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Original Research

Comparison of tacrolimus and clobetasol in management of Oral Lichen Planus

Dr. Ritika Agarwal[1], Dr. Sakshi Kumari[2]

[1]MDS, Senior Resident, Patna Medical College & Hospital, Bihar, India;
[2]BDS, PGDPH (PG Diploma in Public Health), Dentist, Ashiyana Nagar, Patna, Bihar, India

ABSTRACT:
Background: Lichen planus (LP) is a common, chronic inflammatory mucocutaneous disease of unknown etiology and putative autoimmune pathogenesis. The present study compared tacrolimus and clobetasol in management of oral lichen planus. **Materials & Methods:** This study was conducted on 58 cases of clinically and histopathological confirmed cases of oral lichen planus. Patients were divided into 2 group of 29 each. Group I patients were given tacrolimus (0.1%) cream for 3 weeks and group II patients were given topical application of clobetasol propionate (0.05%) for 3 weeks. Pain on VAS and size of the lesion was recorded at baseline, after 3 weeks and 5 weeks. **Results:** The mean VAS at baseline, 3 wees and 5 weeks was 2.5, 1.2 and 0.4 in group I and 2.8, 1.7 and 0.9 in group II respectively. The mean size (cm2) at baseline, 3 weeks and 5 weeks in group I was 5.4, 3.1 and 1.2 and in group II was 4.9, 3.5 and 1.4 respectively. **Conclusion:** Authors found that tacrolimus (0.1%) cream is more effective than clobetasol propionate (0.05%) in the cases of oral lichen planus.
Key words: Clobetasol propionate, Oral lichen planus, Tacrolimus

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Correspondence: Dr. Sakshi Kumari, BDS, PGDPH (PG Diploma in Public Health), Dentist, Ashiyana Nagar, Patna, Bihar, India

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INTRODUCTION

Lichen planus (LP) is a common, chronic inflammatory mucocutaneous disease of unknown etiology and putative autoimmune pathogenesis. It was first described by Erasmus Wilson in 1869. Oral LP (OLP) has an unknown true prevalence, but its incidence is reported to be approximately 0.5-2% of the world's population. [1]OLP affects women more often than men at a ratio of 3:2. The etiology and pathogenesis of OLP have been the focus of much research, and several antigen-specific and non-specific inflammatory mechanisms have been put forward to explain the pathogenesis. Antigen-specific mechanisms in OLP include antigen presentation by basal keratinocytes and antigen-specific keratinocyte killing by cytotoxic CD8+ T-cells. Non-specific mechanisms include mast cell degranulation and matrix metalloproteinase activation in OLP lesions.[2]

Multiple treatment options exist for OLP, including corticosteroids, topical and systemic retinoids, cyclosporins, psoralen-U-VA, photochemotherapy, photodynamic therapy, griseofulvin, hydroxyquinone, dapsone, mycophenolate, CO2 laser, thalidomide, and low-molecular-weight heparin. The choice of treatment of OLP depends on the severity of discomfort, the site of lesions in the oral cavity, and the overall health and compliance of the patients. Recent reviews on OLP therapy suggest that high-potency topical corticosteroids are the treatment of choice.[3]

Among corticosteriods, clobetasol propionate appears to be the most effective topical steroid. Although topical steroids are commonly used in the treatment of OLP and other immune-related oral lesions, there are refractory lesions to steroids that require different medications.[4] Tacrolimus, also called FK 506, is a potent immunosuppressant macrolide lactone antibiotic produced by Streptomyces tsukubaensis. Tacrolimus acts by inhibiting calcineurin, an ubiquitous calcium-dependent protein phosphatase that is responsible for immune response.18 There have been a few recent reports of successfully-treated cases of OLP with tacrolimus, as well as successful trials of tacrolimus in the treatment of OLP.[5] The

present study compared tacrolimus and clobetasol in management of oral lichen planus.

MATERIALS & METHODS

This study was conducted on 58 cases of clinically and histopathological confirmed cases of oral lichen planus of both genders. All were informed regarding the study and their consent in the form of written form was taken. Ethical approval was also obtained.

Data such as name, age, gender etc. was recorded. Patients were divided into 2 group of 29 each. Group I patients were given tacrolimus (0.1%) cream for 3 weeks and group II patients were given topical application of clobetasol propionate (0.05%) for 3 weeks.

Parameters such as pain on VAS and size of the lesion was recorded at baseline, after 3 weeks and 5 weeks. The patients were asked to score their pain intensity using a visual analog scale (VAS) where the pain scores ranged from zero (no pain) to 10 (extreme pain). Results were tabulated and subjected to statistical analysis. P value less than 0.05 was considered significant.

RESULTS

Table I Distribution of patients

Groups	Group I	Group II
Agent	Tacrolimus	Clobetasol propionate
Number	29	29

Table I shows that group I patients were given tacrolimus (0.1%) cream and group II patients were given topical application of clobetasol propionate (0.05%). Each group had 29 patients.

Table II Comparison of VAS in both groups

Groups	Baseline	3 weeks	5 weeks	P value
Group I	2.5	1.2	0.4	0.04
Group II	2.8	1.7	0.9	0.05
P value	0.96	0.05	0.04	

Table II, graph I shows that mean VAS at baseline, 3 wees and 5 weeks was 2.5, 1.2 and 0.4 in group I and 2.8, 1.7 and 0.9 in group II respectively. The difference was significant (P< 0.05).

Graph I Comparison of VAS in both groups

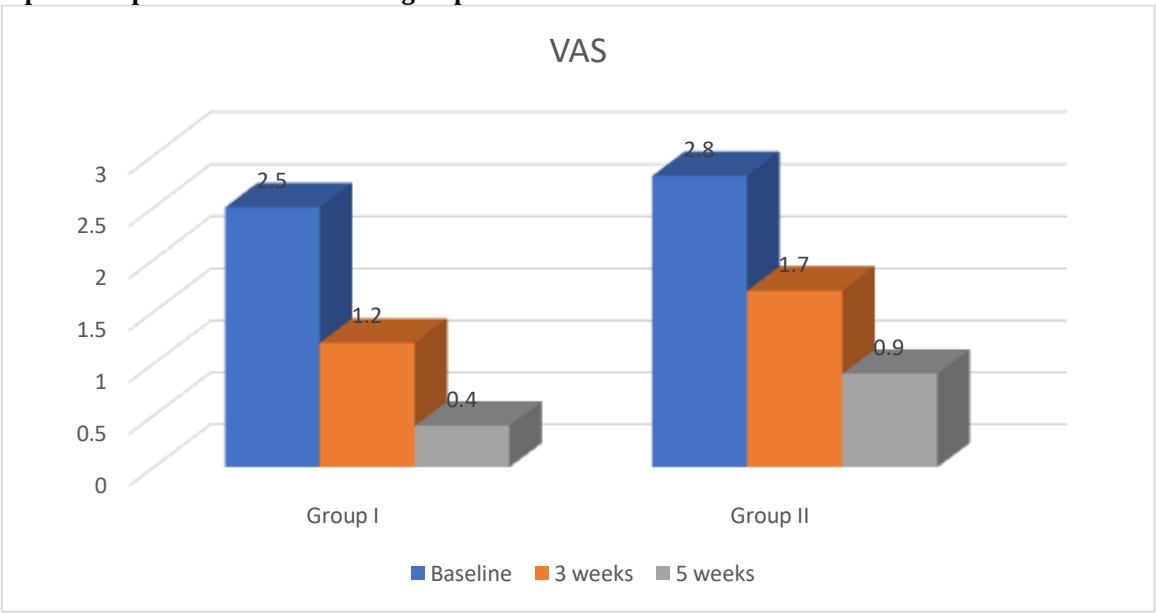
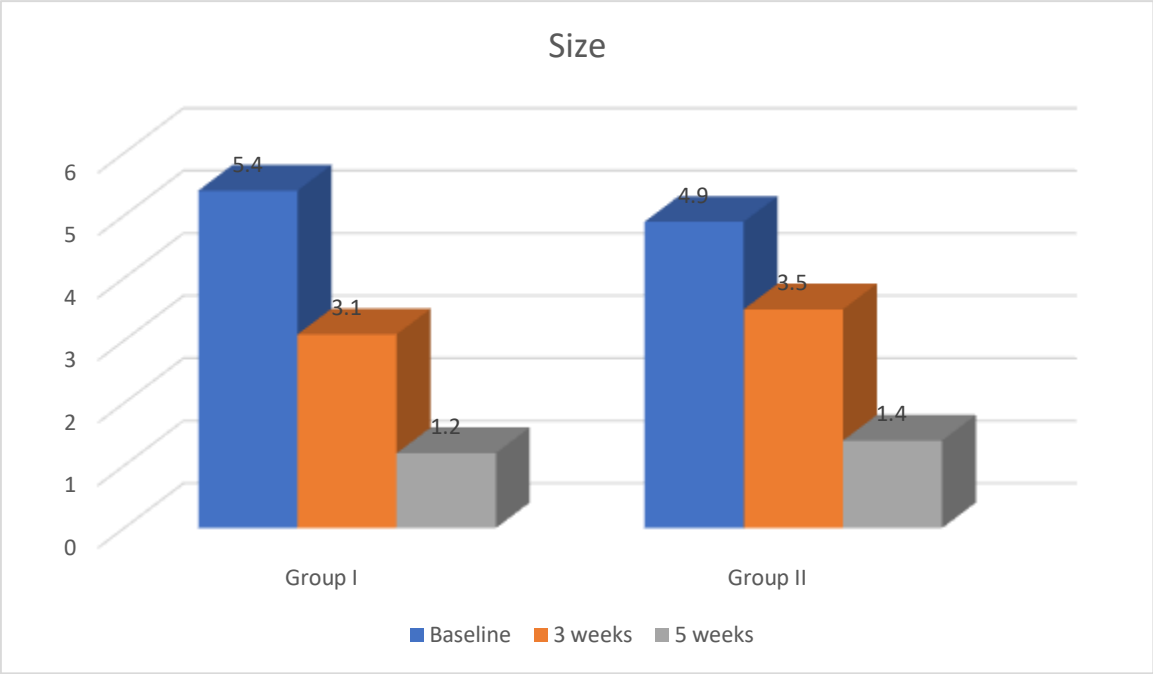


Table III Comparison of size of lesion in both groups

Groups	Baseline	3 weeks	5 weeks	P value
Group I	5.4	3.1	1.2	0.01
Group II	4.9	3.5	1.4	0.04
P value	0.96	0.91	0.93	

Table III, graph II shows that mean size (cm^2) at baseline, 3 weeks and 5 weeks in group I was 5.4, 3.1 and 1.2 and in group II was 4.9, 3.5 and 1.4 respectively. Intragroup comparison showed significant and inter- group comparison showed non- significant difference (P> 0.05).

Graph II Comparison of size of lesion in both groups



DISCUSSION

OLP was originally classified as one of six forms by Andreason: reticular, papular, plaque-like, atrophic, erosive, and bullous. This classification has been difficult, as many patients might have several forms at any given time.[6] 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.[7] Drugs used in the topical form are corticosteroids, immunosuppressives, retinoids, and immunomodulators. Drugs used systemically are thalidomide, metronidazole, griseofulvin, hydroxychloroquine, some retinoids, and corticosteroids.[8] The present study compared tacrolimus and clobetasol in management of oral lichen planus.

In this study, group I patients were given tacrolimus (0.1%) cream and group II patients were given topical application of clobetasol propionate (0.05%). Each group had 29 patients. Hettiarachchi et al[9] compared the effectiveness of topically-applied clobetasol and tacrolimus in the symptomatic management of OLP. A randomized, comparative, double-blind study with 68 patients (43 females, 25 males; mean age: 46.76 years) was undertaken. 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). The results suggest that tacrolimus 0.1% cream is an effective alternative to topical steroid and can be considered a first-line therapy in OLP.

We found that mean VAS at baseline, 3 wees and 5 weeks was 2.5, 1.2 and 0.4 in group I and 2.8, 1.7 and 0.9 in group II respectively. Radfar et al[10] compared the effectiveness of clobetasol and tacrolimus in the topical management of OLP. 30 consecutive patients with oral lesions consistent clinically and histologically with OLP were recruited. The patients were divided into 2 groups to receive clobetasol 0.05% or tacrolimus 0.1% ointment and were treated for 6 weeks. Results. The profiles of mean lesion sizes and mean pain measures did not differ between the tacrolimus and clobetasol treatment groups. Authors found tacrolimus to be as useful as clobetasol in treatment of OLP. We believe that up-to-date evidence indicates the effectiveness of tacrolimus in treating OLP.

We found that the mean size (cm^2) at baseline, 3 weeks and 5 weeks in group I was 5.4, 3.1 and 1.2 and in group II was 4.9, 3.5 and 1.4 respectively. Hodgson 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. Rozycki et al[12] reported rapid improvement in the 0.1% tacrolimus group, with significant relapse 3-9 weeks following treatment, but this was comparatively less for tacrolimus group (72%) than the triamcinolone group (78%).

The limitation of the study is small sample size and short follow up.

CONCLUSION

Authors found that tacrolimus (0.1%) cream is more effective than clobetasol propionate (0.05%) in the cases of oral lichen planus.

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