Yemen Journal of Medicine

https://yemenjmed.com

Article information

DOI: 10.63475/yjm.v4i2.0185

Article history:
Received: 07 August 2025
Accepted: 07 September 2025
Published: 22 September 2025

Correspondence to:
Ayesha Arshad Chattha
Email: ayeshahmed57@gmail.com
ORCID: 0000-0002-5542-9360

How to cite this article
Chattha AA, Siddiqui S, Asad F, Aman S. Comparison of efficacy of topical clobetasol propionate 0.05% and topical tacrolimus 0.1% in the treatment of lichen planus. Yemen J Med.2025;4(2): 422-427

Original Article

Comparison of Efficacy of Topical Clobetasol Propionate 0.05% and Topical Tacrolimus 0.1% in the Treatment of Lichen Planus

Ayesha Arshad Chattha[1], Saadiya Siddiqui[2], Faria Asad[3], Shahbaz Aman[4]

1 Senior Registrar, Department of Dermatology, Ghurki Trust Teaching Hospital, Lahore, Pakistan
2 Assistant Professor, Department of Dermatology, Ameer-Ud-Din Medical College, Lahore General Hospital, Lahore, Pakistan
3 Professor, Department of Dermatology, Services Institute of Medical Sciences, Services Hospital Lahore, Lahore, Pakistan
4 Professor, Department of Dermatology, Sahara Medical College, Narowal, Pakistan

ABSTRACT

Background: Lichen planus (LP) is a papulosquamous cutaneous disorder that manifests as intensely itchy violaceous flat-topped polygonal papules and plaques. To compare the efficacy of topical clobetasol propionate 0.05% versus topical tacrolimus 0.1% in the treatment of LP.

Methods: This prospective Comparative Study was conducted at the Dermatology Department, Services Institute of Medical Sciences (SIMS)/Services Hospital, Lahore, from May 1, 2022, to April 30, 2023. Ethical approval was obtained from the institutional review board at the Department of Dermatology, SIMS/Services Hospital, Lahore. A total of 80 patients were selected after fulfilling the selection criteria. The study participants were placed into two groups, A and B. In group A, the patients were advised to use the topical application of clobetasol propionate (0.05%) ointment twice daily. In group B, tacrolimus ointment (0.1%) was used twice daily. Treatment response was assessed at 3 weeks, and then finally efficacy was evaluated at 6 weeks.

Results: Treatment efficacy was observed in 34 patients (42.5%). Group A (Clobetasol) demonstrated a significantly higher efficacy of 55% compared to 30% in Group B (Tacrolimus; $p = 0.024$).

Conclusions: The 0.05% clobetasol propionate topical formulation demonstrated superior efficacy in treating LP compared to 0.1% topical tacrolimus. Further validation of these findings through large-scale clinical trials is warranted.

Key words: Lichen planus, mucocutaneous lesions, tacrolimus, clobetasol, efficacy

INTRODUCTION

Lichen planus (LP) is a papulosquamous cutaneous disorder that manifests as intensely itchy violaceous flat-topped polygonal papules and plaques. Genetic predisposition, autoimmune responses, and environmental triggers are suspected contributing factors. Certain medications, stress, and viral infections may also play a role. [1] LP commonly affects the extremities, particularly the flexural areas, but can also involve other body regions characterized by hallmark features, often referred to as "6 Ps," that is purple, planar, polygonal, pruritic, papules, and plaques. Genital and oral mucosal sites may be affected by two distinct types: the hyperkeratotic form, which is usually asymptomatic, and the erosive form, which is more likely to be symptomatic. [2] Although the disease

is typically benign, its symptoms can be distressing. Cosmetic concerns and intense pruritus are the primary motivations for seeking medical attention. Treatment is often sought to alleviate these symptoms and improve quality of life. [1,3]

Despite ongoing research, managing LP continues to pose therapeutic challenges, primarily due to the inconsistent efficacy of various therapeutic options. [4] A variety of therapeutic alternatives are available to reduce inflammation, decrease symptoms, and improve quality of life. Treatment modalities are topical approaches, such as high-potency corticosteroids (considered first-line treatment in many clinical trials), topical retinoids, vitamin D receptor analogues, tacrolimus, and hyaluronic acid. Phototherapy and photochemotherapy are also effective for widespread or resistant cases, while systemic treatments, including systemic corticosteroids, hydroxychloroquine, retinoids, and immunomodulators, are reserved for severe, widespread, or recalcitrant cases. Ultimately, each patient's response to treatment may vary, and a combination of therapies may be necessary to achieve optimal results, making consultation with a dermatologist or healthcare professional crucial to determine the most effective treatment plan. [5,6] The clobetasol propionate, a potent topical corticosteroid, is mostly used for LP. The steroid alternatives are now being searched vigorously due to refractory lesions and undesirable side effects. Tacrolimus and pimecrolimus belong to the topical immunomodulator group and are good alternatives to steroids. Tacrolimus (FK 506) is an inhibitor of calcium-dependent protein phosphatase: calcineurin, thereby reducing the number of lymphocytes. This mechanism is analogous to cyclosporine; however, this drug is less nephrotoxic. [7] The use of topical tacrolimus has been approved for both cutaneous and mucous forms of LP. [8,9] Ozkur et al. compared topical clobetasol propionate 0.05% versus topical tacrolimus 0.1% for cutaneous LP and found that the complete response was observed in the clobetasol group, which was 63% versus the tacrolimus group, which was 26% by the end of 12 weeks of treatment (p value <0.05). [10]

Topical steroids are linked with verified side effects such as skin thinning, increased risk of infections, striae, and systemic absorption, particularly when applied to more than 10% body surface area, leading to hormonal disturbances such as Cushing's syndrome and adrenal suppression. Moreover, prolonged use of topical steroids can cause telangiectasias, rosacea, and peri-oral dermatitis. Therefore, there is growing concern in using steroid-free treatment options for LP, driving research into alternative therapies like topical immune modulators, retinoids, and phototherapy with the view of providing an effective and safer management of the disease. [10,11]

The present study aimed to assess the comparative efficacy of topical tacrolimus and clobetasol propionate for the treatment of mucocutaneous LP. The current national and international research on this subject has been limited in recent years. Therefore, the results of current research will help us choose a better drug for the treatment of LP and help reduce the morbidity of patients.

MATERIALS AND METHODS

Study design and setting

It was a prospective comparative study, conducted on 80 participants selected through a non-probability consecutive sampling technique, enrolled after approval from the institutional review board at the Department of Dermatology, Services Institute of Medical Sciences (SIMS)/Services Hospital, Lahore (Ref No.: IRB/2022/961/SIMS).

Sample size calculation

Sample size was calculated by taking the expected complete response in the clobetasol group as 63% and in the tacrolimus group as 26%. [10] The power of the test was 90% and the level of significance was 5% with 40 in each group (total=80).

Eligibility criteria

Patients from both genders, diagnosed with cutaneous and mucosal forms of LP, within the age range of 20 to 60 years, were enrolled. All those who had diabetes, ischemic heart disease, chronic renal/liver failures, were taking immunosuppressive medication, or were lost to follow-up were excluded. Also, those with prior topical treatment of LP during the last month and systemic therapy for the last two months, allergic to corticosteroids or tacrolimus, pregnant/lactating women, and patients with skin atrophy were not included. LP was diagnosed clinically as small, itchy, violaceous papulosquamous lesions on the skin or violaceous mucosal lesions with a lacy pattern.

Patients recruitment

All participants provided informed written consent before enrollment after being informed of study objectives, intervention details, potential risks, and benefits. Participants were assured of confidentiality, and they were free to leave the study at any time.

Intervention protocol

Clobetasol is a topical steroid. It was used as a 30 g tube and applied in the form of clobetasol propionate ointment 0.05%. Tacrolimus is a calcineurin inhibitor that was used in a 30 g tube and applied in the form of tacrolimus ointment 0.1%. Patients were divided into two groups using a non-randomized technique. In group A, the patients were advised to use the topical application of clobetasol propionate (0.05%) ointment twice daily. In group B, tacrolimus ointment (0.1%) was used twice daily (**Figure 1**).

Treatment response assessment

Responses were assessed at baseline, 3 weeks, and final efficacy was assessed at 6 weeks, defined as >90% improvement in pruritus and pigmentation. Both pruritus and pigmentation were graded using a 10-point visual analogue scale (VAS) based on Ozkur et al. [10] Patients were counselled regarding adherence to treatment and were checked at follow-up visits.

Statistical analysis

Collected data was entered and analyzed using SPSS, version 25. The quantitative variables, such as duration of disease and age, were presented as mean ± standard deviation. Qualitative variables like gender, type of LP (cutaneous/mucosal), and efficacy were interpreted as frequency and percentages. Both groups were compared with each other in terms of efficacy by the chi-square test. The effect modifiers,

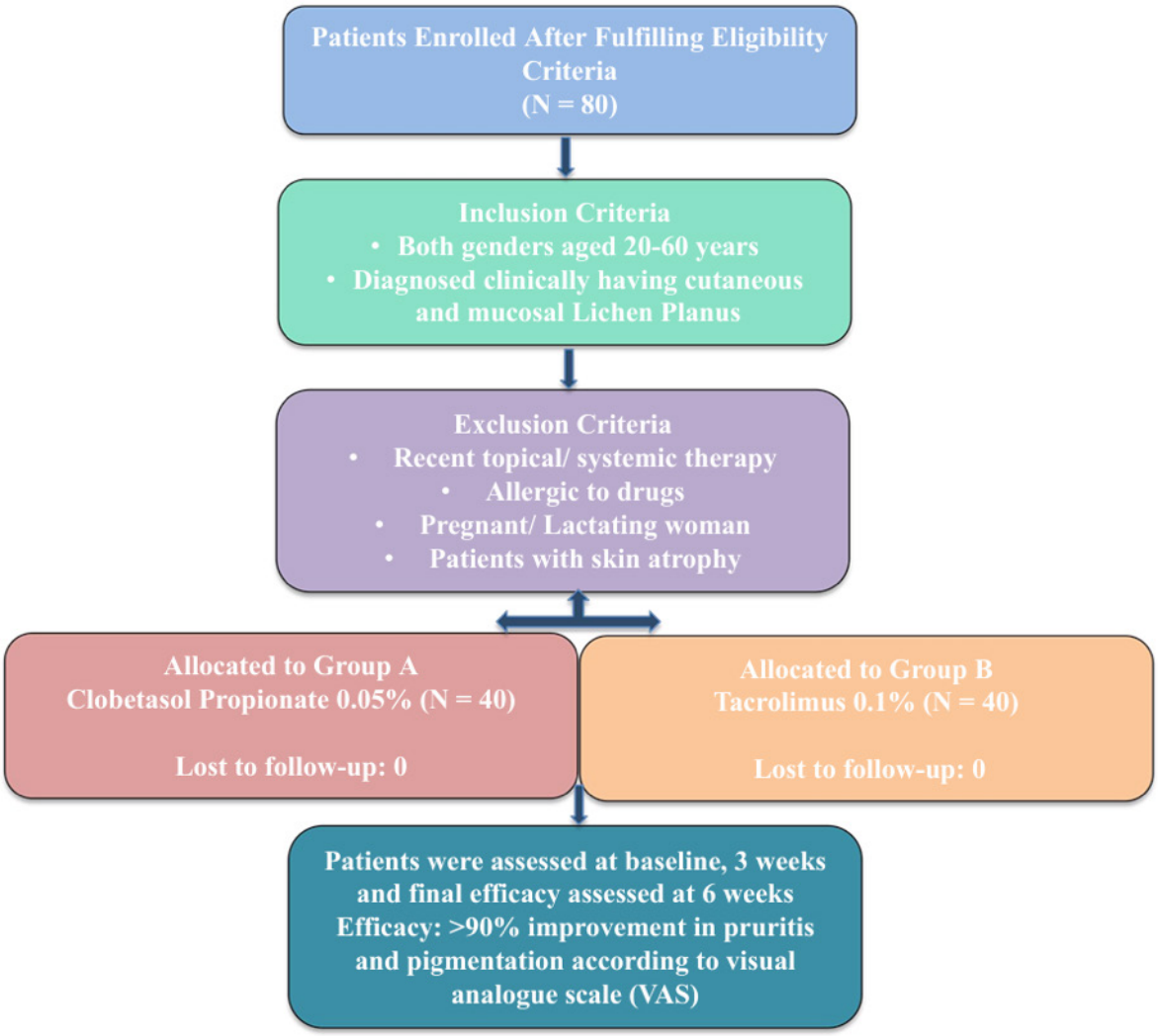

Figure 1: Intervention protocol.

like gender, age, disease duration, and type of disease, were adjusted by stratification. Results were considered significant with a *p*-value ≤ 0.05.

RESULTS

SUMMARY OF DEMOGRAPHIC AND CLINICAL CHARACTERISTICS

The demographic and clinical characteristics of the total 80 patients were generally well balanced between group A and group B. There was no statistically significant difference regarding gender distribution between the groups, with females comprising 55% in group A and 52.5% in group B ($p = 0.823$). The mean age was slightly higher in group A (42.7 ± 12.6 years) compared to group B (37.45 ± 11.13 years), and this difference was not significant ($p = 0.052$).

Regarding the type of lesion, mucous-type lesions were more common in group A (65%) compared to group B (52.5%), whereas cutaneous lesions were more prevalent in group B (47.5% vs. 35% in group A); however, this difference lacks statistical significance ($p = 0.256$).

As per the efficacy of treatment, a statistically significant difference was noted between the two groups. Group A demonstrated a higher response rate, with 55% of participants showing a positive response compared to only 30% in group B ($p = 0.024$). This finding suggests a potential advantage of the intervention or condition associated with group A in achieving better clinical outcomes (**Table 1**).

Subgroup analysis revealed that group A consistently showed higher treatment efficacy compared to group B across all examined categories. In terms of illness duration, group A had equal numbers of effective responses in both the <6 months and >6 months subgroups. In contrast, group B showed reduced efficacy in patients with a longer illness duration. Similarly, when stratified by age, group A maintained favorable efficacy in both the <40 and >40 years groups, while group B exhibited markedly lower response rates, particularly among younger participants. These findings suggest that group A's treatment approach may be more robust across varying patient profiles. (**Figures 2 and 3**) In group A, no side effects were observed; however, in group B, $n = 4$ patients demonstrated a burning sensation only at the first visit.

Table 1: Comparison of demographics, clinical characteristics, and treatment efficacy between group A and group B (*n* = 80).

Variable	Categories	Total (*n* = 80)	Group A (*n* = 40)	Group B (*n* = 40)	*p*-value
Gender	Female	43 (53.75%)	22 (55%)	21 (52.5%)	
	Male	37 (46.25%)	18 (45%)	19 (47.5%)	0.823
Age (years)		40.08 ± 12.10	42.7 ± 12.60	37.45 ± 11.13	0.052
Type of lesion	Cutaneous	33 (41.25%)	14 (35%)	19 (47.5%)	
	Mucous	47 (58.75%)	26 (65%)	21 (52.5%)	0.256
Treatment efficacy	Yes	34 (42.5%)	22 (55%)	12 (30%)	
	No	46 (57.5%)	18 (45%)	28 (70%)	0.024

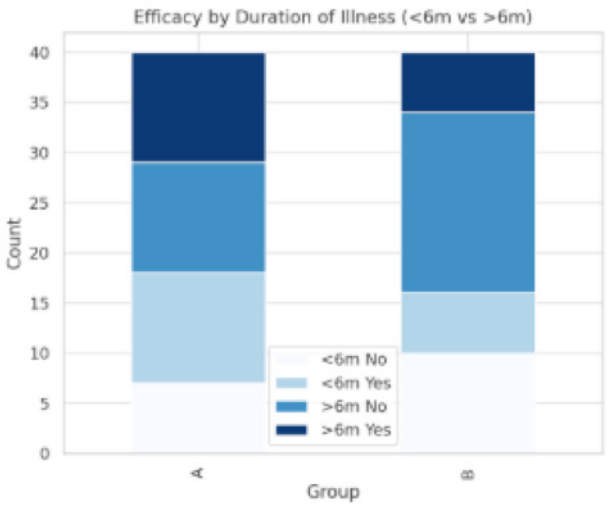

Figure 2: Efficacy by duration of illness (<6 months vs. >6 months).

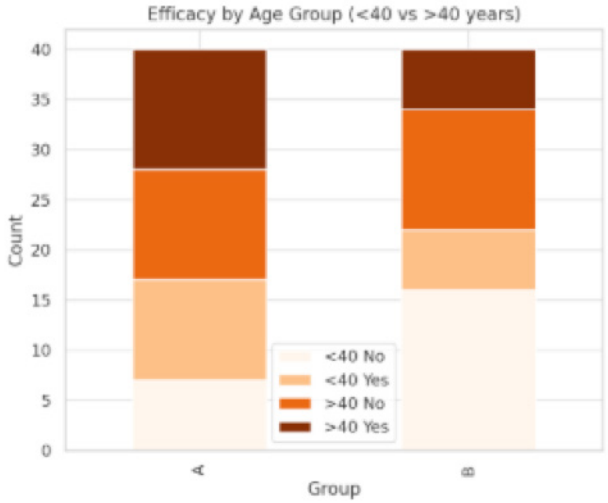

Figure 3: Efficacy by age group (<40 years vs. >40 years).

Table 2: Effect estimates for failure (bad outcome)—main coding used.

Measure	Estimate	95% CI	*z* statistic	*p*-value
Risk (failure)—group A	0.45 (18/40)	–	–	–
Risk (failure)—group B	0.70 (28/40)	–	–	–
Relative risk for failure (A vs. B)	**0.6429**	0.4317 – 0.9573	2.175	0.0296
Odds ratio for failure (A vs. B)	**0.3506**	0.1398 – 0.8794	2.234	0.0255

Using failure as the event of interest, group A had a failure risk of 45.0% (18/40) versus 70.0% (28/40) in group B. The relative risk of failure for group A compared with group B was 0.6429 (95% CI, 0.4317–0.9573; $z = 2.175$; $p = 0.0296$), and the odds ratio for failure was 0.3506 (95% CI, 0.1398–0.8794; $z = 2.234$; $p = 0.0255$; **Table 2**).

DISCUSSION

For all forms of LP, including genital, erosive oral LP, and cutaneous type, highly potent corticosteroids are thought to be the best treatment available. [12–14] The present study compared the efficacy of topical clobetasol propionate 0.05% with topical tacrolimus 0.1% in the treatment of mucocutaneous LP. In our cohort, females constituted 54% and males 46% aligning with the findings of Ozkur et al. [10] who reported a similar female predominance (64% females and 36% males), suggesting a possible predilection of LP towards the female gender. In terms of therapeutic response, 55% of patients in the clobetasol group achieved desired efficacy compared to 30% in the tacrolimus group ($p = 0.024$), demonstrating a statistically significant difference. These results are comparable to those of Ozkur et al., [10] who reported complete remission in 63% of patients treated with clobetasol and 26% treated with tacrolimus, confirming the superior efficacy of clobetasol for symptomatic control and pigmentation improvement.

In our study, the majority of patients presented with mucosal LP, and efficacy, as assessed by VAS scores, was observed in 53% of patients treated with clobetasol versus 33% treated with tacrolimus. However, these findings differ from those of Hettiarachchi et al., [3] who demonstrated comparable improvement in both clinical appearance and pain scores between clobetasol and tacrolimus. This variation could be attributed to differences in patient ethnicity, lesion distribution, and longer treatment duration in the Sri Lankan study.

A recent meta-analysis also supports the superior efficacy of clobetasol propionate in OLP regarding lesion size reduction, symptom control, and overall clinical improvement. [15] Similarly, Sivaraman et al. [1] evaluated 30 Oral Lichen Planus (OLP) patients and found clobetasol 0.05% ointment to be significantly more effective than triamcinolone 0.1% and tacrolimus 0.03% further supporting our findings. Conversely, Zafar et al. [16] compared clobetasol and tacrolimus and reported a notable reduction in VAS scores and lesion size in both groups; however, the overall difference in efficacy was statistically insignificant ($p = 0.61$), suggesting that tacrolimus may still serve as a reasonable therapeutic option in certain cases.

A randomized clinical trial comparing clobetasol with photodynamic therapy for OLP revealed slightly lower rates of clearance initially; however, there was a significant remission of 56.3% for clobetasol against 79.88% in the Photodynamic therapy group. [17] Similarly, topical tacrolimus patches demonstrated better early efficacy and patient compliance compared to tacrolimus and triamcinolone gels; however, outcomes were statistically insignificant. [18]

Innovative therapeutic combinations have also shown promise. For example, a study demonstrated that platelet-rich plasma gel (PRP gel) combined with tacrolimus was more effective than tacrolimus monotherapy for OLP. [19] However, despite these alternatives, a recent meta-analysis concluded that tacrolimus is not superior to other standard topical agents. [20]

A German retrospective observational study further reported a high prevalence of LP and highlighted the limited efficacy of available topical treatments, which often leads to early consideration of systemic therapies. [21] Nevertheless, topical corticosteroids remain the first-line treatment due to their proven efficacy and safety profile. [22,23] Importantly, however, robust evidence from large-scale randomized controlled trials remains limited, emphasizing the need for further high-quality studies to establish optimal treatment algorithms.

Our findings confirm that both clobetasol and tacrolimus are effective for managing mucocutaneous LP, but clobetasol demonstrates superior efficacy. Tacrolimus, however, remains a valuable second-line option, particularly in cases where corticosteroids are ineffective. Furthermore, tacrolimus may be preferred in sensitive areas such as the face, neck, and intertriginous regions where prolonged corticosteroid use carries a higher risk of adverse effects. [24]

LIMITATIONS

The study was limited by the single-center study design and the relatively small sample size of 80 participants. There was a lack of randomization and blinding technique, which may introduce allocation bias. In addition to this, the lack of post-treatment follow-up precluded the evaluation of the long-term efficacy of the therapeutic interventions.

CONCLUSIONS

The topical application of 0.05% clobetasol propionate is more effective in the treatment of LP than 0.1% topical tacrolimus. Further randomized, multicenter studies with larger cohorts and longer follow-up are recommended.

AUTHOR'S CONTRIBUTION

Each author has made a substantial contribution to the present work in one or more areas, including conception, study design, conduct, data collection, analysis, and interpretation. The final version of the work has been approved by all authors, who have also decided on the journal to which the article will be published and agreed to take responsibility for all aspects of the work.

SOURCE OF FUNDING

None.

CONFLICT OF INTEREST

None.

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