



ORIGINAL ARTICLE

## Comparison and evaluation of efficacy of tacrolimus 0.1% and triamcinolone acetonide 0.1% in the management of symptomatic oral lichen planus.

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**ABSTRACT... Objective:** To evaluate and compare the effectiveness of tacrolimus 0.1% and triamcinolone acetonide 0.1% used topically to treat symptomatic OLP. **Study Design:** Cross sectional study. **Setting:** Oral Medicine Isra Dental College Hyderabad. **Period:** 1<sup>st</sup> February 2022 to 31<sup>st</sup> January 2023. **Material & Methods:** Total 60 clinically diagnosed patients of symptomatic oral lichen planus were included in study, 60 patients were equally divided into two groups as Group A and group B. Thirty patients of OLP group A were treated with Tacrolimus 0.1% four times per day for four weeks and patients of group B were treated with Triamcinolone Acetonide 0.1% ointment. **Results:** Total 60 symptomatic OLP patients were categorized into to equal groups A and B group. OLP was commonly found in female as compare to male, VAS score and clinical score was calculated before and after the treatment, the mean VAS score of group A was 9.2 (SD±2.07) and group B was 8.9 (SD±2.07) before the treatment. While VAS score of group A 1.9 (SD±1.18) which was treated with tacrolimus (0.1%) and group B score was 2.3 (SD±1.49) which was treated with triamcinolone (0.1%) after the treatment. The mean clinical score of group A was 4.2 (SD±1.14) and 4.6 (SD±1.28) in group B before treatment. Mean clinical score was 1.8 (SD±0.87) in group A and 2.4 (SD±0.9) in group-B after treatment. **Conclusion:** Study reported Tacrolimus 0.1% is more effective then triamcinolone 0.1% for the treatment of symptomatic OLP however there was no reoccurrence found.

**Key words:** Oral Lichen Planus, Tacrolimus 0.1%, Triamcinolone Acetonide 0.1%.

### INTRODUCTION

Oral lichen planus is a chronic inflammatory condition that affects the mucous membranes in the mouth. It is a type of lichen planus, which can also affect the skin, nails, and scalp.<sup>1</sup> Oral lichen planus usually appears as white, lacy patches or lesions on the inside of the cheeks, tongue, gums, or roof of the mouth.<sup>2</sup> The exact cause of oral lichen planus is unknown, but it is believed to be an autoimmune disorder in which the body's immune system attacks the mucous membranes in the mouth.<sup>3</sup> Certain medications, allergies, and infections may also contribute to the development of the condition. Symptoms of oral lichen planus can vary from mild to severe and may include pain, burning, or itching in the mouth, difficulty eating or drinking, and sensitivity

to hot or spicy foods. Although there is no cure for oral lichen planus, treatment can help to manage symptoms and prevent complications. Treatment may include topical or systemic corticosteroids, immunosuppressive drugs, or phototherapy.<sup>4</sup>

The prevalence of oral lichen planus (OLP) varies widely depending on the population being studied and the diagnostic criteria used. In general, OLP is considered a relatively rare condition, with a prevalence ranging from 0.1% to 4% of the general population.<sup>5</sup> Studies have found that OLP is more common in middle-aged or older adults and affects women more frequently than men. It is also more prevalent in certain populations, such as individuals of Asian or Hispanic descent. In addition, individuals with certain underlying

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health conditions, such as hepatitis C infection, may be at a higher risk of developing OLP. It is important to note that OLP is considered a chronic condition, meaning that symptoms can persist for months or even years.<sup>6</sup>

Tacrolimus is belongs to a class of drugs called calcineurin inhibitors. It is primarily used as an immunosuppressive agent to prevent organ rejection in individuals who have received a transplant.<sup>7</sup> Tacrolimus works by suppressing the immune system, which helps to prevent the body from attacking the transplanted organ. In addition to its use as an immunosuppressant, tacrolimus has also been found to be effective in the treatment of certain inflammatory skin conditions, including atopic Oral lichen planus and psoriasis. It works by inhibiting the activation of T-cells, which are involved in the inflammatory response.<sup>8</sup> Tacrolimus is proven an effective steroid in the treatment of oral lichen planus by many research studies.

Triamcinolone acetonide 0.1% is a synthetic corticosteroid that is used to reduce inflammation, swelling, redness, and itching associated with various skin conditions such as eczema, dermatitis, psoriasis, and allergic reactions. It is available in various forms such as creams, ointments, lotions, and solutions. Triamcinolone is most commonly prescribed ointment for the effective treatment of oral lichen planus.<sup>9</sup>

The progression of OLP into oral squamous cell carcinoma is its most serious medical condition, according to the World Health Organization, which classifies OLP as one of a group of potentially malignant illnesses.<sup>10</sup> Oral lichen planus association has been reported with hepatitis C and diabetes which may effect on survival and quality of life of patients.<sup>11</sup> Therefore study was planned to evaluate Tacrolimus 0.1% and Triamcinolone for the effective treatment therapy of symptomatic oral lichen planus.

## MATERIAL & METHODS

This comparative cross sectional study was carried out at the oral medicine department and oral Pathology Department, Isra dental

college, Faculty of dentistry and allied sciences, Hyderabad Sindh, from 1st February 2022 to 31st January 2023. The Ethical Committee of Isra University Hyderabad reviewed and approved (IU/RR-10/AQK/2021/1962) the study protocol.

Total sixty patients of clinically diagnosed patients symptomatic oral lichen planus after taking written consent were enrolled in study. Patients with diabetes mellitus, hypertension, and known history of hypersensitivity to tacrolimus and triamcinolone acetonide as well as those on systemic steroid therapy were excluded from the study.

All sixty patients were randomly divided equally into two groups as "group A" and "group B". VAS score before treatment of both group recorded to compare the results before and after the treatment. In group A, 30 OLP patients were treated with topical tacrolimus 0.1% ointment by the finger, which was applied four times a day onto the symptomatic oral lesions, patients were advised to not eat or drink minimum half hour after using ointment. In group B 30 patients were treated with Triamcinolone acetonide 0.1% four times in a day for four weeks.

After four weeks, patients of both group were assessed by visual analogue scale, the symptoms associated with the lesions were graded on a VAS during each clinical evaluation, with the severity of symptoms ranging from '0' (no pain or discomfort) to '10' (severe most pain/discomfort), At every clinical evaluation, patients were asked to rate the severity of their symptoms on the VAS, which helped the treating physician to assess the effectiveness of the treatment. By using a VAS, the study could capture the patients' subjective experience of their symptoms, including pain and discomfort, which can be difficult to measure objectively.

According to the standards outlined by Thongaprasom et al., the lesions' size and degree of erythema were clinically scored. Complete, partial, or no response were used to classify clinical scores.

All the recorded data were compiled on the MS excel (2007) and analyzed by SPSS version 2.0.

**RESULTS**

Total 60 patients of OLP were included in this study. Study found OLP is more common in female as compare to male, there were thirty eight female OLP patient and 22 patients were male OLP patients. The mean age was 36.8 years for males and 38.1 years for females (shown in Table-I).

The site of lesion were recorded at the time of diagnosis for each patient, the most common site of lesion was buccal mucosa (bilaterally) 37% followed by tongue 27%, gingiva 20%, lip 10% and palate was observed least common site of lesion (As shown in Table-II).

Visual analogue scale score was calculated to assess the severity of pain, the mean VAS score of group A was 9.2 (SD±2.07) and group B was 8.9 (SD±2.07), before the treatment. While VAS score of group A 1.9 (SD±1.18) which was treated with tacrolimus (0.1%) and group B score was 2.3 (SD±1.49) which was treated with triamcinolone (0.1%) after the treatment. There was found significance in score of both A and B group before and after the treatment (shown in Table-III).

The clinical scoring of the lesions for the size and degree of erythema was also done as per the criteria described by Thongaprasom et al (as shown in table-V) before and after the treatment. The mean clinical score of group A was 4.2 (SD±1.14) and 4.6 (SD±1.28) in group B before treatment. Mean clinical score was 1.8 (SD±0.87) in group A and 2.4 (SD±0.9) in group 2 after treatment (shown in Table-IV). There was also found significance in both groups after and before the treatment.

After the data analysis, study found reductions of complications and clinical sign and symptoms of symptomatic OLP in patients after use of both Tacrolimus 0.1% and Triamcinolone 0.1%, but tacrolimus ointment is more effective as compare to Triamcinolone 0.1%. There was no any

reoccurrence reported after treatment.

Gender	N (%)	Mean Age
Male	22 (37%)	36.8
Female	38 (63%)	38.1
Total	60 (100%)	-

**Table-I. Demographical features of OLP patients**

Commonest Site Involved at Onset		
Site	N	%
Buccal mucosa	22	37%
Tongue	16	27%
Gingiva	12	20%
Lip	06	10%
Palate	04	6%
Total	60	100%

**Table-II. Site of lesion in OLP patients**

Group	Before Treatment	After Treatment	P-Value
	Mean±SD	Mean±SD	
Group-A	9.2±2.07	1.9±1.18	<0.003
Group-B	8.9±2.07	2.3±1.49	<0.003

**Table-III. VAS score of OLP patients of group-A and Group-B**

Group	Before Treatment		After Treatment		P-Value
	Mean	SD	Mean	SD	
Group-A	4.2	1.14	1.8	0.87	<0.002
Group-B	4.6	1.28	2.4	0.9	<0.004

**Table-IV. Clinical score of OLP patients group-A and group-B**

Stage Sign	
Score 0	No lesion, normal mucosa
Score 1	Mild white striae, no erythematous area
Score 2	White striae with atrophic area less than 1 cm <sup>2</sup>
Score 3	White striae with atrophic area more than 1 cm <sup>2</sup>
Score 4	White striae with erosive area less than 1 cm <sup>2</sup>
Score 5	White striae with erosive area more than 1 cm <sup>2</sup>

**Table-V. Sign and stage by thongprasom**

**DISCUSSION**

A chronic inflammatory oral mucosal is relatively common disorder of the stratified squamous epithelia. It is a chronic, immunological, mucocutaneous disease with a wide range of clinical manifestation and unclear etiology, which is mediated by T cells.



Figure-1. Clinical evaluation of OPL patients before treatment

OLP mostly affects the buccal mucosa, tongue, and gingiva and manifests as white striations, papules, plaques, erythema, erosions, or blisters.<sup>12</sup> OLP is reported as premalignant lesion which can transform into oral squamous cell carcinoma.<sup>13</sup>

OLP effective treatment along with lesser side effects is a major health discussion, OLP is treated with steroids since many years but after treatment side effects are also recorded in many researches, this current study investigated the effective treatment for the OLP patient by Tacrolimus 0.1% and triamcinolone 0.1%.

In current study 60 patients of symptomatic OLP were included in study and demographical features including age, gender and site lesion were recorded. Study reported symptomatic OLP found more commonly female (63%) as compare to male (37%). The mean age of man was 36.8 and women was 38 (as shown in Table-I). Buccal mucosa (37%) was found most common site of lesion followed by tongue (27%), gingiva (20%), lip (10%) and palate was found least common site as shown in Table-II.

According to Manjunatha M Revanappa et al (2012) male was found most common gender found in study as compare to female and study also found buccal mucosa as common site of lesion as current study reported.<sup>14</sup>

Severity of pain was measure by visual analogue

scale before treatment and after treatment of both groups of OLP patients. Mean VAS score of Group-A was calculated before treatment as  $9.2 \pm 2.07$ . VAS score of group-B was  $8.9 \pm 2.07$  before the treatment. While mean VAS score of Group-A was  $1.9 \pm 1.18$  after treatment with Tacrolimus 0.1%, and mean VAS score of group-B was  $2.31.4 \pm 9$  after treatment with Triamcinolone 0.1% as shown in Table-III.

Oral lichen planus patients were clinically evaluated before treatment and after treatment by the "Thongprasom" criteria and was scored according to given parameters as shown in Table-V. Clinical score of group-A was  $4.2 \pm 1.14$  and group-B was  $4.6 \pm 1.28$  before the treatment. After treatment given to both of groups, mean clinically score was measure as  $1.8 \pm 0.87$  for group-A and  $2.4 \pm 0.9$  as mention in Table-IV.

The current study result was comparable with Chalkoo, et al (2022) study had done in sarinagar, this study also reported that both Tacrolimus 0.1% and Triamcinolone 0.1% was effective treatment for the symptomatic oral lichen planus in both groups but according to VAS score and clinically evaluated score indication Tacrolimus 0.1% is proven more effective than Triamcinolone 0.1%.<sup>15</sup>

## CONCLUSION

The study's findings suggest that tacrolimus 0.1% is more effective than triamcinolone acetonide 0.1%, for the management of symptomatic oral lichen planus. Additionally, the lack of noticeable







side effects is encouraging. The study didn't find reoccurrence of symptomatic oral lichen planus after treatment.

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### AUTHORSHIP AND CONTRIBUTION DECLARATION

No.	Author(s) Full Name	Contribution to the paper	Author(s) Signature
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2	Manorma Maheshwari	Data analysis, suggestions, Data interpretation, experimental work.	
3	Marhaba Shaikh	Data analysis and result interpretation.	
4	Wajid Ali Rajper	Study design, Patient selection, data collection, experimental work and results interpretation.	
5	Shafqat Hussain Khuwaja	Data collection, drafting in literature search.	
6	Arjeet Kumar	Drafting discussion chapter, Data analysis, drafting the manuscript.	
7	Waqas Iqbal	Results interpretation.	