A Comparative Analysis of different Treatment Modalities of Oral Lichen Planus

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ABSTRACT:
Background: Lichen planus (LP) is a common, chronic inflammatory mucocutaneous disease of unknown etiology and putative autoimmune pathogenesis. The present study compared different treatment modalities of oral lichen planus.

Materials & Methods: 78 clinically and histopathological diagnosed cases of oral lichen planus were divided into 2 groups of 39 each. Group I patients were given 0.1% tacrolimus cream and group II patients were given 0.05% topical application of clobetasol propionate. Parameters such as pain on VAS and size of the lesion was recorded at baseline, after 3 weeks and 6 weeks.

Results: The mean size (cm²) in group I was 5.8, 3.4 and 1.6 and in group II was 4.7, 3.2 and 1.2 at baseline, 3 weeks and 6 weeks respectively. A non-significant difference was observed (P> 0.05). The mean VAS was 2.8, 1.4 and 0.6 in group I and 2.9, 1.8 and 0.8 at baseline, 3 weeks and 6 weeks in group II respectively. The difference was significant (P< 0.05).

Conclusion: 0.1% tacrolimus reduced size of the lesion and pain score efficiently than 0.5% clobetasol propionate in patients of oral lichen planus.

Key words: Oral lichen planus, Tacrolimus, VAS

INTRODUCTION
Lichen planus (LP) is a common, chronic inflammatory mucocutaneous disease of unknown etiology and putative autoimmune pathogenesis.¹ 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.² OLP affects women more often than men at a ratio of 3:2.³ As early event in the disease mechanism involves keratinocyte antigen expression or unmasking of an antigen that may be self–peptide or a heat shock protein following this T cells (mostly CD8+ and some CD4+ cells) migrate in to the epithelium either due to random encounter of antigen during surveillance or a chemokine–mediated migration towards basal keratinocytes.⁴ These migrated CD8+ cells are activated directly by an antigen binding to major histocompatibility complex (MHC)-1 on keratinocyte or through activated CD4+ lymphocytes. In addition, the number of Langerhans cells in OLP lesions is increased along with upregulation of MCH expression subsequent antigen presentation to CD4+ cells and interleukin (IL)-12 activates CD4+T helper cells which activate CD8+T through receptor interaction, interferon γ (INF-γ) and IL-2. Cells in turn kill the basal keratinocytes through tumor necrosis factor (TNF)α, Fas-FasL –mediated or granzyme B –activated apoptosis.⁵ 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.
corticosteroids, 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. The present study compared different treatment modalities of oral lichen planus.

MATERIALS & METHODS
This study comprised of 78 clinically and histopathological diagnosed cases of oral lichen planus of both genders. All were informed regarding the study and written their consent was obtained.

Data such as name, age, gender etc. was recorded. Patients were divided into 2 groups of 39 each. Group I patients were given 0.1% tacrolimus cream and group II patients were given 0.05% topical application of clobetasol propionate. Each medication was prescribed for 3 weeks. Parameters such as pain on VAS and size of the lesion was recorded at baseline, after 3 weeks and 6 weeks. Visual analog scale (VAS) was recorded which 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

<table>
<thead>
<tr>
<th>Groups</th>
<th>Group I</th>
<th>Group II</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug</td>
<td>Tacrolimus</td>
<td>Clobetasol propionate</td>
</tr>
<tr>
<td>Number</td>
<td>39</td>
<td>39</td>
</tr>
</tbody>
</table>

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

Table II Measurement of size of lesion

<table>
<thead>
<tr>
<th>Groups</th>
<th>Baseline</th>
<th>3 weeks</th>
<th>6 weeks</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group I</td>
<td>5.8</td>
<td>3.4</td>
<td>1.6</td>
<td>0.01</td>
</tr>
<tr>
<td>Group II</td>
<td>4.7</td>
<td>3.2</td>
<td>1.2</td>
<td>0.02</td>
</tr>
<tr>
<td>P value</td>
<td>0.82</td>
<td>0.94</td>
<td>0.96</td>
<td></td>
</tr>
</tbody>
</table>

Table II, graph II shows that mean size (cm²) in group I was 5.8, 3.4 and 1.6 and in group II was 4.7, 3.2 and 1.2 at baseline, 3 weeks and 6 weeks respectively. A non-significant difference was observed (P> 0.05).

Table III Recording of VAS in both groups

<table>
<thead>
<tr>
<th>Groups</th>
<th>Baseline</th>
<th>3 weeks</th>
<th>6 weeks</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group I</td>
<td>2.8</td>
<td>1.4</td>
<td>0.6</td>
<td>0.03</td>
</tr>
<tr>
<td>Group II</td>
<td>2.9</td>
<td>1.8</td>
<td>0.8</td>
<td>0.05</td>
</tr>
<tr>
<td>P value</td>
<td>0.91</td>
<td>0.05</td>
<td>0.02</td>
<td></td>
</tr>
</tbody>
</table>

Table II, graph I shows that mean VAS was 2.8, 1.4 and 0.6 in group I and 2.9, 1.8 and 0.8 at baseline, 3 weeks and 6 weeks in group II respectively. The difference was significant (P< 0.05).
Graph I: Measurement of size of lesion

Graph II: Recording of VAS 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. 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. 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. The present study compared tacrolimus and clobetasol in management of oral lichen planus.
In present study, group I patients were given 0.1% tacrolimus cream and group II patients were given 0.05% topical application of clobetasol propionate. Each group had 29 patients. Hodgson et al. 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 found that mean size (cm$^2$) in group I was 5.8, 3.4 and 1.6 and in group II was 4.7, 3.2 and 1.2 at baseline, 3 weeks and 6 weeks respectively. Radfar et al. compared the effectiveness of clobetasol and tacrolimus in the topical management of OLP. In this randomized comparative double-blind study, 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. 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. Authors believe that up-to-date evidence indicates the effectiveness of tacrolimus in treating OLP. We found that mean VAS was 2.8, 1.4 and 0.6 in group I and 2.9, 1.8 and 0.8 at baseline, 3 weeks and 6 weeks in group II respectively. Singh et al. in their study used tulsi for local application twice/day for a period of 3 months. Exclusion criteria included systemic diseases and pregnancy. All the patients were divided into two groups, first group was treated with turmeric and second group was treated with Tulsi. All the patients were instructed to report after every 2 weeks for check-up and to collect ointment. Evaluation was done on the basis of clinical symptoms like burning sensation, intolerance to spicy food, redness, ulceration, strai and pain. The data was collected, tabulated and analyzed. Results showed significant improvement in all clinical features of the lichen planus. Tulsi shows better result in halitosis. On other hand Turmeric is better in reducing burning sensation, pain and white lesions. Corrocher et al. in their study tacrolimus 0.1% ointment and clobetasol 0.05% ointment for the treatment of OLP. A total of 32 patients (20 females and 12 males; all white, Italian origin, mean age of 43.6 years; 16 patients per treatment group) were treated with tacrolimus or clobetasol ointment for 4 weeks in a randomized, double-blind, clinical trial. Pain severity, burning sensation, and mucosal lesion extension were assessed using a four-point scale. At the end of the treatment period, symptom scores were significantly lower in the tacrolimus group than in the clobetasol group. The results of this study suggest that tacrolimus 0.1% ointment is more effective than clobetasol propionate 0.05% ointment in the treatment of OLP. However, other studies are needed to confirm the effectiveness of this treatment before it can be recommended for use in clinical practice.

**CONCLUSION**

Authors found that 0.1% tacrolimus reduced size of the lesion and pain score efficiently than 0.5% clobetasol propionate in patients of oral lichen planus.

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