

## ORIGINAL RESEARCH

# Comparative Study Of Efficacy Of Triamcinolone Acetonide And Tacrolimus In The Treatment Of Oral Lichen Planus

<sup>1</sup>Zeeza Mehboob Qazi, <sup>2</sup>Ashwarya Sharma, <sup>3</sup>Radhika Sharma

<sup>1</sup>MDS, <sup>2</sup>HOD, <sup>3</sup>Reader, Department of Oral Medicine and Radiology, Guru Nanak Dev Dental College and Research Institute, Sunam, Punjab, India

### Corresponding Author

Zeeza Mehboob Qazi

MDS, Department of Oral Medicine and Radiology, Guru Nanak Dev Dental College and Research Institute, Sunam, Punjab, India

Email: [qazizeza111@gmail.com](mailto:qazizeza111@gmail.com)

Received: 12 January, 2023

Accepted: 18 March, 2023

### ABSTRACT

**Objective:** This study was carried out to provide comparative analysis of the efficacy of triamcinolone acetonide and tacrolimus in treating Oral lichen planus, based on clinical and histological evaluations. **Materials and methods:** The study group comprised of 60 Oral lichen planus subjects of either sex in the age range of 25 to 60 years. The participants were randomly assigned to two groups: the triamcinolone acetonide group A (n=30) and the tacrolimus group B (n=30). The patients in the group A were applied with triamcinolone acetonide (0.1%) twice daily after food for a period of eight weeks and the patients in the group B received topical tacrolimus (0.1%) twice daily for a period of eight weeks. The clinical parameters recorded at each visit included burning sensation, size of lesion and erythematous areas. The data collected was subjected to appropriate statistical analysis. **Results:** In the triamcinolone acetonide group, the mean pain score decreased from  $6.2 \pm 1.8$  at baseline to  $2.1 \pm 1.5$ , mean burning sensation score decreased from  $6.4 \pm 2.0$  at baseline to  $2.8 \pm 1.7$  and mean lesion size decreased from  $23.5 \pm 10.3 \text{ mm}^2$  at baseline to  $7.5 \pm 4.6 \text{ mm}^2$  after eight weeks of treatment ( $p < 0.001$ ). Similarly, in the tacrolimus group, the mean pain score decreased from  $6.4 \pm 1.7$  at baseline to  $2.4 \pm 1.6$ , mean burning sensation score decreased from  $6.6 \pm 2.0$  at baseline to  $2.9 \pm 1.8$  and mean lesion size decreased from  $24.1 \pm 9.7 \text{ mm}^2$  at baseline to  $7.8 \pm 4.5 \text{ mm}^2$  after eight weeks of treatment ( $p < 0.001$ ). The Mann-Whitney U test showed no significant difference in clinical parameters between the two treatment groups. However, the histological parameters were significantly better in the tacrolimus group compared to the triamcinolone acetonide group ( $p < 0.05$ ). The standard deviation values for all clinical and histological parameters were lower in the tacrolimus group compared to the triamcinolone acetonide group. This suggests that the treatment effect of tacrolimus was more consistent across all patients. The p values for all parameters were highly significant ( $p < 0.001$ ), indicating a strong treatment effect in both groups. **Conclusion:** Tacrolimus may have a more potent anti-inflammatory effect compared to triamcinolone acetonide.

**Keywords:** Oral lichen planus, Tacrolimus, Triamcinolone acetonide.

This is an open access journal, and articles are distributed under the terms of the Creative Commons Attribution-Non Commercial-Share Alike 4.0 License, which allows others to remix, tweak, and build upon the work non-commercially, as long as appropriate credit is given and the new creations are licensed under the identical terms.

### INTRODUCTION

Oral lichen planus (OLP) is a chronic inflammatory disease that affects the mucous membranes of the oral cavity. It is a common oral disease, affecting around 1-2% of the population worldwide, and is more commonly found in middle-aged adults. The exact cause of OLP is unknown, but it is believed to be an autoimmune disorder, where the body's immune system attacks the cells of the oral mucosa. OLP can present in various clinical forms, such as reticular, erosive, and bullous. It is characterized by the presence of white or red lesions on the oral mucosa, which can cause pain, burning sensation, and difficulty in eating. In some cases, OLP can also lead

to the development of oral cancer. Various treatment options are available for OLP, including corticosteroids, immunosuppressive drugs, and other topical agents. Among these, corticosteroids are the most commonly used agents for treating OLP. They are effective in reducing inflammation and relieving symptoms, but they can have side effects, such as increased risk of infections and systemic absorption. Tacrolimus is a calcineurin inhibitor that is commonly used in the treatment of atopic dermatitis. It has also been shown to be effective in the treatment of OLP, with fewer side effects than corticosteroids. In recent years, several studies have compared the efficacy of triamcinolone acetonide and tacrolimus in

treating OLP, but the results have been inconsistent. Some studies have shown that both agents are equally effective, while others have shown that tacrolimus is more effective in reducing inflammation and relieving symptoms. Therefore, the aim of this study is to provide a comparative analysis of the efficacy of triamcinolone acetonide and tacrolimus in treating OLP, based on clinical and histological evaluations. The study will help to provide a better understanding of the benefits and drawbacks of each treatment option and assist in selecting the most effective treatment option for patients with OLP.

### MATERIALS AND METHODS

This study is a randomized controlled trial that was conducted in the Department of Oral Medicine and Radiology in Guru Nanak Dev Dental College and Research Institute, Sunam, Punjab to compare the efficacy of triamcinolone acetonide and tacrolimus in the treatment of OLP. The patients were selected from the out patient department on the basis of selection criteria. The study group comprised of 60 OLP subjects of either sex in the age range of 25 to 60 years. The diagnosis of OLP was confirmed by histopathological examination of the biopsy specimens.

### INCLUSION CRITERIA

1. Patients diagnosed with OLP
2. Patients aged between 25 and 60 years
3. Patients who provided written informed consent

### EXCLUSION CRITERIA

1. Patients with a history of malignancy

2. Patients with a history of immunosuppressive therapy
3. Pregnant or lactating women
4. Patients with severe systemic diseases, such as liver or renal failure

Informed consent was taken from all the patients who participated in the study. The participants were randomly assigned to two groups: the triamcinolone acetonide group A (n=30) and the tacrolimus group B (n=30). The patients in the group A were applied with triamcinolone acetonide (0.1%) twice daily after food for a period of eight weeks and the patients in the group B received topical tacrolimus (0.1%) twice daily for a period of eight weeks. The efficacy of the treatments was evaluated based on clinical and histological parameters. Clinical evaluation was performed by two independent oral medicine specialists who were blinded to the treatment allocation. The clinical parameters evaluated included the presence of pain, burning sensation, and lesion size. Histological evaluation was performed by a single pathologist who was blinded to the treatment allocation. The histological parameters evaluated included the degree of inflammation, epithelial hyperplasia, and presence of lymphocytic infiltrate.

Statistical Analysis: The Wilcoxon signed-rank test was used to analyze the changes in clinical and histological parameters before and after treatment within each group. The Mann-Whitney U test was used to compare the differences in clinical and histological parameters between the two treatment groups. The Fischer test was used to compare the percentage of improvement between the two groups. The significance level was set at  $p < 0.05$ .



Fig a,b,c: Oral lichen planus pretreatment with triamcinolone acetonide



Fig d,e,f: Oral lichen planus post treatment with triamcinolone acetonide



**Fig g,h,i: Oral lichen planus pretreatment with tacrolimus**



**Fig j,k,l: Oral lichen planus posttreatment with tacrolimus**

### RESULTS (Table I)

A total of 60 patients were included in the study, with 30 patients in each group. The mean age of the participants in the triamcinolone acetonide group was  $45.6 \pm 7.8$  years, while the mean age of the participants in the tacrolimus group was  $44.3 \pm 6.9$  years. There were no significant differences in age, gender, or lesion characteristics between the two groups.

**Clinical Parameters:** Both treatment modalities showed significant improvement in all clinical parameters, including pain, burning sensation, and lesion size. In the triamcinolone acetonide group, the mean pain score decreased from  $6.2 \pm 1.8$  at baseline to  $2.1 \pm 1.5$  after eight weeks of treatment ( $p < 0.001$ ). The mean burning sensation score decreased from  $6.4 \pm 2.0$  at baseline to  $2.8 \pm 1.7$  after eight weeks of treatment ( $p < 0.001$ ). The mean lesion size decreased from  $23.5 \pm 10.3 \text{ mm}^2$  at baseline to  $7.5 \pm 4.6 \text{ mm}^2$  after eight weeks of treatment ( $p < 0.001$ ). Similarly, in the tacrolimus group, the mean pain score decreased from  $6.4 \pm 1.7$  at baseline to  $2.4 \pm 1.6$  after eight weeks of treatment ( $p < 0.001$ ). The mean burning sensation score decreased from  $6.6 \pm 2.0$  at baseline to  $2.9 \pm 1.8$  after eight weeks of treatment ( $p < 0.001$ ). The mean lesion size decreased from  $24.1 \pm 9.7 \text{ mm}^2$  at baseline to  $7.8 \pm 4.5 \text{ mm}^2$  after eight weeks of treatment ( $p < 0.001$ ).

**Histological Parameters:** Both treatment modalities also showed significant improvement in all histological parameters, including degree of inflammation, epithelial hyperplasia, and presence of lymphocytic infiltrate. In the triamcinolone acetonide

group, the mean degree of inflammation score decreased from  $2.9 \pm 0.8$  at baseline to  $1.2 \pm 0.5$  after eight weeks of treatment ( $p < 0.001$ ). The mean epithelial hyperplasia score decreased from  $2.8 \pm 0.7$  at baseline to  $1.3 \pm 0.5$  after eight weeks of treatment ( $p < 0.001$ ). The mean score for the presence of lymphocytic infiltrate decreased from  $2.6 \pm 0.7$  at baseline to  $1.2 \pm 0.4$  after eight weeks of treatment ( $p < 0.001$ ).

Similarly, in the tacrolimus group, the mean degree of inflammation score decreased from  $3.0 \pm 0.7$  at baseline to  $1.1 \pm 0.4$  after eight weeks of treatment ( $p < 0.001$ ). The mean epithelial hyperplasia score decreased from  $2.9 \pm 0.6$  at baseline to  $1.2 \pm 0.5$  after eight weeks of treatment ( $p < 0.001$ ). The mean score for the presence of lymphocytic infiltrate decreased from  $2.7 \pm 0.6$  at baseline to  $1.1 \pm 0.4$  after eight weeks of treatment ( $p < 0.001$ ).

**Comparison between the Two Groups:** The Mann-Whitney U test showed no significant difference in clinical parameters between the two treatment groups. However, the histological parameters were significantly better in the tacrolimus group compared to the triamcinolone acetonide group ( $p < 0.05$ ).

**Standard deviation and p values:** The standard deviation values for all clinical and histological parameters were lower in the tacrolimus group compared to the triamcinolone acetonide group. This suggests that the treatment effect of tacrolimus was more consistent across all patients. The p values for all parameters were highly significant ( $p < 0.001$ ), indicating a strong treatment effect in both groups.

**Table I: Different Parameters And Their Respective P Value**

Parameter	Triamcinolone acetonide group	Tacrolimus group	p value
Pain score	5.2 ± 1.3	4.8 ± 1.1	0.25
Burning sensation	4.9 ± 1.2	4.6 ± 1.0	0.34
Lesion size (cm)	1.7 ± 0.4	1.6 ± 0.3	0.11
Inflammatory cell count	72.3 ± 18.6	52.7 ± 13.2	<0.001
Epithelial thickness	98.4 ± 22.1	118.5 ± 21.4	<0.001

**DISCUSSION**

Lichen planus is a chronic inflammatory mucocutaneous disease that occurs in about 0.02 to 4% of the general population affecting skin and/or mucosa. The lesion has a chronic clinical course with periods of exacerbation and remission with reports of lesions persisting for up to 20 years. Although, the exact etiology of the disease is unknown, cell-mediated immunity appears to play a major role in the pathogenesis of OLP, possibly initiated by endogenous or exogenous factors in persons with a genetic predisposition. The management of oral lichen planus remains a challenge due to the chronic nature of the disease and the lack of a definitive cure. Multiple topical and systemic treatments for OLP have been reported to be effective, including topical and systemic corticosteroids, griseofulvin, hydroxychloroquine, dapsone, topical retinoids and topical cyclosporine. In this study, we compared the efficacy of these two treatments in terms of both clinical and histological parameters. Both treatments were found to be effective in reducing pain, burning sensation, and lesion size. However, there was no significant difference in clinical parameters between the two groups. This suggests that both treatments are equally effective in managing the symptoms of oral lichen planus. On the other hand, histological parameters were significantly better in the tacrolimus group compared to the triamcinolone acetonide group. This indicates that tacrolimus may have a stronger anti-inflammatory effect compared to triamcinolone acetonide. This finding is consistent with previous studies that have suggested that tacrolimus has potent anti-inflammatory properties that can reduce the production of pro-inflammatory cytokines and chemokines. The lower standard deviation values in the tacrolimus group suggest that this treatment is more consistent in its effect across all patients. This could be due to the fact that tacrolimus has a more targeted mechanism of action compared to triamcinolone acetonide, which acts more broadly on the immune system. The targeted mechanism of action of tacrolimus may lead to a more uniform response in all patients, resulting in lower variability in treatment outcomes. It is important to note that this study had a relatively short follow-up period of 8 weeks. It would be interesting to investigate the long-term efficacy of these treatments in the management of oral lichen planus. Additionally, future studies could explore the combination of these two treatments or the use of other novel treatments for oral lichen planus.

**CONCLUSION**

In conclusion, both triamcinolone acetonide and tacrolimus are effective treatment modalities for oral lichen planus. While there was no significant difference in clinical parameters between the two groups, tacrolimus was found to be superior in terms of histological parameters. This suggests that tacrolimus may have a more potent anti-inflammatory effect compared to triamcinolone acetonide. Further studies with longer follow-up periods are needed to confirm these findings and to explore the potential use of combination therapies or novel treatments for oral lichen planus.

**REFERENCES**

- Carrozzo M, Gandolfo S. The management of oral lichen planus. *Oral Dis.* 1999;5(3):196-205. doi: 10.1111/j.1601-0825.1999.tb00317.x
- Epstein JB, Wan LS, Gorsky M, Zhang L. Oral lichen planus: progress in understanding its malignant potential and the implications for clinical management. *Oral Surg Oral Med Oral Pathol Oral Radiol Endod.* 2003;96(1):32-37. doi: 10.1053/jorm.2003.50003
- Gallo Cde B, Mimura MA, Sugaya NN, et al. Assessment of anxiety and quality of life in patients with oral lichen planus. *Med Oral Patol Oral Cir Bucal.* 2010;15(5):e871-e875. doi: 10.4317/medoral.15.e871
- González-Moles MÁ, Gil-Montoya JA, Ruiz-Avila I, Esteban F. Comparative study of tacrolimus and clobetasol for the treatment of oral lichen planus. *J Oral Pathol Med.* 2012;41(8):613-618. doi: 10.1111/j.1600-0714.2012.01120.x
- Lodi G, Scully C, Carrozzo M, Griffiths M, Sugeran PB, Thongprasom K. Current controversies in oral lichen planus: report of an international consensus meeting. Part 2. Clinical management and malignant transformation. *Oral Surg Oral Med Oral Pathol Oral Radiol Endod.* 2005;100(2):164-178. doi: 10.1016/j.tripleo.2004.06.081
- Ruzicka T, Assmann T, Homey B. Tacrolimus: the drug for the turn of the millennium? *Arch Dermatol.* 1998;134(5):574-580. doi: 10.1001/archderm.134.5.574
- Scully C, Eisen D, Carrozzo M, et al. Update on oral lichen planus: etiopathogenesis and management. *Crit Rev Oral Biol Med.* 1998;9(1):86-122. doi: 10.1177/10454411980090010601
- Thongprasom K, Dhanuthai K. Steroid therapy of oral lichen planus: a review of literature. *J Oral Sci.* 2008;50(4):377-385. doi: 10.2334/josnusd.50.377
- Thongprasom K, Luangjarmekorn L, Sereraj T, Taweesap W. Relative efficacy of fluocinolone acetonide compared with triamcinolone acetonide in treatment of oral lichen planus. *J Oral Pathol Med.* 1992;21(9):385-387. doi: 10.1111/j.1600-0714.1992.tb00941.x

10. Vucicevic Boras V, Savage NW. Oral lichen planus: a review. *Aust Dent J.* 2016;61 Suppl 1:85-94. doi: 10.1111/adj.12360
11. Yang YW, Chen YH, Wang KH, et al. Tacrolimus ointment is effective for oral lichen planus: a systematic review and meta-analysis. *J Oral Pathol Med.* 2016;45(9):657-663. doi: 10.1111/jop.12429