

Original Research Article

Evaluation of therapeutic effect of Aloe Vera juice and gel in the management of symptomatic oral lichen planus

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ABSTRACT

Background: Oral lichen planus is a chronic inflammatory mucocutaneous disease. The anti-inflammatory, immunomodulatory and wound healing properties of aloe vera suggest its possible use in the management of oral lichen planus.

Objectives: To clinically determine the effect of aloe vera juice and gel in the management of symptomatic oral lichen planus.

Study Design: 30 subjects with symptomatic oral lichen planus and were randomly assigned into group A (n=15) and group B (n=15). Group A patients were instructed to drink 30ml of aloe vera juice twice daily before food and to apply aloe vera gel over the lesion twice daily for 8 weeks. Group B patients were instructed to apply aloe vera gel over the lesion twice daily for 8 weeks. The parameter assessed was burning sensation / pain and the size of the lesion. The follow up was done at intervals of 1 week, 2 weeks, 4 weeks and 8 weeks

Results: The mean VAS scores of both the groups showed a statistically significant reduction ($P < 0.001$). The reduction in the mean VAS scores of group A was more when compared with that of group B. No difference was observed with respect to the size of the lesion

Conclusion: The study concluded that aloe vera is effective in the management of symptomatic oral lichen planus with minimal side

effects.

Key words: Aloe vera, lichen planus, erosive, topical, systemic

Introduction

Oral lichen planus (OLP) is a common mucocutaneous disorder that tends to follow a chronic course and rarely undergoes spontaneous remission. It affects 1-2% of the adult general population and slight predominance in females at ratio of approximately 1.4: 1 has been observed. [1,

2] Clinically, OLP appears in various combinations of reticular or papular forms with or without the expression of plaque-type, atrophic, erosive and bullous forms. Approximately two thirds of patients with OLP report oral discomfort. The intensely painful episodes which interfere with

chewing can produce considerable morbidity and alter patients quality of life.

[3,4] Many different therapeutic agents like corticosteroids, cyclosporin, azathioprine, levamisole, griseofulvin, retinoids, hydroxychloroquine sulphate, dapsone and psoralen/UVA etc have been described for the management of OLP. [5,6] However these do not provide complete resolution and are associated with significant side effects⁶. The main focus in the management of OLP is the use of drugs that counter tissue inflammation and the underlying immunological mechanisms with minimal side effects. Considering the same

parameters recent research proposes the use of aloe vera for the management of OLP.

The plant aloe vera has a history dating back to biblical time. It is a stemless, drought resistant succulent plant of the lily family. There are more than 300 varieties of the aloe vera plant but the aloe barbadensis variety exhibits the best medicinal properties.^[7] The aloe leaf can be divided into two major parts, namely the outer green rind and the inner colourless parenchyma containing the aloe gel. Aloe vera contains 75 potentially active constituents like vitamins, enzymes, minerals, polysaccharides, lignin, saponins, salicylic acids and aminoacids. In vitro and in vivo studies have shown anti-inflammatory, immunomodulatory, analgesic, anti-neoplastic, anti-diabetic, anti-microbial effects along with a potent wound healing property.^[8,9] In literature various studies have been reported where has been used to treat various medical and dental conditions and has proved to be effective with minimal side effects.^[10]

The present study is conducted to clinically evaluate the therapeutic effects of aloe vera juice and gel in the management of oral lichen planus and to determine the presence of any side effects.

Material and Methods

Patients visiting the department of oral medicine, with the chief complaint of burning sensation or pain were screened for the presence of oral lichen planus. A thorough history and clinical examination of the lesion was recorded on a proforma by oral medicine specialist. After obtaining the consent from the patient a biopsy was performed and 30 patients with histopathological diagnosis of oral lichen

planus were included in the study. Patients who had received any treatment for oral lichen planus 4 weeks prior to study, patients with lichenoid reaction or with a known history of serious drug hypersensitivities, pregnant women and lactating mothers were excluded from the study.

The study protocol was approved by the institutional ethical committee. The subjects were explained about the study protocol and an informed consent was obtained. A randomized clinical study design was adopted for duration of 8 weeks. 30 symptomatic oral lichen planus patients were assigned into group A (n=15) and group B (n=15) randomly. Group A patients were instructed to drink 30ml of aloe vera juice twice daily before food and to apply aloe vera gel over the lesion twice daily for 8 weeks. Group B patients were instructed to apply aloe vera gel over the lesion twice daily for 8 weeks. The parameters assessed were burning sensation / pain, size and type of the lesion. To assess the burning sensation or pain, patients were requested to grade the same on a visual analogue scale of 0 to 10 (0- no pain and 10- worst pain). The size of the lesion was recorded using the Thongprasom et al criteria^[11] [0 - no lesions; 1-mild white striae, no erythematous area; 2-white striae with atrophic area < 1cm² ; 3- white striae with atrophic area > 1cm² ; 4-white striae with erosive area < 1cm² ; 5- white striae with erosive area > 1 cm² or ulcerative lesion.] The follow up was done at intervals of 1, 2, 4 and 8 weeks. Data were analysed using SPSS 12(IBM). The Mann-Whitney U test was used for intergroup comparison and the Wilcoxon matched pair test ranks was used for intragroup comparison. Statistical significance was set at P<0.05.

Results

30 symptomatic OLP subjects (17 male, 13 female) were enrolled in the study. The mean age of study subjects was 42.03 years. Out of 30 study subjects, 16 had erosive lichen planus (54%), 13 had reticular lichen planus (43%) and 1 had papular lichen planus (3%). Two out of 30 had cutaneous involvement also. One patient from group A had diarrhea and one more patient from group B experienced

hypersensitivity reaction, they dropped out from at the end of 1st and 2nd week respectively. The mean VAS score of group A reduced from 8.93 to 8.00 (1week), 6.43 (2 weeks), 3.29 (4 weeks) and to 0.29 (8 weeks). This reduction in mean VAS scores is statistically significant for all the time intervals. The mean VAS scores of group B subjects reduced from 6.93 to 6.64 (1week), 5.43 (2 weeks), 3.93 (4 weeks) and to 2.14 (8 weeks) (Table 1).

Table: 1 Comparison of Mean VAS Scores between group A and B before treatment & at recall intervals

VAS	Group	N	Mean±SD	Z	P-Value
Before Treatment	Group 1	15	8.93±1.22	-3.317	0.001 *
	Group 2	15	6.93±1.53		
1 Week	Group 1	15	8.00±1.20	-2.529	0.011 *
	Group 2	14	6.64±1.39		
2 Weeks	Group 1	14	6.43±1.09	-1.949	0.051
	Group 2	14	5.43±1.28		
4 weeks	Group 1	14	3.29±0.83	-1.432	0.152
	Group 2	14	3.93±1.21		
8 weeks	Group 1	14	0.29±0.61	-3.635	<0.001 *
	Group 2	14	2.14±1.41		

*Denotes significant difference

This reduction in mean VAS scores was also statistically significant for all the time intervals (Graph 1). A statistically significant difference was observed between the group A and group B with respect to mean VAS scores at 1st week and 8th week time intervals ($P < 0.001$). No difference was observed in Thongprasom et al criteria score in both groups throughout the study period (Table 2).

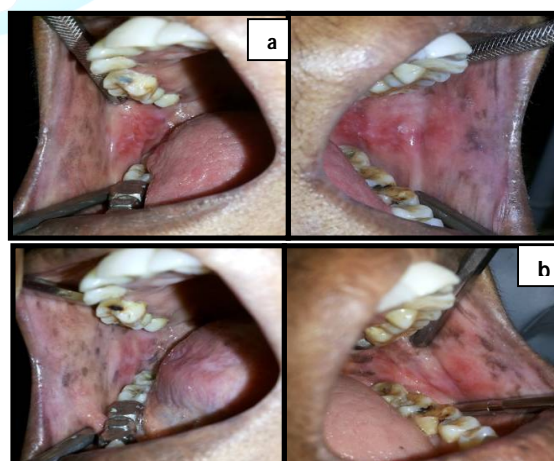


Fig.1 Patient 1 – pre (a) and post treatment (b) images of lichen planus on right and left the buccal mucosa

Table: 2 Comparison of mean of Thongprasom et al criteria score between two groups before treatment & at recall intervals

Lesion Size	Group	n	Mean±SD	Z	P-Value
Before Treatment	Group 1	15	3.07±1.33	-2.318	0.020*
	Group 2	15	1.87±1.30		
1 Week	Group 1	15	3.07±1.33	-2.318	0.020*
	Group 2	15	1.87±1.30		
2 Weeks	Group 1	15	3.07±1.33	-2.318	0.020*
	Group 2	15	1.87±1.30		
4 weeks	Group 1	15	3.07±1.33	-2.318	0.020*
	Group 2	15	1.87±1.30		
8 weeks	Group 1	15	3.07±1.33	-2.318	0.020*
	Group 2	15	1.87±1.30		

Discussion

The anti-inflammatory, wound healing and immune modulating effects of aloe vera ^[7] forms the basis of this clinical study where the therapeutic effect of aloe vera in the management of oral lichen planus has been studied. The results of our present study show that aloe vera is effective in reducing the burning sensation. The mean VAS scores of both the groups showed a statistically significant reduction ($P<0.001$) (Table 1). This reduction was gradual in both the groups and was observed at all recall intervals. Similar results have been reported in the literature. The first case report of successful treatment of oral lichen planus along with cutaneous manifestations was reported by Hayes (1999).^[12] He placed a patient on aloe vera treatment which involved drinking of 2.0 ounces of stabilized Aloe vera juice daily for 3 months, topical application of Aloe vera lip balm and aloe cream for itching hands. The oral lesions cleared up within 4 weeks. The previous studies on aloe vera in management of oral lichen planus has been summarized in Table 3. ^[13,14,15,16,17] All the mentioned studies have evaluated the efficacy of topical aloe vera gel. Only in one case report the use of

aloe vera juice has been reported. In the present study both the forms of aloe vera i.e, juice and gel have been used and an attempt has been made to determine the most efficacious form and mode of administration of aloe vera in the management of OLP.

The reduction in the mean VAS scores of group A (AV juice & gel) was more when compared with that of group B (AV gel). Group A mean VAS score dropped from 8.93 to 0.29, in group B from 6.93 to 2.14. ($P<0.001$) (Fig. 1) These results signify that the combined use of juice and gel was more effective than the use of aloe vera gel alone. However the use of aloe vera gel alone also showed statistically significant reduction in the mean VAS scores. The higher efficacy of combination of juice and gel that has been observed can be attributed to synergistic action of topical application (gel) and systemic administration (juice) of aloe vera. There was no clinical improvement observed with respect to the size of lesion as the mean Thongprasom score remained the same from initial visit to the end of 8 weeks. Since study subjects had good clinical response we continued the therapy.

Table: 3 Previous studies on management of OLP using aloe vera [13,14,15,16,17]

Author & year	Study design	No. of patients & duration	Study Group	Control Group	Parameter assessed	Outcome	
						With regard to size of lesion	Burning sensation & Pain
Choonha karn et al (2008)	randomized, double-blind, placebo-controlled trial	n-54, 8 weeks	Topical 70% AV gel (n-27) twice daily	placebo (n-27)	Burning sensation/ Pain (VAS) and size the of lesion	AV gel group (81%) had a good response 7% had a complete clinical remission.	Complete response in 9 patients (33%)& good response in 17 patients treated with AV (63%)
Salazar-sanchez (2010)	randomized double-blind	n-64, 12 weeks	Topical 0.4 ml (70%) Av gel / 3 times a day (n-32)	placebo group (n-32)	Burning sensation/ Pain (VAS) and size the of lesion and HAD,	Complete remission in 19 patients (61.29%), partial remission in 9 patients (29.03%). In relation to quality of life, significant differences were observed between the two groups in the psychological disability domain and total OHIP-49 score.	
Reddy et al (2012)	randomized double blind study	n-40, 8 weeks	Topical AV gel (n-20) three times a day	Topical triamcinolone acetamide (n-20) 3 times / day	Burning sensation/ Pain (VAS) and size the of lesion	AV treated group showed complete response in 15 (75%), good response in 3 (15%) & poor response in 2 (10%) patients	Complete remission in 15 (75%), partial remission in 5(25%) patients
Kareman El-Soudany (2013)	A self-controlled single blind and placebo controlled	n-20, 8 weeks	Topical AHM gel to right side of oral mucosa, 3 times/day	Placebo to left side of oral mucosa	Pain response / clinical improvement	Fifteen patients (75%) had complete remission at treated side and two patients (10%) had partial remission, while one patient showed no response to treatment (5%), and placebo sides showed partial remission.	
Sinha Abhishek (2013)	Randomized study	n-10, 12 weeks	30 ml AV juice for 5 days and 50ml for next ten days (n-5)	0.01% Triamcinolone acetamide (n-5)	Burning sensation/ Pain (VAS) and size the of lesion	In group AV, 4 patients had complete remission and 1 patient showed good than Placebo	

*None of the above studies showed any serious side effects.

AV- Aloe vera, VAS- visual analogue scale, HAD- Hospital anxiety and depression scale, OHIP-Oral health impact profile, AHM- Aloe vera high molecular weight fraction.

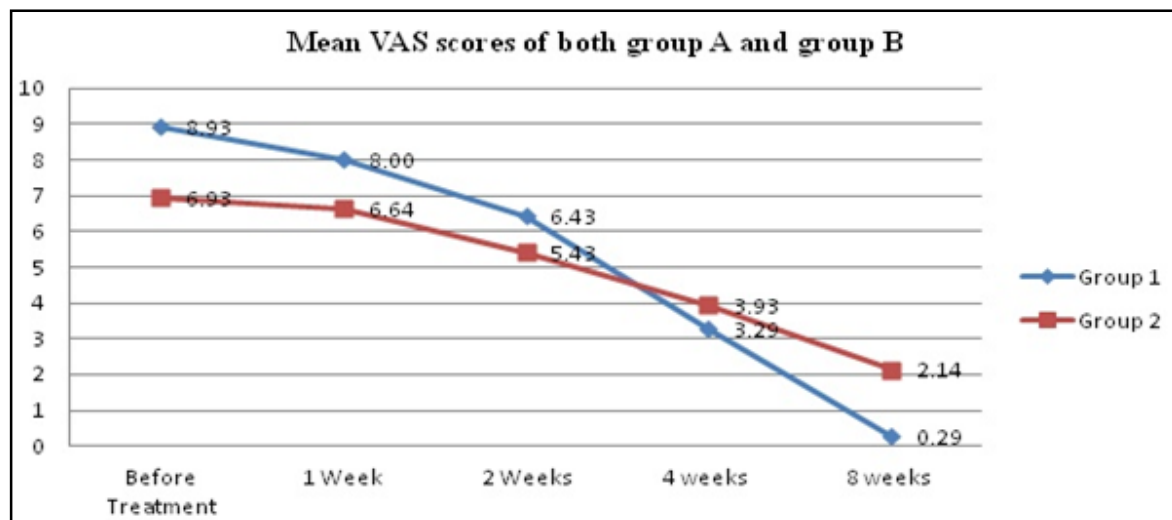


Fig. 1 Comparison of Mean VAS Scores Between Group A And Group B before treatment & at recall intervals

Over the next 6 to 9 months period reduction in the lesion size was noted in 6 subjects (Fig. 1). The lesion disappeared completely in one subject after 9 months of use of aloe vera juice and gel. Post inflammatory pigmentation was noticed in 2 subjects. The above findings defer significantly from those reported earlier. Authors have reported complete / partial remission of the lesion at the end of 2 to 3 months duration (Table 3). This difference can be attributed to the heterogeneous nature of aloe vera and the use of different formulations. A systematic review on clinical effectiveness of aloe vera published by BK Vogler reports no withdrawals owing to adverse effects of aloe vera in any of the trials. In those trials some patients experienced burning sensation after topical application, contact dermatitis, and mild itching.^[8] All adverse effects were reversible and aloe vera was generally very well tolerated. However in the present study one subject in group A complained of itching at the extensor surface of hands and in group B one subject had diarrhea. These subjects discontinued the use of aloe vera

and dropped out from the study at the end of 2 week and 1 week respectively. The side effects subsided on withdrawal of aloe vera.

Aloe vera can be advocated as an effective treatment modality available in the management of OLP with minimal side effects. Future recommendation- We consider that further studies involving longer periods of treatment are needed. The heterogenous nature of aloe vera may contribute to the diverse biological and therapeutic activities. It is vital that aloe vera products be certified with respect to content and identification of active compounds. Only then will this allow for an accurate comparison of products as well as their efficacy in the clinical trials.

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