Evaluation of efficacy of indigenously prepared formulation of Aloe vera, licorice and sesame oil in treatment of oral lichen planus: An in vivo study

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Abstract

Background: Oral lichen planus (OLP) is a chronic mucocutaneous inflammatory disease characterized by eruptions on the skin and oral mucous membranes. Various therapies have been tried for the treatment of lichen planus with varying results. Aloe barbadensis, Aloe capensis is scientific name for Aloe vera (AV). AV is a very versatile plant that has many different uses. AV is a promising herb with its various clinical applications in medicine and dentistry.

Objectives: To assess decrease in pain, burning sensation, erythema, functional disturbances and recurrence in patients diagnosed with lichen planus treated with the prepared formulation of AV and licorice and sesame oil.

Materials and Methods: A total of 30 adult patients who came to Dr. D.Y. Patil Dental College and Hospital, Pimpri, Pune and were diagnosed with OLP were included in the study. Each patient was administered 50 ml prepared formulation of AV and licorice and sesame oil in the form of a gargle which was swished for a minimum of 5 min in the oral cavity twice daily for a period of 6-week.

Results: After evaluation with Tukey’s test and Wincoxin test it was found that there is a decrease in pain, erythema, burning sensation, functional disturbances and recurrence after using prepared formulation.

Keywords
Aloe capensis, apoptosis, autoimmune, basal keratinocytes, corticosteroids, oral lichen planus

Introduction

Oral lichen planus (OLP) is a chronic mucocutaneous inflammatory disease characterized by eruptions on the skin and oral mucous membrane.[1] The cause of disease is unknown and is attributed to stress, viral infections.[1] This disease can be typically painful in atrophic and erosive forms. Various therapies have been tried for the treatment of lichen planus with varying results.[1]

Lichen planus occurs in adulthood generally within the 4-5th decade of life. Females are more commonly affected than males. It may involve skin and oral mucosa as well as other mucosal areas. About 50% people with skin lesions have oral lesions. 25% cases with lichen planus have only oral lesions. Moreover, there is no definitive etiology for lichen planus, and also there is no definite treatment for lichen planus. Recurrence is also seen in many patients. Furthermore, there have been limited studies in relation to AV and their effectiveness in lichen planus.[3]

In 1978, the WHO[4] formulated a clinical definition of OLP: “Lichen planus commonly affects the oral mucosa, and lesions may occur in the mouth in the absence of skin lesions. Mucosal lesions are usually multiple and often have a symmetrical distribution. They commonly take the form of minute white papules which gradually enlarge and coalesce to form either a reticular, annular, or plaque pattern. A characteristic feature is the presence of slender white lines (Wickham’s striae) radiating from the papules. In the reticular form, there is a lacelike network of slightly raised gray-white lines, often interspersed with papules or rings.”

AV, a great immune stimulant, contains 90% rhodium and iridium (trace minerals) in the acemannan which is one of the polysaccharides which dramatically increases the white blood cells or macrophages and T-cells. Thus, immunomodulating effects occur via activation of macrophage cells to generate nitric oxide, secrete cytokines (e.g., tumor necrosis factor, interleukin-1, interleukin-6, and interferon-γ), and present cell
surface markers. It helps enlarge the thymus gland in size by 40%. The thymus is what produces the T-cells of the immune system.\(^5\)

The variety of nutrients in the *Aloe* leaf is what gives it the potential to be used in many ways. AV is considered an adaptogen. An adaptogen is a substance that invigorates or strengthens the system. Specifically, the terms apply to herbs that maintain health by increasing the body’s ability to adapt to environmental and internal stressors. This can range from smog in the air, food that you eat, or simply even a bad day at work. AV is known to have 75 “known” nutrients that are documented: 20 minerals, 20 amino acids, 12 vitamins, and water. It is rumored though that AV easily contains more than 100 different nutrients. Vitamins are defined as a group of organic micro nutrients present in minute quantities in natural foods that are essential to normal metabolism. Vitamins present in AV are vitamin A (otherwise known as beta carotene), vitamin B (known as thiamine), B2 (riboflavin), B3 (niacin), B5, B6 (pyridoxine), B12, vitamin C, vitamin E, and folic acid. Vitamin B complex and C are considered to play an important role in reducing stress and inflammation.\(^6,7\)

AV has very strong antioxidant nutrients. Glutathione peroxide activity, superoxide dismutase enzymes, and a phenolic antioxidant were found to be present in AV gel, which may be responsible for these antioxidant effects. Apart from these, it also contains A, C, and E vitamins. These free radical components get rid of the toxins and carcinogenic properties we have in our bodies from the pollution and poor quality foods we eat. We acquire these free radicals in our bodies through absorption of our skin and through digestion.\(^7\)

Sesame seed oil has been used as healing oil for thousands of years. Sesame oil is mentioned in the Vedas as excellent for humans. It is naturally antibacterial for common skin pathogens, such as *Staphylococcus* and *Streptococcus* as well as common skin fungi, such as athlete’s foot fungus. It is naturally antiviral. It is a natural anti-inflammatory agent.\(^6,7\)

Research shows that sesame seed oil is a potent antioxidant. In the tissues beneath the skin, this oil will neutralize oxygen radicals. It penetrates into the skin quickly and enters the blood stream through the capillaries. Molecules of sesame seed oil maintain good cholesterol (high-density lipoprotein) and lower bad cholesterol (low-density lipoprotein). Sesame seed oil is a cell growth regulator and slows down cell growth and replication.\(^8\)

**Materials and Methods**

30 adult patients who came to Dr. D.Y. Patil Dental College and Hospital, Pimpri, Pune and were diagnosed with OLP were included in the study. Following parameters were included in the establishment of diagnosis and the following parameters to be satisfied for inclusion in the study. Patients suffering from OLP and diagnosed using normal clinical investigation methods consisting of inspection, stretchability test, scrapability test and biopsy where necessary. A detailed case history form was taken into consideration all aspects related to OLP consisting of recording of chief complaint and history of complaint was taken into account. Each patient was administered 50 ml prepared formulation of AV and licorice and sesame oil in the form of a gargle which was swished for a minimum of 5 min in the oral cavity in such a way that the prepared formulation is in contact with the lesion. This was followed by gargle with lukewarm water. This procedure was carried out twice daily for 6 weeks. The medication was taken once in the morning at 10 a.m. and once in the evening at 6 p.m. Patients were evaluated every week for assessment of pain, sensation, functional disturbances, erythema on the basis of visual analog scale and verbal analog scale for burning sensation.

**Inclusion criteria**

1. Patients suffering from chronic OLP lesions
2. Adult patients of either sex aged between 18 and 65 years
3. Has not participated in any treatment modality for the treatment of OLP in past 4 weeks
4. Willing to give a written informed consent and follow the schedule.

**Exclusion criteria**

1. Severe systemic disorders pertaining to cardiac, respiratory, central nervous system, renal or hepatic disorders
2. Patients taking certain drugs which may induce lichenoid reactions in patients like:
   - Anti-microbials like dapsone tetracycline
   - Anti-parasitic like chloroquine and antimony compounds
   - Anti-hypertensives like angiotensin-converting-enzyme inhibitors, diuretics, hydrochlorothiazide
   - Anti-arthritic drugs like colloidal gold, sodium thiomalate
   - Oral hypoglycemic agents of sulfonyl urea type like chlorbutamide
   - Miscellaneous drugs such as iodides, penicillamine
   - Presence of metallic restoration in oral cavity which would induce a similar lesion.
3. Subjects who refuse to sign inform consent
4. Pre-existing systemic disease necessitating long-term medication

**Method of data analysis**

Pain, erythema, burning sensation and function disturbance were compared pre- and post-treatment. Scores obtained were tabulated suitably and subjected to suitable statistical analysis. The test used was \(b\) Friedmann test followed by Tukey’s test.

**Discussion**

OLP is a relatively common chronic disease of the mucous membranes which may have more transient cutaneous manifestations. The etiology of the disease is unknown, some authors state that it is a psychosomatic disorder caused by anxiety or stress.\(^9\)
Very few studies have been conducted to assess the efficacy of AV on lichen planus. AV has strong wound healing, immunomodulating properties, anti-bacterial, anti-fungal and anti-viral properties. Moreover being herbal AV has no side effects and is well tolerated by the patient.[6]

Hayes[10] was the first to use AV gel for treating lichen planus and experienced improvement of oral lesions after 4 weeks of therapy. More recently, in 2008, Choonhakarn et al.[11] conducted a double-blind study of AV gel in the treatment of OLP.

**Epidemiology**

**Age distribution**

In our study, we found more number of OLP patients in the age range of 20-70 years with a mean age ± standard deviation range of 40 ± 13. The age range noted in our study was similar to observation mentioned in the past reported studies.[12,13]

Axell and Rundquist[14] also found that OLP is found to be commonly seen in middle age population, but numerous cases have been reported in children as well as elderly patients. Age range for males with OLP has been found to be lower than that for females.

**Gender distribution**

In our study, slight male predilection was noted with 18 compared with females 12 and with the ratio 1.5:1 of between males and females.

Gender distribution of OLP has an inclination for female gender. In a comprehensive review, authors have stated that OLP affects both the sexes, vast majority of surveys have revealed 60-65% female predilection and with a mean of 62.6% of patients.[15] Occasional surveys have suggested male predominance. The ratio of female to male was 2.2:1, was reported in a follow-up study 326 patients by Jandinski and Shklar.[16] Similar sex predilection with a ratio of female: male, i.e., 2:1 was reported by Boyd and Neldner[17] in a study of 48 patients.

**Clinical presentation**

In our study, we found that buccal mucosa was the most predominant site for OLP accounting for 70% of cases. Our observation was in agreement with the other studies, manifestation of OLP at various sites and in various forms.

In majority of reported studies and surveys, OLP can present with various clinical forms and at multiple oral sites.[13,17] In a clinical study by Marder and Deesen[18] in 674 patients with OLP, buccal mucosa was the most predominant site, followed by the tongue and lower lip, gingival and labial mucosa. OLP can present with variety of clinical forms, most among this is reticulate form.[19]

**Evaluation of pain**

In our study patients showed significant reduction in pain from 2nd week which was evaluated by Tukey’s test. The observation was in agreement with other studies that pain was considerably reduced in 80% of cases after use of AV in lichen planus.

According to the study conducted by Salaser-Sanchar with respect to the VAS score for pain, after 6 and 12 weeks the patients treated with AV showed a greater reduction in pain than the placebo group.[18]

**Evaluation of recurrence**

In our study also there was considerable reduction in erythema in about 90% of cases showing similar observation with the similar studies conducted. Only 1 case had functional disturbances which also showed improvement after 1 week of using prepared AV formulation.

Choonhakarn et al.[11] carried out a randomized, double-blind study to explore the efficacy of AV gel in the management of OLP. They treated a group of patients with OLP and the results revealed that AV gel is statistically significantly more effective than placebo in inducing clinical and symptomatologic improvement of OLP.

Reddy et al.[20] also carried out randomized, double blind clinical trial and treated patients of OLP with Aloe gel. When clinical signs and symptoms were observed after 8 weeks of therapy, it was determined that AV gel was more effective than triamcinolone acetonide in the treatment of OLP and hence AV gel can be considered a safe alternative treatment for OLP.

Over all changes in the pain, erythema, burning sensation and Functional disturbance of 30 patients were evaluated from 1 week to 6 months. Mean visual analogue scores among all the study subjects for pain, erythema, burning sensation and functional disturbance showed a statistically significant reduction in the entire four parameters across the study period when analyzed using Tukey’s test.[Tables 1-4]. The major reduction was observed in the first 2-week of the study period.

**Evaluation of recurrence**

During the 6 months follow-up, out of the 30 patients treated by herbal preparation of AV, four patients complained from
## Table 1: Effect of prepared AV formation on pain in study group

<table>
<thead>
<tr>
<th>Prepared AV formation</th>
<th>Pain score</th>
<th>F value</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>At 1st week</td>
<td>1.07</td>
<td>0.94</td>
<td>8.70</td>
</tr>
<tr>
<td>At 2nd week</td>
<td>1</td>
<td>0.91</td>
<td></td>
</tr>
<tr>
<td>At 3rd week</td>
<td>0.57</td>
<td>0.86</td>
<td></td>
</tr>
<tr>
<td>At 4th week</td>
<td>0.40</td>
<td>0.67</td>
<td></td>
</tr>
<tr>
<td>At 5th week</td>
<td>0.27</td>
<td>0.52</td>
<td></td>
</tr>
<tr>
<td>At 6th week</td>
<td>0.07</td>
<td>0.25</td>
<td></td>
</tr>
</tbody>
</table>

By Tukey’s test: At 1st week versus at 2nd week: P>0.05, At 1st week versus at 3rd week: P>0.05, At 1st week versus at 4th week: P<0.01, At 1st week versus at 5th week: P<0.001, At 1st week versus at 6th week: P<0.0001. AV: Aloe vera, SD: Standard deviation

## Table 2: Effect of prepared AV formation on erythema in study group

<table>
<thead>
<tr>
<th>Prepared AV formation</th>
<th>Erythema score</th>
<th>F value</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>At 1st week</td>
<td>1.07</td>
<td>0.64</td>
<td>21.66</td>
</tr>
<tr>
<td>At 2nd week</td>
<td>0.97</td>
<td>0.72</td>
<td></td>
</tr>
<tr>
<td>At 3rd week</td>
<td>0.33</td>
<td>0.55</td>
<td></td>
</tr>
<tr>
<td>At 4th week</td>
<td>0.20</td>
<td>0.41</td>
<td></td>
</tr>
<tr>
<td>At 5th week</td>
<td>0.10</td>
<td>0.30</td>
<td></td>
</tr>
<tr>
<td>At 6th week</td>
<td>0.20</td>
<td>0.48</td>
<td></td>
</tr>
</tbody>
</table>

By Tukey’s test: At 1st week versus at 2nd week: P>0.05, At 1st week versus at 3rd week: P>0.0001, At 1st week versus at 4th week: P>0.0001, At 1st week versus at 5th week: P>0.0001, At 1st week versus at 6th week: P>0.0001. AV: Aloe vera, SD: Standard deviation

## Table 3: Effect of prepared AV formation on burning sensation in study group

<table>
<thead>
<tr>
<th>Prepared AV formation</th>
<th>Burning sensation score</th>
<th>F value</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>At 1st week</td>
<td>3.07</td>
<td>1.01</td>
<td>97.07</td>
</tr>
<tr>
<td>At 2nd week</td>
<td>2.77</td>
<td>1.10</td>
<td></td>
</tr>
<tr>
<td>At 3rd week</td>
<td>1.97</td>
<td>0.96</td>
<td></td>
</tr>
<tr>
<td>At 4th week</td>
<td>1.53</td>
<td>1.04</td>
<td></td>
</tr>
<tr>
<td>At 5th week</td>
<td>1.03</td>
<td>0.93</td>
<td></td>
</tr>
<tr>
<td>At 6th week</td>
<td>0.63</td>
<td>0.89</td>
<td></td>
</tr>
</tbody>
</table>

By Tukey’s test: At 1st week versus at 2nd week: P>0.05, At 1st week versus at 3rd week: P>0.0001, At 1st week versus at 4th week: P>0.0001, At 1st week versus at 5th week: P>0.0001, At 1st week versus at 6th week: P>0.0001. AV: Aloe vera, SD: Standard deviation

## Table 4: Effect of prepared AV formation on function disturbance in study group

<table>
<thead>
<tr>
<th>Prepared AV formation</th>
<th>Function disturbance score</th>
<th>F value</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>At 1st week</td>
<td>0.03</td>
<td>0.18</td>
<td>1</td>
</tr>
<tr>
<td>At 2nd week</td>
<td>0.03</td>
<td>0.18</td>
<td></td>
</tr>
<tr>
<td>At 3rd week</td>
<td>0.03</td>
<td>0.18</td>
<td></td>
</tr>
<tr>
<td>At 4th week</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>At 5th week</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>At 6th week</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

By Tukey’s test: At 1st week versus at 2nd week: P>0.05, At 1st week versus at 3rd week: P>0.05, At 1st week versus at 4th week: P>0.05, At 1st week versus at 5th week: P>0.05, At 1st week versus at 6th week: P>0.05. AV: Aloe vera, SD: Standard deviation

Recurrence that occurred after 3 months and two cases and after 6 months. No recurrence was detected in the rest of cases. It was evaluated by Wilcoxin test and the P > 0.05.

## Conclusion

Based on the clinical examination, clinical photographs, and biopsy and statistical analysis of data collected the following conclusions were drawn from the present study.

1. OLP was more commonly seen among females than males (1.2:1) and mostly affected patients were above 20 years of age, with mean age 40 ± 13 years. Our study showed male predilection and male to female ratio was 1.5:1. It was easier to convince male patients for using the new treatment modality.

2. In our study we had recurrence of 6 cases which are erosive type of OLP, after treatment turn-out to be reticular form, so we can conclude that more severe form (erosive type) of OLP can converted in reticular type which might be require further intervention for cure.

3. On the basis of the favorable results obtained it would be fair to conclude that AV could be used more frequently as an effective treatment modality in the treatment of lichen planus. A larger study group would possibly educate us to the benefits and/or drawbacks of the use of A. vera in the treatment of this troubled condition.

## References


Efficacy of *Aloe vera* in the treatment of OLP

Inamdar, et al.


