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Original Research

Tacrolimus and clobetasol in management of oral lichen planus- A comparative study

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ABSTRACT:

Background: Oral lichen planus is a common disease of the oral mucosa with a worldwide distribution. The present study was conducted to compare tacrolimus and clobetasol in management of oral lichen planus. **Materials & Methods:** The present study was conducted on 84 patients of oral lichen planus of both genders. Patients were divided into 2 groups of 42 each. Group I was those who were prescribed tacrolimus (0.1%) cream and group II patients were prescribed clobetasol propionate (0.05%). Patients were examined and recalled regularly to see size of the lesions. VAS score and TC score was compared before treatment, after 3 weeks and 5 weeks. **Results:** Group I patients received tacrolimus (0.1%) cream and group II patients were prescribed clobetasol propionate (0.05%). Both groups had 42 patients each. Mean VAS score in group I before treatment was 2.1, after 3 weeks was 1.2 and 5 weeks was 0.7. Mean VAS score in group II before treatment was 2.4, after 3 weeks was 1.6 and 5 weeks was 1.0. The difference was significant (P< 0.05). Mean TC score (cm) in group I before treatment was 2.9, after 3 weeks was 1.5 and 5 weeks was 0.8. In group II before treatment was 2.8, after 3 weeks was 1.7 and 5 weeks was 1.2. The difference was significant (P< 0.05). **Conclusion:** Authors found that tacrolimus 0.1% cream is an effective alternative to topical steroid and can be considered a first-line therapy in OLP.

Key words: Clobetasol, tacrolimus, Oral lichen planus

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INTRODUCTION

Oral lichen planus (OLP) is a common disease of the oral mucosa with a worldwide distribution and an overall prevalence of 0.5–2.2%.[1] A wide range of factors have been implicated in the occurrence and exacerbation of this condition, but its exact etiology remains unclear. The role of autoimmunity is supported by its association with other autoimmune diseases and the presence of autocytotoxic T cell clones in the lesions. Oral lichen planus commonly presents in subjects aged 30–60 years and has a slightly higher prevalence in women. The symptoms of OLP can be extremely distressing and disabling at times, and the condition is known to undergo malignant transformation in 0.4–5.6% of cases.[2]

Various treatment regimens have been developed to manage symptomatic OLP, but a permanent cure is not yet available. Different drugs have been used in the form of topical or systemic administration for the treatment of OLP.[3] Drugs used in the topical form are corticosteroids, immunosuppressives, retinoids, and immunomodulators. Drugs used systemically are thalidomide, metronidazole, griseofulvin, hydroxychloroquine, some retinoids, and corticosteroids. Recent reviews on OLP therapy suggest high-potency topical corticosteroids as the treatment of choice, and recommend clobetasol propionate to be the most effective topical steroid.[4]

Nevertheless, refractory lesions to steroids require alternative medications. Topical immunomodulators, including both tacrolimus and pimecrolimus, are recent

additions to the therapeutic armamentarium against OLP. Tacrolimus, also called FK 506, is a potent immunosuppressant macrolide lactone antibiotic produced by Streptomyces tsukubaensis.[5] The present study was conducted to compare tacrolimus and clobetasol in management of oral lichen planus.

MATERIALS & METHODS

The present study comprised of 84 patients of oral lichen planus of both genders. The study was approved from the institutional ethical committee. All were informed regarding the study and written consent was obtained.

Data such as name, age, gender etc. was recorded. Patients were divided into 2 groups of 42 each. Group I was those who were prescribed tacrolimus (0.1%) cream and group II patients were prescribed clobetasol propionate (0.05%). Patients were examined and recalled regularly to see size of the lesions. VAS score and TC score was compared before treatment, after 3 weeks and 5 weeks. Thongprasom Classification (TC) score was 5 = white striae with erosive area more than 1 cm, score 4 = white striae with erosive area less than 1 cm, score 3 = white striae with atrophic area more than 1 cm, score 2 = white striae with atrophic area less than 1 cm, score 1 =mild white striae, no erythematous area, and score 0 = no lesion, normal mucosa. Results were subjected to statistical analysis. P value less than 0.05 was considered significant.

RESULTS

Table I Distribution of patients

Groups	Group I (tacrolimus (0.1%)	Group II (clobetasol propionate 0.05%)
Number	42	42

Table I shows that group I patients received tacrolimus (0.1%) cream and group II patients were prescribed clobetasol propionate (0.05%). Both groups had 42 patients each.

Table II Mean VAS scores in both groups

Groups	Before	After 3 weeks	After 5 weeks	P value
Group I	2.1	1.2	0.7	0.031
Group II	2.4	1.6	1.0	0.04

Table II, graph I shows that mean VAS score in group I before treatment was 2.1, after 3 weeks was 1.2 and 5 weeks was 0.7. Mean VAS score in group II before treatment was 2.4, after 3 weeks was 1.6 and 5 weeks was 1.0. The difference was significant (P< 0.05).

Graph I Mean VAS scores in both groups

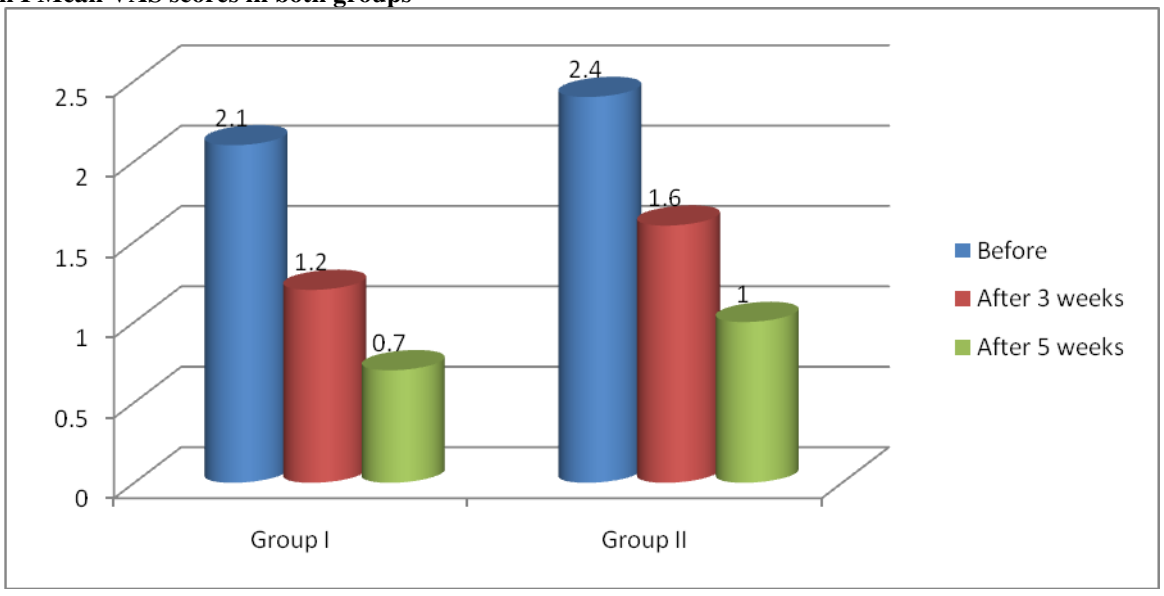
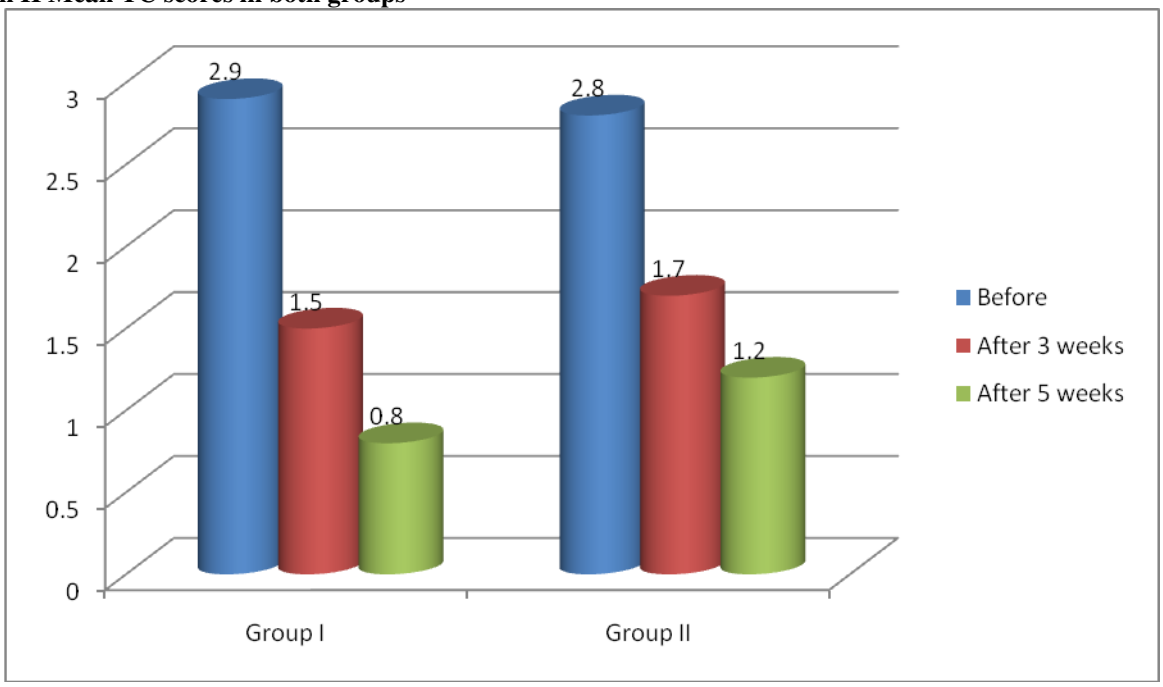


Table III Mean TC scores in both groups

Groups	Before	After 3 weeks	After 5 weeks	P value
Group I	2.9	1.5	0.8	0.01
Group II	2.8	1.7	1.2	0.05

Table III, graph II shows that mean TC score (cm) in group I before treatment was 2.9, after 3 weeks was 1.5 and 5 weeks was 0.8. In group II before treatment was 2.8, after 3 weeks was 1.7 and 5 weeks was 1.2. The difference was significant (P< 0.05).

Graph II Mean TC scores in both groups



DISCUSSION

Topical immunomodulators such as tacrolimus is recent addition to the therapeutic armamentarium against OLP. Tacrolimus, also known as FK 506, is a potent immunosuppressant that chiefly inhibits T cell activation by blocking the calcineurin pathway; it also exerts inhibitory activity over mast cells and proinflammatory mediators such as interleukin-8 (IL-8).[6] It has been used effectively in many inflammatory skin disorders, especially atopic dermatitis, for which it is approved by the US Food and Drug Administration (FDA).[7] Recent studies have shown that tacrolimus ointment 0.1% is an efficacious and well-tolerated topical therapy for OLP that causes few local side effects. Potent topical steroids, such as clobetasol, are considered to be the first-line therapy for symptomatic OLP.[8,9] The present study was conducted to compare tacrolimus and clobetasol in management of oral lichen planus.

In this study, group I patients received tacrolimus (0.1%) cream and group II patients were prescribed clobetasol propionate (0.05%). Both groups had 42 patients each. Sonthalia et al[10] conducted a randomized, comparative, double-blind study with 68 patients (43 females, 25 males; mean age: 46.76 years). Patients were randomly divided into two groups of 34 patients each to receive topical tacrolimus 0.1% cream or clobetasol propionate 0.05% cream for 3 weeks. After 3 weeks of treatment, the mean pain score dropped by 1.59 (right) and 1.53 (left) in the tacrolimus group, while in clobetasol group these values were 0.94 and 0.85, respectively. The mean scores for clinical appearance reduced by 1.18 (right) and 1.0 (left) in the tacrolimus group compared with a reduction of 0.5 and 0.26, respectively, in the clobetasol group. These reductions were statistically significant (P < .05).

We found that mean VAS score in group I before treatment was 2.1, after 3 weeks was 1.2 and 5 weeks was 0.7. Mean VAS score in group II before treatment was 2.4, after 3 weeks was 1.6 and 5 weeks was 1.0. Bains et al[11] observed a partial response in 80% and complete response in 14% of patients treated with a topical application of 0.1% tacrolimus ointment twice daily for 8 weeks. However, for the majority of patients, sustainable improvement required the continuous use of tacrolimus.

We observed that mean TC score (cm) in group I before treatment was 2.9, after 3 weeks was 1.5 and 5 weeks was 0.8. In group II before treatment was 2.8, after 3 weeks

was 1.7 and 5 weeks was 1.2. Radfar et al[12] in their study patient-observed improvement was evaluated at each visit. Demographic parameters and pretreatment disease characteristics were comparable between the groups. The mean net clinical score (NCS) declined progressively from baseline at each follow-up visit in both groups. In the clobetasol group, the mean NCS declined from 8.00 ± 2.65 at baseline to 2.00 ± 1.49 at 12 weeks. In the tacrolimus group, the mean NCS declined from 7.78 ± 3.25 at baseline to 1.31 ± 1.06 at 12 weeks. At each visit, the decline in mean NCS from baseline was statistically significant ($P < 0.05$) in both groups. Complete response rates of 40% and 70%, respectively, were achieved in the clobetasol and tacrolimus groups ($P = 0.057$). The percentages of patients reporting ''good'' or ''very good'' treatment responses at week 8 were 74% in the clobetasol group and 100% in the tacrolimus group ($P > 0.05$). No severe adverse events were reported. Tacrolimus 0.1% ointment is an effective alternative to topical steroid and may be considered as a first-line therapy in OLP.

CONCLUSION

Authors found that tacrolimus 0.1% cream is an effective alternative to topical steroid and can be considered a first-line therapy in OLP.

REFERENCES

1. Pindborg JJ, Mehta FS, Daftary DK, et al. Prevalence of oral lichen planus among 7639 Indian villagers in Kerala, South India. Acta Derm Venereol 1972; 52: 216–220.
2. Bhonsle RB, Pindborg JJ, Gupta PC, et al. Incidence rate of oral lichen planus among Indian villagers. Acta Derm Venereol 1979; 5: 255–257.
3. Brown RS, Bottomley WK, Puente E, Lavigne GI. A retrospective evaluation of 193 patient with oral lichen planus. J Oral Pathol Med. 1993;22:69-72.
4. Eisen D. The therapy of oral lichen planus. Crit Rev Oral Biol Med. 1993;4:141-158.
5. Strassburg M, Knolle G. Diseases of the oral mucosa. Quintessence Int. 1974;5:53-60.
6. Sugerman PB, Savage NW, Walsh LJ, et al. The pathogenesis of oral lichen planus. Crit Rev Oral Biol Med. 2002;13:350-365.
7. Andreasen JO. Oral lichen planus. 1. A clinical evaluation of 115 cases. Oral Surg Oral Med Oral Pathol Oral Radiol Endod. 1968;25:31-42.
8. Mollaoglu N. Oral lichen planus: a review. Br J Oral Maxillofac Surg. 2000;38:370-377.
9. Chainani-Wu N, Silverman S Jr, Lozada-Nur F, Mayer P, Watson JJ. Oral lichen planus: patient profile, disease progression and treatment responses. J Am Dent Assoc. 2001;132:901-909.
10. Sonthalia S, Singal A. Comparative efficacy of tacrolimus 0.1% ointment and clobetasol propionate 0.05% ointment in oral lichen planus: a randomized double-blind trial. Int J Dermatol. 2012;51:1371-1378.
11. Bains SK, Bhatia A, Singh HP, Bansal T, Bansal R, Yadav S. Efficacy of Tacrolimus in the management of erosive Oral lichen planus. Inter J Comp pharmacy 2012; 3(10): 1-5.
12. Radfar L, Wild RC, Suresh L. A comparative treatment study of topical tacrolimus and clobetasol in oral lichen planus. Oral Surg Oral Med Oral Pathol Oral RadiolEndod. 2008;105:187-193.