (clobetasol) applied to the thickened skin lesions twice daily versus a steroid injection (triamcinolone) given directly into the lesion every two weeks to determine which provides better and faster relief of the thickened plaques and itching.
- My participation involves a clinical examination at baseline and follow-up visits at 2 weeks, 4 weeks and 8 weeks. At each visit, the doctor will assess my lesions, record my itch score and measure the lesion size.
- My routine medical care and treatment will not be negatively affected by participation in this study. I will receive one of the two standard treatment options available for my condition.
- My medical records and personal information will be kept strictly confidential. I will be identified only by a serial number, not by name. All data will be stored securely and used only for research purposes.
- My participation is completely voluntary. I may withdraw from the study at any time without giving any reason and this will not affect my medical care in any way.
- There are no additional risks beyond the known side effects of the treatments — possible skin thinning or colour change with the topical steroid cream, and mild pain or temporary skin depression at the injection site with the intralesional treatment — all of which will be monitored and managed promptly.
- The results of this study may help improve treatment decisions for hypertrophic lichen planus patients at our centre and nationally.
- If I have any questions or concerns, I may contact Dr. _____ at the Department.

I have read and fully understood the information provided above and all my questions have been answered to my satisfaction. I voluntarily give my informed consent to participate in this research study.

PATIENT/GUARDIAN INFORMATION

Name: _____
Relationship to Patient (if guardian): _____
Identity Card Number: _____

Contact Number: _____
Address: _____
Signature / Thumbprint of Patient/Guardian: _____
Date: _____ / _____ / 20____

WITNESS

Name of Witness: _____
Witness Signature: _____ Date: _____ / _____ / 20____