International Journal of Basic & Clinical Pharmacology
Sindhu SJ et al. Int J Basic Clin Pharmacol. 2026 Jan;15(1):139-146
http://www.ijbcp.com
pISSN 2319-2003 | eISSN 2279-0780

DOI: https://dx.doi.org/10.18203/2319-2003.ijbcp20254164

Case Series

Beyond steroids: clinical outcomes of intralesional low molecular weight heparin in the management of oral lichen planus: a case series

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Received: 12 November 2025
Revised: 09 December 2025
Accepted: 10 December 2025

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ABSTRACT

The objective was to assess the clinical efficacy and safety of intralesional enoxaparin in symptomatic oral Lichen planus (OLP) management, coupled with a review of the literature. Ten patients with clinically and histopathologically diagnosed OLP were enrolled and treated with intralesional injections of enoxaparin (3 mg/ml) weekly for a period of eight weeks. Clinical parameters assessed were lesion type, pain according to the visual analogue scale (VAS), lesion severity according to the T-score, and quality of life (QoL) at both the initial visit and follow-up. Of the 10 patients included, the mean age was 40.0±17.78 years, with 60% female distribution, presenting most with erosive and reticular lesions in equal proportions. Outcomes revealed significant symptomatic improvement and clinical resolution, as highlighted by a sharp drop in VAS scores from 8.0 to 0.0, a drop in T-scores from 3.6 to 0.67, and an increase in QoL scores from 4.4 to 10.0, indicating complete resolution in daily functioning; there were no reported side effects. Weekly intralesional injections of enoxaparin are safe and represent an effective treatment modality in symptomatic OLP, improving pain symptoms, leading to resolution of lesions, and enhancing the QoL.

Keywords: Oral lichen planus, Intralesional injection, Low molecular weight heparin, Enoxaparin, Mucosal lesions

INTRODUCTION

Oral lichen planus (OLP) is a long-standing inflammatory condition that has a tendency to affect the skin and the oral mucous membrane but mucous membrane such as conjunctiva, esophagus and genitalia can be affected with a predominance of middle-aged female patients. The most frequent type of OLP is the reticular type and is typified by white lacy striae designated as Wickham striae followed by erosive type which is symptomatic and clinically apparent with desquamative gingivitis.

OLP is characterized by mechanism specific as well as nonspecific mechanism such as antigen specific killing of keratinocytes by CD 8 + cytotoxic T cells and other mechanism such as mast cell degranulation and activation of matrix metalloproteinase. The chronicity of the disease is due to the impaired antigen specific TGF B1 mediated immunosuppression.[1]

There are a number of treatment modalities of OLP have been reported like corticosteroid, immunomodulators like tacrolimus, pimecrolimus, dapsone, methotrexate etc., retinoid, phototherapy, photobiomodulation and others but no treatment modality has yet proven to be the single effective measure in controlling the disease. Corticosteroid have been used as first choice agent in the treatment of OLP. Intralesional injection of steroid has given successful result in OLP but continuous and long-

term use is related with several systemic adverse effect.[1] Low molecular weight heparin has emerged as a potential alternative due to the considerable side effects linked to chronic corticosteroid use. Keeping these considerations in view, there have been some authors who have explored the therapeutic potential of low molecular weight heparin in OLP treatment with encouraging outcomes in different clinical situations.

Heparin is an anticoagulant that inhibits the formation and extension of clots. Anticoagulants are a class of parenteral and oral drugs of which heparins fall under parenteral rapid onset anticoagulants.

Heparin comes in three forms unfractionated heparin, Low-molecular-weight heparin (e.g. Enoxaparin, Tinzaparin, Dalteparin) and Heparinoids (e.g. Danaparoid). Unfractionated heparin is now replaced by low molecular weight heparins as they are effective and safer. Enoxaparin, an FDA-approved low molecular weight heparin, offers several advantages including a longer half-life, simplified dose adjustment, and a reduced risk of bleeding complications.[2] Low doses of low molecular weight heparin have lymphoid anti proliferative and immunomodulatory actions. LP is defined by characteristics of a cell-mediated assault on the epidermis by activated T-lymphocytes.

The lymphocytes secrete an endoglycosidase (heparinase) during inflammation, enabling them to invade the sub epithelial basal lamina. Heparin inhibits T-lymphocyte heparinase, and thus T-cell hypersensitivity.[3] Enoxaparin inhibits T-cell-mediated release of a number of pro-inflammatory cytokines-such as IL-4, IL-5, IL-13, and TNF-α-that are involved in the pathogenesis of a number of inflammatory conditions.[4] This study seeks to assess the therapeutic potential of intralesional enoxaparin in OLP, while also reviewing relevant literature to support its clinical application.

CASE SERIES

Ten patients were included in this series with clinically and histopathologically (Figure 1) confirmed symptomatic OLP. Hematoxylin and eosin–stained sections reveal stratified squamous epithelium with focal areas of ulceration. The epithelium exhibits hyperkeratosis, hypergranulosis, saw-tooth rete ridges, and degeneration of basal cells. The subepithelial connective tissue stroma shows dense chronic inflammatory cell infiltration along with melanin incontinence. Deeper areas reveal the presence of muscle and adipose tissue. Features were suggestive of oral lichen planus. Each patient received intralesional injections of low molecular weight heparin (Enoxaparin) once a week. The treatment was continued until either complete regression of the lesion was observed or a maximum duration of eight weeks was reached, whichever occurred earlier.

Enoxaparin was prepared by diluting a pre-filled syringe containing 60 mg/0.6 ml of the drug with 19.4 ml of normal saline in a sterile biopsy container to obtain a concentration of 3 mg/ml. From this solution, 1 ml was administered intralesionally at each weekly visit. The clinical improvement was assessed using a VAS for pain at baseline and follow-up intervals, with T-scores for lesion severity and QoL was measured using the American chronic pain association scale.

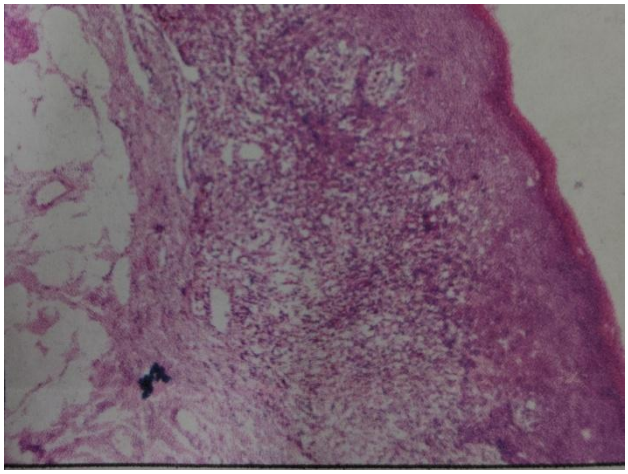

Figure 1: Histopathological image 10X.

Case 1

A 62-year-old female patient presented with 2-year history of OLP. At that time patient had atrophic erythematous area centrally circumscribed by white lacy reticular pattern on buccal mucosa bilaterally and the same lacy pattern also present on palatal region right side from the midline. At baseline, she reported severe pain, VAS of 8, and high lesion severity, T-score of 5, in association with a compromised QoL, QOL of 3. After the eight-week protocol with enoxaparin, the patient reached complete pain resolution, VAS of 0, and significant clinical healing, T-score of 1. QoL improved substantially to the maximum score, QOL of 10. The treatment was completed with no side effects reported and no further recurrence (Figure 2).

Case 2

A 51-year-old female patient presented with 1-year history of burning sensation in her cheek region. Patient had been previously treated with oral corticosteroids. After few months with little to no improvement in her lesion patient discontinued the corticosteroids. On intraoral examination white striae's present bilaterally on buccal mucosa with erosive content. The highest baseline pain score (VAS: 10) and a T-score of 4, with a severe clinical presentation. She completed the full treatment course and attained excellent therapeutic results. Her pain totally disappeared; VAS became 0, and the lesions regressed remarkably, as revealed by a T-score of 0. The QoL became normalized, that is, QOL was 10, and no adverse effects or signs of relapse were seen (Figure 3).

Case 3

A 39-year-old female patient presented with 1-year history of blisters in her upper lip. On intraoral examination striae's on upper labial mucosa with some atrophic erythematous areas were present. Her pain was initially moderate at VAS 8, and the T-score was similarly at 2 for lesion severity, but her QOL was compromised at 6. The patient was relieved up to 6 weeks of treatment. On final assessment, the pain had resolved to VAS 0, the lesion severity was minimal at a T-score of 1, and QOL reached the maximum score at 10 (Figure 4).

Case 4

A 32-year-old-man reported to Outpatient department with a 2-year history of burning sensation while having food. At presentation patient had white reticular striae's present at the periphery and centrally erosive area in vestibule w.r.t 34-37 and also on right buccal mucosa and lateral border of tongue. Patient has undergone laser ablation of the respective lesion 1 month later he returned with the same lesion. at baseline, severe pain (VAS: 8) and lesion severity (T-score: 5). The patient received all eight injections. This case demonstrated marked response, with VAS score dropping to 0, the T-score being reduced to 1, and the QoL improving to 9 (Figure 5).

Case 5

A 24-year-old female presented with reticular OLP. The initial metrics were VAS: 8, T-score: 4, and QOL: 4. While the treatment was completed, the pain, though much reduced, remained minimal at VAS: 1 on the final assessment. The T-score reduced to 1, and QOL normalized to 10.

Case 6

A 50-year-old female patient with reticular OLP presented with a high pain score at the beginning, VAS: 10, and T-score of 3. She completed the course of treatment, after which her pain completely resolved, VAS: 0, with the improvement of T-score to 1. This was, however, the only case that was reported to have a relapse, one month after completion on the left buccal mucosa. No immediate side effects were noted during the treatment.

Case 7

A 52-year-old female with erosive OLP was referred and had the following scores at presentation: VAS: 8, T-score: 3, and QOL: 5. She completed entire treatment schedule. At the final visit, her pain was completely gone (VAS: 0), the T-score dropped to 1, and QOL improved to 10.

Case 8

A 40-year-old male patient with reticular OLP had initial scores of VAS: 8, T-score: 3, and QOL: 5 and was successfully treated. All the final scores indicated full symptomatic and clinical control: VAS: 0, T-score: 1, and QOL: 10. No adverse events or relapses were noted.

Case 9

A male patient, whose age is not specified, was diagnosed with erosive OLP but presented only mild initial pain (VAS: 3). His T-score was 4, which means he had a moderate lesion with low pain. After completing his treatment, he had no more pain, VAS 0; his T-score was 1, and the quality of his life turned out to be 10.

Case 10

A 56-year-old male with reticular OLP presented with severe baseline pain (VAS: 9) and T-score of 3. This patient showed the least response among the cohort, though he completed the full eight-week course of treatment, with a final VAS score of 4 and T-score of 2. QOL score improved to 8. No side effects or relapse were noted.

Over the study period, 10 patients diagnosed with symptomatic OLP were included, with a mean age of 40.00±17.78 years**.** There were 4 males and 6 females, suggesting a slight female predominance in the study sample. Erosive type and reticular type LP were observed in 5 participants each. The lesions were predominantly bilateral, involving the buccal mucosa and/or lateral borders of the tongue. Table 1 summarizes the demographic and clinical characteristics of the study population.

Table 1: Demographic and clinical characteristics of the study participants.

Variables	Estimate
Age (in years)	40.00±17.78 Range: 5-62
Gender	Male: 4 Female: 6
Lesion	Erosive: 5 Reticular: 5

Evaluation of VAS score

Table 2 presents the results of VAS score over 8-week period. At baseline, the mean VAS score was 8.00±1.94, with scores ranging from 3 to 10, indicating a high level of pain/discomfort at the start. Thereafter, a progressive decrease in VAS scores was observed over the 8-week period, reflecting clinical improvement and healing. The decline in sample size over time (from 10 at baseline to 3 at 8 weeks) corresponds to healing of lesions and resolution of symptoms, leading to discontinuation of follow-up once recovery occurred. The results clearly demonstrate a steady and substantial reduction in pain intensity, with complete symptom resolution by week 8 in the remaining cases.

Evaluation of T score (Size of the lesion)

Table 3 presents the results of T score over 8-week period. The baseline mean T-score was 3.60±0.97, with scores ranging from 2-5, suggesting moderate to severe tissue involvement at start of observation. Thereafter, progressive decline in T-score was observed across the 8-week period, indicating clinical improvement and tissue healing. Overall trend shows consistent clinical improvement, with T-scores reducing toward zero, denoting near-complete or complete healing in the last weeks. By week 8, only 3 participants remained under observation, all showing minimal or no signs of lesion activity.

Evaluation of QoL score

Table 4 presents the results of QoL score over 8-week period. At baseline, the mean QoL score was 4.40±0.84, with a range of 3 to 6, indicating a moderate impairment in QoL due to the lesion. Thereafter, a consistent and progressive increase in QoL scores was observed over the 8-week period, reflecting improvement in daily functioning and well-being. The steady rise in QoL scores corresponds with the decline in VAS and T-scores, affirming that as pain and lesion severity decreased, patients' QoL improved significantly. By week 8, all remaining participants had reached the maximum QoL score (10), indicating complete recovery and restoration of normal life activities. Substantial decreases in VAS and T-scores were noted, which suggest a gradual reduction in pain severity and lesion severity, respectively. The VAS score from 8.0 at baseline improved to 0.0 by week 8, whereas T-scores decreased from 3.6 to 0.67, showing sustained mucosal healing. In contrast, QoL scores improved progressively from 4.4 to 10.0, showing overall improvement in patient health and daily function. The graphical trends observed in Figure 6 strongly support the clinical effectiveness of the intervention.

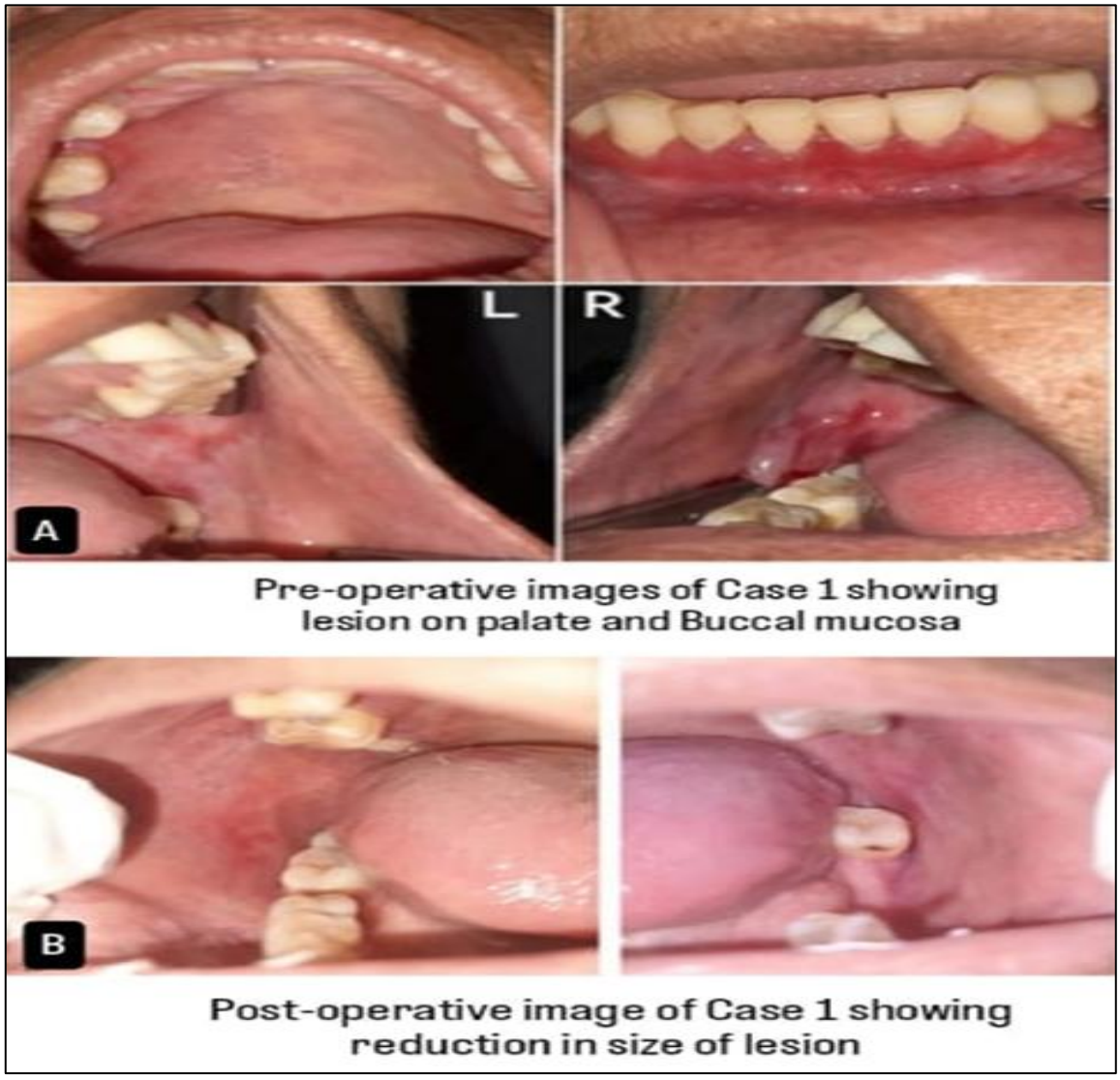

Figure 2 (A and B): Intraoral photographic series of case 1.

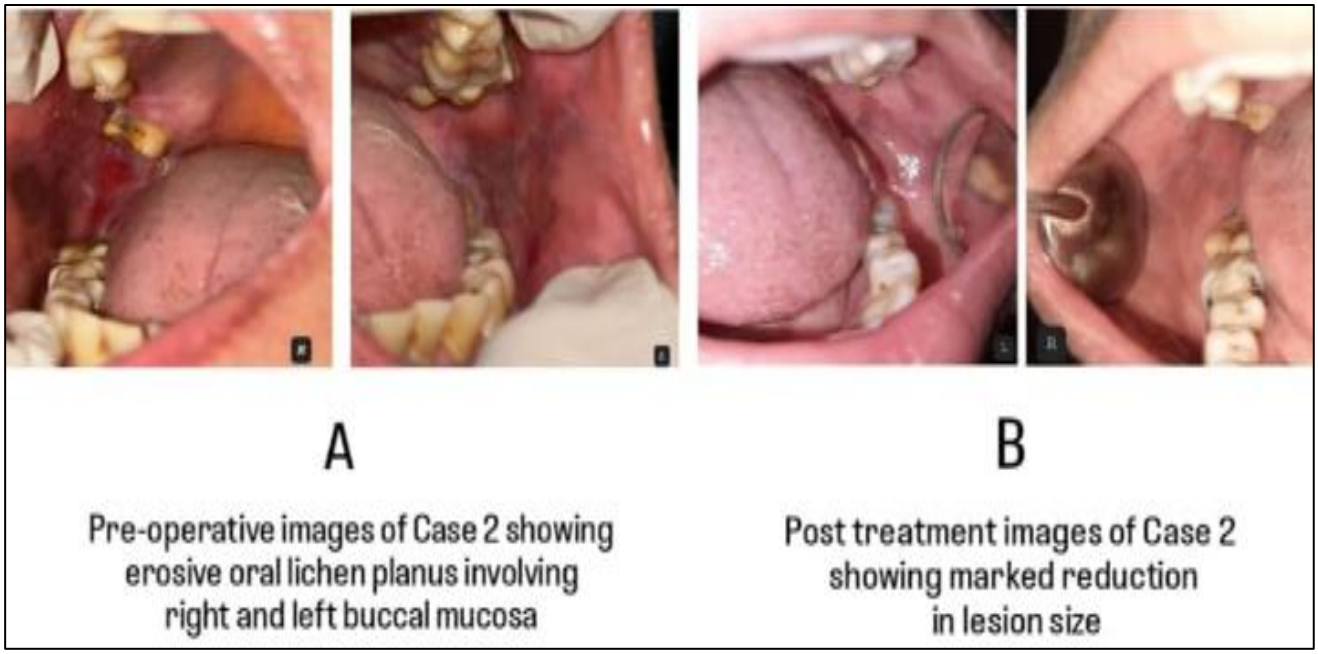

Figure 3 (A and B): Intraoral photographic series of case 2.

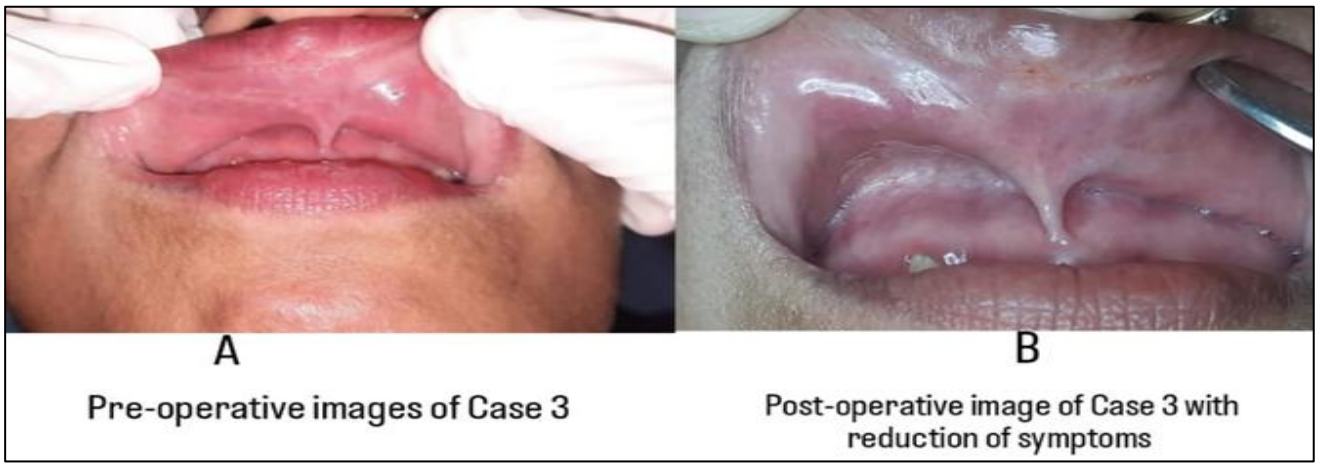

Figure 4 (A and B): Intraoral photographic series of case 3.

Figure 5 (A and B): Intraoral photographic series of case 4.

Table 2: Evaluation of VAS scores for pain over the 8-week follow-up period.

VAS score	N	Mean	SD	Minimum	Maximum
Baseline	10	8.00	1.94	3	10
1 week	10	6.30	1.95	2	9
2 weeks	10	5.50	1.72	2	7
3 weeks	10	4.30	1.89	0	7
4 weeks	9	3.78	1.79	1	7
5 weeks	8	3.38	2.39	0	6
6 weeks	7	1.86	2.12	0	5
7 weeks	4	2.25	1.50	1	4
8 weeks	3	0.00	0.00	0	0

Table 3: Evaluation of Thongprasom score for size over the 8-week follow up period.

T score	N	Mean	SD	Minimum	Maximum
Baseline	10	3.60	0.97	2	5
1 week	10	2.90	0.88	2	4
2 weeks	10	2.50	0.97	1	4
3 weeks	10	1.90	0.88	1	3
4 weeks	9	1.56	0.73	0	2
5 weeks	8	1.88	0.64	1	3
6 weeks	7	1.43	0.79	1	3
7 weeks	4	1.00	0.82	0	2
8 weeks	3	0.67	0.58	0	1

Table 4: Evaluation of QoL scores over the 8-week follow-up period.

QoL score	N	Mean	SD	Minimum	Maximum
Baseline	10	4.40	0.84	3	6
1 week	10	5.30	1.06	4	7
2 weeks	10	6.00	0.82	5	7
3 weeks	10	7.20	1.23	6	10
4 weeks	9	7.56	1.13	6	10
5 weeks	8	7.63	1.60	5	10
6 weeks	7	8.43	1.27	7	10
7 weeks	4	8.75	1.50	7	10
8 weeks	3	10.00	0.00	10	10

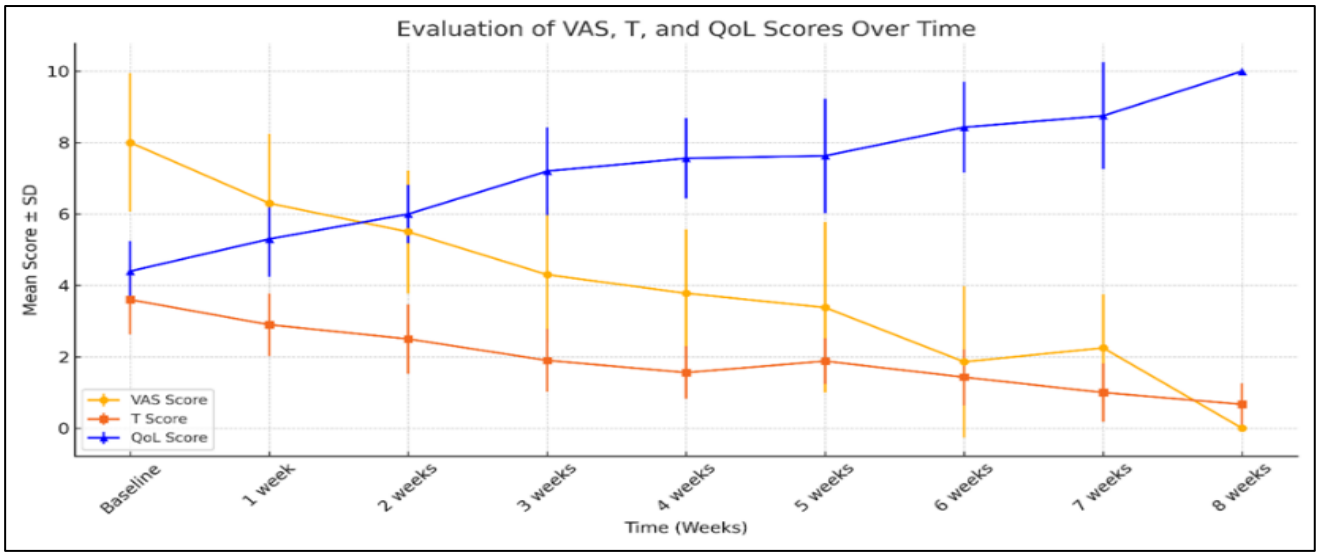

Figure 6: Evaluation of mean VAS, T-score, and QoL scores.

DISCUSSION

LP is a chronic mucocutaneous disease of the stratified squamous epithelium that occurs on oral and genital mucous membranes, skin, nails, and scalp. OLP is the mucosal equivalent of cutaneous LP. It is named from Greek word "leichen" means tree moss and Latin word "planus" means flat. In 1895, Wickham described the typical reticulate white lines on the surface of papules, now known as Wickham striae which is the characteristic feature of this disease.[5] While LP is a fairly frequent dermatological condition, the precise epidemiological figures are unknown; available data suggest a general prevalence of 1% with a global prevalence of 0.22-5% while in Western nations, aged 30-60 years are more impacted while in India, it is more common between 20 to 40 years. In our case series mean age group is 24-62 years.[6] In India, LP is more common among men, whereas in the west, slight female preponderance is reported. There are reports of equal incidence in both genders.[6] In our case series, there was a female predominance, consistent with previous reports suggesting a higher prevalence of OLP in women, potentially due to hormonal or autoimmune factors. The buccal mucosa was the most frequently affected site, with bilateral involvement observed in the majority of cases.

OLP is a T-cell mediated autoimmune disorder where cytotoxic CD8+ T cells induce apoptosis of basal keratinocytes in the oral epithelium. This process is triggered by the expression or unmasking of self-antigens (e.g., heat shock proteins) on keratinocytes. Langerhans cell activity is increased, enhancing antigen presentation.[5,6] It has been suggested that an unknown antigen is being processed by Langerhans cells, which activate T-lymphocytes that subsequently destroy the basal layer.[7] LMWHs block T-cell migration and delayed-type hypersensitivity action at a very low dose by competitively inhibiting the activity of heparinase from T lymphocytes. Heparinase is released by activated T lymphocytes in the inflammation area and is associated with the capacity of activated T lymphocytes to invade the extracellular matrix and migrate towards the target tissue. In addition to this, heparin could suppress tumor necrosis factor alpha production, which plays an important part in inflammation. It was shown that heparin also exhibits antiproliferative effects through interaction with keratinocyte generated, heparin-binding autocrine growth factors.[8,9] Low molecular weight heparins (LMWHs) are usually well-tolerated with minimal side effects, but rare severe reactions can occur. Routine monitoring is not required, except in certain groups like obese patients, children, pregnant women, or those with renal impairment, where factor Xa level monitoring is advised. Although LMWHs have primarily been used in a limited number of dermatological conditions, most studies have focused on LP. Additional evidence also suggests potential benefits in conditions such as recurrent aphthous stomatitis, chronic urticaria, contact hypersensitivity, and skin wound healing.[4,6]

Hodak et al first reported the use of low-dose enoxaparin (3 mg/week subcutaneously) in LP, achieving complete remission in 80% of patients, with early response seen within 2 weeks.[10] Iraji et al treated 25 patients with disseminated LP using 5 mg enoxaparin weekly for up to 8 weeks, resulting in complete remission in 32% and partial improvement in 40%; 7 showed no response.[11] Lunge et al used the same dose over a longer period (16-24 weeks) in 20 patients with generalized LP, achieving 65% complete remission; relapses were linked to treatment discontinuation.[5] Ghaffari et al demonstrated the effectiveness of systemic enoxaparin in managing recurrent aphthous stomatitis, showing significant reductions in pain, lesion size, and recurrence without side effects.[12] Similarly, our study found that intralesional LMWH led to marked improvement in pain, lesion severity (Figure 3 and 6), and QoL in OLP. Despite different administration routes, both studies support the efficacy of LMWH in immune-mediated oral conditions. In this study, there was a significant enhancement in the VAS scores in most of the patients by the fifth week of treatment. Although pain relief to some extent was reported as early as the first two weeks, an increase in relief of pain was consistently noted around the fifth week. Conversely, the lesion size showed a pronounced decrease in the first three weeks after the initiation of therapy. The QoL scores was also seen to respond early after injection, with considerable improvement by the third week. It should be noted that due to the low sample size, quantitative statistical analysis was not possible; therefore, results are based on clinical qualitative observations. Narendra Gajula et al reported that low-dose enoxaparin showed comparable efficacy to oral corticosteroids in treating LP, with fewer side effects. Corticosteroids remain the mainstay of treatment for OLP however, their long-term use is associated with notable side effects, such as gastric irritation, facial puffiness, and acneiform eruptions, often necessitating symptomatic management.3 In our case series, low-dose intralesional enoxaparin or low molecular weight heparin (3 mg weekly) was well tolerated, with no adverse effects reported in any of the patients. Clinical improvement was observed gradually, with most patients responding by the end of the 8-week treatment period suggest that LMWH may be more suitable as a second-line option. One patient experienced mild relapse during follow-up, highlighting the chronic and potentially recurrent nature of the disease.

CONCLUSION

This case series establishes that weekly intralesional injections of low molecular weight heparin (Enoxaparin) constitute a safe and extremely effective therapeutic modality for symptomatic OLP management. The marked improvements in clinical and symptomatic parameters, especially the sharp drop in mean Visual Analog Scale scores, lesion severity, as reflected by the mean Thongprasom score, coupled with concurrent normalization of QoL scores, highlight the robust efficacy of this intervention. More importantly, the absence of

reported adverse events confirms its favorable safety compared to the long-term use of conventional corticosteroid treatments. Thus, targeting the T cell-mediated autoimmune pathogenesis of OLP through inhibition of heparinase and pro-inflammatory cytokine release, this trial provides strong supportive clinical evidence for LMWH as a potent and well-tolerated therapeutic option, particularly in chronic and recurrent OLP, which recommends consideration for use as an alternative or adjuvant second-line agent to the corticosteroid standard of care.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: Not required

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Cite this article as: Sindhu SJ, Gupta S, Nagaraju K, Malik S, Singh S, Talwar A, et al. Beyond steroids: clinical outcomes of intralesional low molecular weight heparin in the management of oral lichen planus: a case series. Int J Basic Clin Pharmacol 2026;15:139-46.