

Assessment of different treatment modalities for the treatment of Oral Lichen Planus: A comparative study

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Abstract

Background: Oral lichen planus (OLP) is chronic inflammatory disease which presents frequently in the fourth decade of life and affects women more than men in a ratio of 1.4:1. Treatment of symptomatic oral lichen planus remains a challenging problem. Hence; we planned the present study to comparatively evaluate the efficacy of 0.1% topical tacrolimus and 0.1% triamcinolone acetonide ointment in the treatment of OLP. **Materials & Methods:** The present study included assessment of 30 patients who were diagnosed with OLP. All the patients were divided broadly into two study groups with 15 patients in each study group. Group A included patients who were treated with topical tacrolimus 0.1% ointment. Group B included patients who were treated with triamcinolone acetonide 0.1% ointment. All the results were analyzed by SPSS software. **Results:** Mean age of the patients of the group A and group B patients was found to be 52.2 and 56.3 years respectively. Healing was seen in 28 and 12 percent of the cases of group A and group B patients respectively. No change in the signs and symptoms was observed in the 10 and 54 percent of the patients of group A and Group B respectively. **Conclusion:** Useful results might be obtained in treating OLP patients with topical tacrolimus.

Key words: Oral Lichen Planus, Tacrolimus, Triamcinolone

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INTRODUCTION

Lichen planus is a chronic inflammatory disease that affects the skin and the mucous membrane. The counterpart of Lichen Planus occurring in oral mucosa is Oral lichen planus (OLP) which presents frequently in the fourth decade of life and affects women more than men in a ratio of 1.4:1.¹ The disease affects 1–2% of the population. It is seen clinically as reticular, papular, plaque-like, erosive, atrophic or bullous types. The buccal mucosa, tongue and the gingiva are commonly involved intra-oral sites although other sites may be rarely affected.² Oral mucosal lesions present alone or with concomitant skin lesions. The skin lesions present as violaceous flat-topped papules in ankles, wrist, and genitalia, but characteristically the facial

skin is spared. Treatment of symptomatic oral lichen planus remains a challenging problem.³ Hence; we planned the present study to comparatively evaluate the efficacy of 0.1% topical tacrolimus and 0.1% triamcinolone acetonide ointment in the treatment of OLP.

MATERIALS & METHODS

The present study was conducted in the department of Oral medicine of the dental institution and included assessment of 30 patients who were diagnosed with OLP.

Exclusion criteria were:

- Patients of age younger than 18 years;
- Histopathological examination with atypical or lichenoid dysplastic features;

- asymptomatic oral lesions and
- specific treatment within one month prior to the study.

Treatment of all the patients was done for two months. Treatment was discontinued earlier when patients showed a complete healing. The follow-up period was for at least 3 months. Treatments were randomly allocated to patients in order of inclusion according to a predetermined randomization-list stratified by sex. Ethical approval was taken from institutional ethical committee and written consent was obtained in written after explaining in detail the entire research protocol. All the patients were divided broadly into two study groups with 15 patients in each study group. Group A included patients who were treated with topical tacrolimus 0.1% ointment. Group B included patients who were treated with triamcinolone acetonide 0.1% ointment. The reasons for this administration schedule in both groups were to achieve a comparable level of patient compliance and to achieve effective numbers of application of the ointments because topical agents do not easily adhere to the moist mucous membranes. The clinical effect of treatment in the patients was graded after 6 weeks by the treating physician using an ordinal score and recorded as worse, unchanged, improved or healed. All the results were analyzed by SPSS software. Chi-square test and student t test was used for the assessment of level of significance. P-value of less than 0.05 was taken as significant.

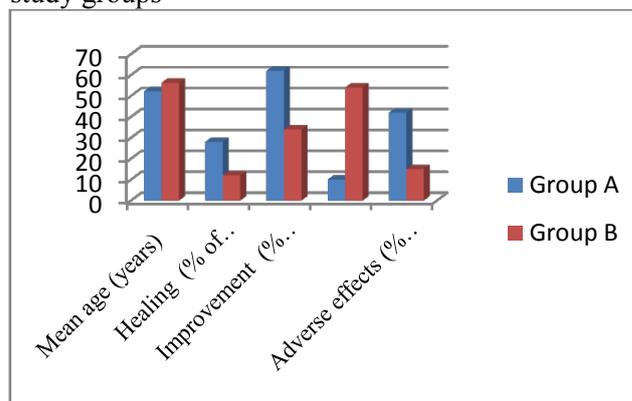
RESULTS

Comparison of improvement in the signs and symptoms and adverse effects in the patients of the two study group is shown in **Table 1** and **Graph 1**. Mean age of the patients of the group A and group B patients was found to be 52.2 and 56.3 years respectively. Healing was seen in 28 and 12 percent of the cases of group A and group B patients respectively. No change in the signs and symptoms was observed in the 10 and 54 percent of the patients of group A and Group B respectively.

Table 1: Comparison of improvement in the to study groups

Parameter	Group A	Group B	P-value
Mean age (years)	52.2	56.3	0.25
Results after 2 months of treatment (% of subjects)	Healing	12	0.02
	Improvement	34	
	No change	54	
Adverse effects (% of subjects)	42	15	0.03

Graph 1: Comparison of improvement in the to study groups



DISCUSSION

Lichen planus is a comparatively common, mucocutaneous disorder that is mediated immunologically. It can also be autoimmune in pathogenesis. It is chronic in occurrence, with periods of exacerbations and remission.⁴⁻⁶ Oral lichen planus is classically present as lesion with radiating whitish gray lines thread like papules, velvety appearance, bilateral in presentation.⁷ They can be lacy or reticular, annular, patches or strings. Several treatment modalities have been proposed for the treatment of OLP.⁸ Hence; we planned the present study to comparatively evaluate the efficacy of 0.1% topical tacrolimus and 0.1% triamcinolone acetonide ointment in the treatment of OLP.

In the present study, we observed that in comparison with triamcinolone acetonide, better results are obtained with topical tacrolimus in treating OLP patients. Malhotra et al evaluated the efficacy and safety of betamethasone OMP in patients with symptomatic moderate to severe oral lichen planus and to compare it with topical triamcinolone acetonide. In all, 49 patients with moderate to severe oral lichen planus were randomly allocated to receive either OMP comprising 5 mg of betamethasone orally on 2 consecutive days per week (group A) or triamcinolone acetonide (0.1%) paste application thrice daily (group B), for 3 months followed by stepwise tapering during the next 3 months. Treatment response was assessed by the change in the score, which was based on the number of sites involved and the area affected. The changes in the symptoms and side effects were also recorded. Patients were followed up after treatment for 3 months to look for relapse. In all, 23 of 25 patients in group A and 23 of 24 patients in group B

completed the study. Good to excellent response was seen in 17 of 25 (68.0%) patients in group A as compared with 16 of 24 (66.0%) in group B at 6 months. Symptom-free state was achieved in 13 of 25 (52%) patients in group A and 12 of 24 (50%) in group B. The difference in the mean scores within each group was statistically significant from the fourth week onward in group A and eighth week onward in group B, whereas in patients with erosive disease it was second and twelfth week onward, respectively. The difference in the treatment response between the two groups was statistically significant only at week 24 when reduction in severity score was more in triamcinolone group. Side effects were seen in 14 (56%) patients in group A and 6 (25%) patients in group B, which were mild and reversible. Relapse occurred in 9 of 23 (39.1%) patients in group A after 13.78 +/- 6.96 weeks as compared with 5 of 23 (21.7%) in group B after 19.20 +/- 1.79 weeks. The study was not blinded and the change in the quality of life with treatment was not measured. Betamethasone OMP improves the clinical outcome in patients with moderate to severe oral lichen planus. When compared with topical triamcinolone acetonide it is equally effective but the response is earlier, especially in erosive disease. It may be a useful and convenient alternative either as a monotherapy or to achieve rapid symptomatic relief during periods of exacerbations.^{9,10}

Gorouhi et al compared the efficacy and safety of pimecrolimus 1% cream with triamcinolone acetonide 0.1% paste in treating OLP. In this investigator-blinded parallel-group randomized clinical trial, 40 patients were randomly assigned in two equal groups to receive either pimecrolimus 1% cream or triamcinolone acetonide 0.1% paste 4 times daily for a total of 2 months and followed up for another 2 months. The patients were assessed for painful symptoms measured by visual analog scale, the Oral Health Impact Profile score, and objective clinical score. Nonparametric tests were used to assess the main outcomes. Intention-to-treat analysis was used. Eighteen patients in pimecrolimus group and 17 patients in triamcinolone group finished the 4-month trial course. Both pimecrolimus and triamcinolone groups showed significant improvement in all measured efficacy end points throughout the visits. There was no significant difference between changes from baseline median values of pimecrolimus and triamcinolone groups after treatment termination in terms of visual analog scale score, Oral Health Impact Profile score, and

clinical score, respectively. Two patients in pimecrolimus group experienced prominent but transient burning sensation whereas none of the patients in triamcinolone group had any prominent adverse event ($P = .24$). Blood levels in pimecrolimus group were not measured and carcinogenicity of pimecrolimus, especially in its long-term use for OLP, is yet to be determined. This study showed that patients with OLP may benefit from both topical pimecrolimus and triamcinolone acetonide therapy with minimal side effects.^{11,12}

CONCLUSION

From the above results, the authors concluded that useful results might be obtained in treating OLP patients with topical tacrolimus. However, future studies are recommended.

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