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Original Research Article

# Analysis of the Efficacy of Two Treatment Protocols for Patients with Symptomatic Oral Lichen Planus: A Randomized Clinical Trial

**Sumanta Kumar Kolay[1], Kumar Pushpanshu[2], Rachna Kaushik[3], Shagufta Syreen[4], Ahtasham Anwar[5]**

[1]Professor and HOD, Department of Dentistry, Darbhanga Medical College and Hospital, Laheriasarai, Darbhanga, Bihar, India

[2]Associate Professor and HOD, Department of Dentistry, Shrikrishna Medical College and Hospital, Muzafferpur, Bihar, India

[3]Professor and HOD, Department of Dentistry, Government Medical College, Bettiah, West Champaran, Bihar, India

[4]Senior Resident, Department of Dentistry, Darbhanga Medical College and Hospital, Laheriasarai, Darbhanga, Bihar, India

[5]Assistant Professor, Department of Dentistry, JNKTMCH, Madhepura, Bihar, India

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**Corresponding Author: Dr. Kumar Pushpanshu**

**Conflict of interest: Nil**

**Abstract:**

**Background:** Oral Lichen Planus (OLP) is a chronic inflammatory condition affecting the mucous membranes of the oral cavity, often leading to significant discomfort and impairment in the quality of life. This study aimed to evaluate the efficacy of two treatment protocols for symptomatic OLP patients through a retrospective analysis.

**Materials and Methods:** A retrospective, randomized clinical trial was conducted over one year in Darbhanga, Bihar, involving 50 patients diagnosed with symptomatic OLP. The patients were randomly assigned to two treatment groups. Group A received topical corticosteroids (0.05% clobetasol propionate), while Group B received a combination therapy of topical corticosteroids and systemic antihistamines (10 mg cetirizine daily). The primary outcomes measured were the reduction in pain and lesion size, assessed at baseline, 3 months, and 6 months using the Visual Analog Scale (VAS) and clinical examination.

**Results:** Of the 50 patients, 25 were assigned to each treatment group. At the end of the study, Group A showed a significant reduction in pain scores (mean VAS score reduction from 7.5 to 3.2, $p<0.05$) and lesion size (mean reduction from 2.4 $cm^2$ to 1.0 $cm^2$, $p<0.05$). Group B exhibited an even greater reduction in pain scores (mean VAS score reduction from 7.4 to 2.0, $p<0.05$) and lesion size (mean reduction from 2.5 $cm^2$ to 0.8 $cm^2$, $p<0.05$). The combination therapy was statistically more effective in reducing both pain and lesion size compared to topical corticosteroids alone.

**Conclusion:** The combination therapy of topical corticosteroids and systemic antihistamines was found to be more effective than topical corticosteroids alone in managing symptomatic OLP. These findings suggest that a combined treatment approach may offer superior clinical benefits for patients suffering from OLP.

**Keywords:** Oral Lichen Planus, Retrospective Study, Randomized Clinical Trial, Topical Corticosteroids, Systemic Antihistamines, Pain Reduction, Lesion Size, Darbhanga.



## Introduction

Oral Lichen Planus (OLP) is a chronic, inflammatory mucocutaneous disorder that predominantly affects the oral mucosa, presenting clinically with reticular, erythematous, or ulcerative lesions. The etiology of OLP remains unclear, but it is widely considered to be an immune-mediated condition, with T-cell-mediated autoimmune reactions playing a significant role in its pathogenesis [1,2]. OLP affects approximately 1-2% of the general population, with a higher prevalence in middle-aged women [3]. Patients with OLP often experience significant discomfort, including pain, burning sensations, and difficulties with eating and speaking, which can severely impact their quality of life [4]. Various treatment modalities have been explored to manage symptomatic OLP, with topical corticosteroids being the first line of treatment due to their anti-inflammatory properties [5]. However, the chronic nature of the disease and the potential side effects

of prolonged corticosteroid use necessitate the exploration of adjunctive therapies. Systemic antihistamines have been considered as an adjunct treatment to corticosteroids due to their immunomodulatory effects, which may provide additional symptomatic relief [6]. Previous studies have indicated the potential benefits of combination therapy in other inflammatory conditions, but data specific to OLP remain limited [7]. Therefore, this study aims to evaluate the efficacy of two treatment protocols—topical corticosteroids alone versus a combination of topical corticosteroids and systemic antihistamines—in managing symptomatic OLP. By conducting a retrospective, randomized clinical trial, this study seeks to provide insights into the comparative effectiveness of these treatment protocols, ultimately guiding clinicians in optimizing therapeutic strategies for OLP patients.

## Materials and Methods

**Study Design and Setting:** This retrospective, randomized clinical trial was conducted at a dental clinic in Darbhanga, Bihar, over a period of one year. The study aimed to compare the efficacy of two treatment protocols for symptomatic Oral Lichen Planus (OLP).

**Study Population:** A total of 50 patients diagnosed with symptomatic OLP were included in the study. Patients were eligible if they had clinically and histologically confirmed OLP, were aged 18 years or older, and had not received any treatment for OLP in the three months preceding the study. Patients with known hypersensitivity to corticosteroids or antihistamines, or those with any other concurrent oral lesions, were excluded.

**Randomization:** Patients were randomly assigned to one of two treatment groups using a computer-generated randomization sequence.

Group A (n=25) received topical corticosteroids, and Group B (n=25) received a combination of topical corticosteroids and systemic antihistamines.

**Interventions:**

**Group A (Topical Corticosteroids):** Patients were treated with 0.05% clobetasol propionate ointment applied topically to the affected oral mucosa twice daily.

**Group B (Combination Therapy):** Patients received the same topical corticosteroid treatment as Group A, in addition to 10 mg of cetirizine administered orally once daily.

**Outcome Measures:** The primary outcomes measured were the reduction in pain and lesion size. Pain was assessed using the Visual Analog Scale (VAS) ranging from 0 (no pain) to 10 (worst pain imaginable). Lesion size was measured using a calibrated periodontal probe to determine the greatest linear dimension of the lesion.

**Data Collection:** Baseline data were collected at the initial visit, including patient demographics, medical history, and baseline VAS scores and lesion sizes. Follow-up assessments were conducted at 3 months and 6 months. At each follow-up visit, VAS scores and lesion sizes were recorded.

**Statistical Analysis:** Data were analyzed using SPSS software version 25.0. Descriptive statistics were used to summarize the baseline characteristics of the study population. Paired t-tests were used to compare within-group changes in VAS scores and lesion sizes from baseline to 6 months. Independent t-tests were used to compare changes between the two groups. A p-value of less than 0.05 was considered statistically significant.

## Results

The study included 50 patients diagnosed with symptomatic Oral Lichen Planus (OLP), randomly assigned to two treatment groups. Both groups were comparable at baseline in terms of demographics and clinical characteristics.

**Table 1: Baseline Characteristics of Study Population**

| Characteristic | Group A (n=25) | Group B (n=25) | p-value |
|---|---|---|---|
| Age (years) | 45.2 ± 10.3 | 46.1 ± 9.8 | 0.75 |
| Gender (M/F) | 12/13 | 11/14 | 0.79 |
| Duration of OLP (months) | 24.5 ± 5.2 | 23.8 ± 5.7 | 0.68 |
| Baseline VAS Score | 7.5 ± 1.2 | 7.4 ± 1.3 | 0.81 |
| Baseline Lesion Size ($cm^2$) | 2.4 ± 0.5 | 2.5 ± 0.6 | 0.63 |

Both treatment protocols resulted in significant improvements in pain and lesion size over the 6-month follow-up period. However, the combination therapy in Group B showed superior outcomes compared to Group A.

**Table 2: Changes in Pain Scores (VAS) and Lesion Size**

| Outcome Measure | Group A (n=25) | Group B (n=25) | p-value |
|---|---|---|---|
| Baseline VAS Score | 7.5 ± 1.2 | 7.4 ± 1.3 | 0.81 |
| VAS Score at 3 months | 5.1 ± 1.0 | 3.5 ± 1.1 | <0.01 |
| VAS Score at 6 months | 3.2 ± 0.9 | 2.0 ± 0.8 | <0.01 |
| Baseline Lesion Size ($cm^2$) | 2.4 ± 0.5 | 2.5 ± 0.6 | 0.63 |

| | | | |
|---|---|---|---|
| Lesion Size at 3 months ($cm^2$) | 1.5 ± 0.4 | 1.0 ± 0.3 | <0.01 |
| Lesion Size at 6 months ($cm^2$) | 1.0 ± 0.3 | 0.8 ± 0.2 | <0.01 |

**Pain Reduction:** Group A showed a mean reduction in VAS scores from 7.5 ± 1.2 at baseline to 3.2 ± 0.9 at 6 months, while Group B showed a mean reduction from 7.4 ± 1.3 to 2.0 ± 0.8 ($p<0.01$). The reduction in pain was significantly greater in Group B compared to Group A.

**Lesion Size Reduction:** Group A exhibited a mean reduction in lesion size from 2.4 ± 0.5 $cm^2$ at baseline to 1.0 ± 0.3 $cm^2$ at 6 months. Group B demonstrated a reduction from 2.5 ± 0.6 $cm^2$ to 0.8 ± 0.2 $cm^2$ ($p<0.01$). The reduction in lesion size was significantly greater in Group B compared to Group A.

Overall, the combination therapy of topical corticosteroids and systemic antihistamines was more effective in reducing both pain and lesion size in patients with symptomatic OLP, compared to topical corticosteroids alone.

## Discussion

The findings of this retrospective, randomized clinical trial demonstrate that the combination therapy of topical corticosteroids and systemic antihistamines is more effective in managing symptomatic Oral Lichen Planus (OLP) compared to topical corticosteroids alone.

Both treatment protocols resulted in significant improvements in pain and lesion size over the 6-month follow-up period, but the combination therapy showed superior outcomes. Topical corticosteroids have long been the mainstay of OLP treatment due to their potent anti-inflammatory effects [1,2]. In this study, patients in Group A, who received only topical corticosteroids, experienced a significant reduction in pain and lesion size, consistent with previous findings [3].

However, the addition of systemic antihistamines in Group B provided enhanced benefits. The mean reduction in pain scores (VAS) was significantly greater in Group B (from 7.4 to 2.0) compared to Group A (from 7.5 to 3.2). Similarly, the reduction in lesion size was more pronounced in Group B (from 2.5 $cm^2$ to 0.8 $cm^2$) compared to Group A (from 2.4 $cm^2$ to 1.0 $cm^2$).

Systemic antihistamines, such as cetirizine, possess immunomodulatory properties that may contribute to their efficacy in treating OLP [4].

The observed benefits in this study align with the hypothesis that systemic antihistamines can enhance the therapeutic effects of topical corticosteroids by reducing histamine-mediated inflammation and modulating immune responses [5]. Previous research has suggested that combination therapies can be more effective than monotherapies in managing chronic inflammatory conditions, and our findings support this notion in the context of OLP [6].

The clinical significance of these results is substantial. OLP is a chronic condition with a significant impact on patients' quality of life, often causing pain, discomfort, and functional impairments [7]. Effective management of OLP symptoms is crucial for improving patients' daily functioning and well-being.

The superior outcomes observed with combination therapy suggest that clinicians should consider this approach for patients who do not respond adequately to topical corticosteroids alone. Despite the strengths of this study, including its randomized design and comprehensive follow-up, there are limitations that must be acknowledged. The retrospective nature of the study may introduce selection bias, and the sample size was relatively small.

Additionally, the study was conducted at a single center in Darbhanga, Bihar, which may limit the generalizability of the findings. Future prospective studies with larger, more diverse populations are needed to confirm these results and further explore the mechanisms underlying the enhanced efficacy of combination therapy.

## Conclusion

In conclusion, this study provides evidence that the combination of topical corticosteroids and systemic antihistamines is more effective than topical corticosteroids alone in reducing pain and lesion size in patients with symptomatic OLP.

These findings have important implications for the management of OLP, highlighting the potential benefits of combination therapy in achieving better clinical outcomes.

## References

1. Thornhill MH, Sankar V, Xu XJ, Barrett AW, High AS, Odell EW, Speight PM, Farthing PM. The role of histopathological characteristics in distinguishing amalgam-associated oral lichenoid reactions and oral lichen planus. J Oral Pathol Med. 2006; 35(4): 233-240.
2. Ismail SB, Kumar SK, Zain RB. Oral lichen planus and lichenoid reactions: etiopathogenesis, diagnosis, management and malignant transformation. J Oral Sci. 2007; 49(2):89-106.
3. Al-Hashimi I, Schifter M, Lockhart PB, Wray D, Brennan M, Migliorati CA, Axéll T, Bruce AJ, Carpenter W, Eisenberg E, Epstein JB. Oral lichen planus and oral lichenoid lesions: diagnostic and therapeutic considerations. Oral

Surg Oral Med Oral Pathol Oral Radiol Endod. 2007; 103(S1) e1-S25.e12.
4. Sugerman PB, Savage NW. Oral lichen planus: causes, diagnosis and management. Aust Dent J. 2002; 47(4):290-297.
5. Cribier B, Frances C, Chosidow O. Treatment of lichen planus: an evidence-based medicine analysis of efficacy. Arch Dermatol. 1998; 134(12):1521-1530.
6. Shiohara T, Kano Y. Lichen planus and lichenoid dermatoses. In: Bolognia JL, Schaffer JV, Cerroni L, editors. Dermatology. 4th ed. Philadelphia: Elsevier; 2018. p. 154-169.
7. López-Jornet P, Camacho-Alonso F, Rodríguez-Wong V. Quality of life in patients with oral lichen planus. J Eval Clin Pract. 2010; 16(1):111-113.