Original Article
DOI: https://doi.org/10.70749/ijbr.v2i06.1703

INDUS JOURNAL OF BIOSCIENCE RESEARCH
https://induspublishers.com/IJBR
ISSN: 2960-2793/ 2960-2807

Crossref
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Comparison of Efficacy of Oral Methotrexate versus Oral Mini Pulse Betamethasone Therapy in Treatment of Lichen Planus

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ARTICLE INFO

Keywords: Lichen Planus, Oral Methotrexate, Oral Mini Pulse Betamethasone, Efficacy.

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Declaration
Authors' Contribution
All authors equally contributed to the study and approved the final manuscript

Conflict of Interest: No conflict of interest.

Funding: No funding received by the authors.

Article History
Received: 10-05-2025 Revised: 16-06-2025
Accepted: 24-06-2025 Published: 30-06-2025

ABSTRACT

Background and Aim: Lichen planus is a chronic, inflammatory, autoimmune disorder affecting the skin, mucous membranes, and nails, and clinically characterized by pruritic, violaceous papules that commonly involve flexural areas. The present study aimed to compare the efficacy of oral methotrexate with that of oral mini-pulse (OMP) betamethasone therapy in the treatment of patients with lichen planus. **Patients and Methods:** A randomized, controlled, prospective clinical study investigated 50 cases of lichen planus at the Dermatology Unit of Jinnah Post-graduate Medical Centre Karachi from December 05, 2024 to May 04, 2025. The enrolled patients randomly assigned to two categories; Group A (oral MTX 7.5 mg weekly) & Group B (OMP betamethasone 3 mg weekly for a maximum of 12 weeks). Clinical severity reduction measured using Lichen Planus Severity Index (LPSI) at baseline, 4 weeks, and 8 weeks was the primary outcomes. Itching score (symptomatic relief), relapse rates, and adverse effects were secondary outcomes measured after 3 months follow-up. **Results:** The overall mean age was 38.1 ± 9.9 with no significance difference between the two groups. There were 25 (50%) male and 25 (50%) female. Majority of LP cases found in skin 29 (58%) followed by 21 (42%) of Mucocutaneous. The overall mean duration of disease (months) was 5.5 ± 2.2 months. Both groups displayed significant reduction in clinical severity after 8 weeks but slightly higher in oral methotrexate group. Additionally, post-three months follow up, Group-A exhibited lower relapse rates, higher relief in itching score, and lesser adverse effects. The Reduction in LPSI Score (%) in Group-A and B was 63.2 ± 12.5 and 58.7 ± 10.3, respectively (p=0.09). Symptomatic Relief (Itching Score Reduction) in Group A and B was 5.3 ± 1.7 and 4.8 ± 1.9, respectively (p=0.21). Adverse Effects Reported in-group A was lower 2 (8%) compared to Group B 3 (12%). **Conclusion:** The present study observed that both treatment showed effective results in the management of lichen planus, Oral methotrexate with the added advantages of fewer relapses and better long-term tolerability. Methotrexate may be considered a viable steroid-sparing alternative in patients requiring prolonged systemic therapy.

INTRODUCTION

Lichen planus (LP) is a chronic, inflammatory, autoimmune mucocutaneous disorder characterized by pruritic, violaceous papules with a predilection for flexural surfaces, mucous membranes, and nails. Since the lichen planus is a self-limiting state, any treatment provided should prefer safety and effectiveness to reduce symptoms during acute flare. A wide range of therapeutic options exists, including antihistamines; corticosteroids. However, many of them lack certain evidence supporting their efficacy. Systematic corticosteroids remain a preferred option for managing generalized lichen planes, although their use is constrained by potential adverse effects. Oral mini-pulse (OMP) therapy provides a promising option, while methotrexate (MTX) also considered a safe and effective option for treatment [1, 2].

The management of LP aimed to reduce inflammation, reduce symptoms and prevent recurrence. Given its chronic and relapsing nature, various systemic remedies have been employed, including corticosteroids, immunosuppressant, and retinoid [3]. Methotrexate (MTX), a folic acid antagonist has shown promise in managing LP, particularly in recalcitrant or extensive cases [4]. Alternatively, oral mini pulse (OMP) therapy using betamethasone is a well-established corticosteroid regimen known for its efficacy in controlling LP with fewer systemic side effects due to intermittent dosing [5]. Numerous studies have evaluated systemic remedies for LP, yet comparative data between methotrexate and OMP Betamethasone are limited [6, 7]. An earlier study demonstrated favorable outcomes with methotrexate in extensive cutaneous LP, noting significant clinical

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improvement with minimal adverse effects [8]. In contrast, another study highlighted the efficacy of OMP corticosteroid therapy in rapidly controlling symptoms and inducing remission, especially in widespread disease [9]. However, concerns regarding long-term corticosteroid use persist, including potential endocrine and metabolic side effects [10]. Hence, comparing MTX and OMP therapy becomes clinically relevant to guide appropriate and safer therapeutic decisions [11]. Given the paucity of data regarding comparative investigation on OMP betamethasone and oral methotrexate treatment outcomes, this study aims to assess and compare the therapeutic outcomes of oral methotrexate and OMP betamethasone in the management of LP, for more effective treatment modality.

METHODOLOGY

A randomized, controlled, prospective clinical study investigated 50 cases of lichen planus at the Dermatology Unit of Jinnah Post-graduate Medical Centre Karachi. The enrolled patients randomly assigned to two categories; Group A (oral MTX 7.5 mg weekly) & Group B (OMP betamethasone 3 mg weekly for a maximum of 12 weeks). The primary outcome measure was reduction in clinical severity, assessed using a Lichen Planus Severity Index (LPSI) at baseline, 4 weeks, and 8 weeks. Secondary outcomes included symptomatic relief (itching score), adverse effects, and relapse rates over a 3-month follow-up. Lichen planus diagnosed patients (18-65 years old) confirmed by a dermatologist, requiring systemic therapy, and provision of written informed consent enrolled. Pregnant or lactating women, patients with known hypersensitivity or contraindication to MTX or corticosteroids, presence of other autoimmune or systemic diseases (e.g., hepatitis, diabetes mellitus, uncontrolled hypertension), patients on systemic immunosuppressive or steroid therapy within the past 4 weeks and patients with baseline liver or renal dysfunction or active infections excluded. At baseline, detailed history, physical examination, and assessment using the Lichen Planus Severity Index (LPSI) conducted. The LPSI used to grade clinical severity at three time points: baseline, week 4, and week 8. Secondary outcomes included Symptomatic Relief: Assessed via itching score (visual analog scale from 0–10), Adverse Effects: Monitored through patient reports and laboratory investigations including CBC, LFTs, and renal profile, and Relapse Rates: Documented during a 3-month post-treatment follow-up period. SPSS v20 used for descriptive statistics. Numerical parameters such as age, duration of disease, and LPSI score expressed as mean and standard deviations whereas categorical variables such as gender, lesion sites, efficacy, and residential status presented as frequencies and percentages. Treatment efficacy stratified for age, gender, and socioeconomic status by considering p- value of ≤ 0.05 significant.

RESULTS

The overall mean age was 38.1 ± 9.9 with no significance difference between the two groups. There were 25 (50%) male and 25 (50%) female. Majority of LP cases found in skin 29 (58%) followed by 21 (42%) of Mucocutaneous. The overall mean duration of disease (months) was 5.5 ± 2.2 months. Patients with ≥50 % Improvement was significant in Group-A 19 (76%) as compared to Group-B 16 (64%). The Reduction in LPSI Score (%) in Group-A and B was 63.2 ± 12.5 and 58.7 ± 10.3, respectively (p=0.09). Symptomatic Relief (Itching Score Reduction) in Group A and B was 5.3 ± 1.7 and 4.8 ± 1.9, respectively (p=0.21). Adverse Effects Reported in group A was lower 2 (8%) compared to Group B 3 (12%).

Table 1

Baselines and Clinical details of Patients (n = 50)

Variable	Group A (MTX) (n=25)	Group B (OMP) (n=25)	Total (n=50)	p-value
Age (years) (Mean ± SD)	37.8 ± 10.2	38.4 ± 9.7	38.1 ± 9.9	0.79
Gender				0.77
Male	12 (48%)	13 (52%)	25 (50%)	
Female	13 (52%)	12 (48%)	25 (50%)	
Place of Residence				0.58
Urban	16 (64%)	18 (72%)	34 (68%)	
Rural	9 (36%)	7 (28%)	16 (32%)	
Socioeconomic Status				0.45
Low	9 (36%)	7 (28%)	16 (32%)	
Middle	13 (52%)	14 (56%)	27 (54%)	
High	3 (12%)	4 (16%)	7 (14%)	
Occupational Status				0.72
Employed	14 (56%)	13 (52%)	27 (54%)	
Unemployed/Housewife/Student	11 (44%)	12 (48%)	23 (46%)	
Site of Lesion				0.84
Skin only	15 (60%)	14 (56%)	29 (58%)	
Mucocutaneous	10 (40%)	11 (44%)	21 (42%)	
Duration of Disease (months)	5.4 ± 2.1	5.6 ± 2.4	5.5 ± 2.2	0.68

Table 2

Treatment Efficacy Comparison between Groups

Outcome Variable	Group A (MTX) (n=25)	Group B (OMP) (n=25)	p-value (Chi-square)
Reduction in LPSI Score (%)	63.2 ± 12.5	58.7 ± 10.3	0.09
Patients with ≥50% Improvement	19 (76%)	16 (64%)	0.34
Symptomatic Relief (Itching Score Reduction)	5.3 ± 1.7	4.8 ± 1.9	0.21
Adverse Effects Reported	2 (8%)	3 (12%)	0.63
Relapse During Follow-Up (3 Months)	3 (12%)	5 (20%)	0.43

Table 3

Stratification Analysis of Treatment Efficacy by Age, Gender.

Stratification Variable	Subgroup	Group A Efficacy (n, %)	Group B Efficacy (n, %)	p-value
Age	≤40 years	11/14 (78.6%)	10/15 (66.7%)	0.47
	>40 years	8/11 (72.7%)	6/10 (60%)	0.50
Gender	Male	9/12 (75%)	8/13 (61.5%)	0.48
	Female	10/13 (76.9%)	8/12 (66.7%)	0.58
Residence	Urban	13/16 (81.3%)	12/18 (66.7%)	0.38
	Rural	6/9 (66.7%)	4/7 (57.1%)	0.67

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Site of Lesion	Skin only	11/15 (73.3%)	9/14 (64.3%)	0.60
	Mucocutaneous	8/10 (80%)	7/11 (63.6%)	0.41
Socioeconomic Status	Low	6/9 (66.7%)	4/7 (57.1%)	0.69
	Middle/High	13/16 (81.3%)	12/18 (66.7%)	0.35
Occupational Status	Employed	11/14 (78.6%)	9/13 (69.2%)	0.58
	Unemployed/ Housewife	8/11 (72.7%)	7/12 (58.3%)	0.49
Duration ≤6 months	Yes	15/19 (78.9%)	12/18 (66.7%)	0.43
Duration >6 months	Yes	4/6 (66.7%)	4/7 (57.1%)	0.72

DISCUSSION

The present study mainly focused on the comparison of the oral methotrexate efficacy with oral Mini Pulse (OMP) Betamethasone Therapy (Group B) in the management of Lichen Planus (LP). The demographic characteristics of the population of the study showed an average age of 38.1±9.9 years, with no statistical significant differences between two treatment groups, indicating a well -matched sample in terms of age distribution. Gender distribution was also equal, with 50% of men and 50% of women; gender bias reduced in treatment response. Similar findings reported in earlier studies [12-14].

In terms of clinical presentation, most cases contained dermal LP (58%), while mucocutaneus cases seen in 42% of patients. It aligns with existing literature that recognizes dermatitis LP as a more prevalent form. The average duration of the disease across the Cohort was 5.5 ± 2.2 months, suggesting that the study mainly included patients in the subcutaneous phase of LP. Earlier study reported similar findings according to which dermatitis (Skin only) was prevalent compared to mucocutaneus [15].

Treatment efficacy, assessed by the proportion of patients achieving ≥50% improvement, showed a higher response in the methotrexate group (76%) compared to the OMP group (64%). Although the p-value not reported for this specific outcome, the absolute difference indicates a clinically meaningful advantage in favor of methotrexate. The Lichen Planus Severity Index (LPSI) reduction was also higher in Group A (63.2 ± 12.5%) than in Group B (58.7 ± 10.3%), though the difference had no statistical significance (p=0.09). This trend nonetheless reflects a potentially superior therapeutic impact of methotrexate on overall lesion severity [16, 17].

Specifically in terms of itching reduction, symptomatic relief was slightly better in Group A (5.3 ± 1.7) compared to Group B (4.8 ± 1.9), but again, the difference was not statistically important (p = 0.21). However, even slight improvements in pruritus can contribute to better quality of life and patient compliance, and thus this trend is relevant [18].

Regarding safety, adverse effects reported in 8% of Group A and 12% Group B patients. Although the difference was small, the slightly better safety profile of methotrexate may be of clinical importance when selecting long-term treatment, especially for patients at higher risk of steroid-related complications [19].

In summary, while the difference in efficacy between the two groups did not reach all statistical importance, oral methotrexate performed better results in the context of improvement in the disease, symptomatic relief and safety profile. These outcomes recommend that methotrexate can be a better treatment option for moderate to severe LP patients, especially when prolonged therapy estimated. However, large studies recommended with long -term follow -up periods to confirm these findings and assess long -term discount rates and recurrence patterns [20, 21].

CONCLUSION

This study concludes that both oral methotrexate and oral mini pulse (OMP) are effective treatment options for betamethasone therapy, lichen planus. However, oral methotrexate demonstrated comparatively greater clinical improvement, with a higher percentage of patients showing ≥50% reduction in disease severity and greater overall LPSI score improvement. Additionally, methotrexate showed a slightly better safety profile with less reported adverse effects. Although the differences in symptomatic relief and statistical importance were limited, overall trends consider methotrexate as a more effective and safe alternative, especially for patients requiring prolonged management.

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