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Comparative Efficacy of Topical Aloe Vera Gel and Topical Triamcinolone Acetonide 0.1 % in the Management of Oral Lichen Planus: A Randomized Clinical Trial

Eficacia Comparativa del Gel de Aloe Vera Tópico y Acetónido de Triamcinolona Tópico al 0,1 % en el Tratamiento del Liquen Plano Oral: Un Ensayo Clínico Aleatorizado

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ABSTRACT: A randomized clinical trial is conducted to compare the efficacy of aloe vera gel and 0.1% triamcinolone acetonide in the management of symptomatic oral lichen planus. The study involved a sample of 30 patients (16 males and 14 females) diagnosed with oral lichen planus clinically and histopathologically, who were randomly allocated into two groups. Patients in Group A were administered Aloe vera gel, while those in Group B received 0.1% triamcinolone acetonide as a local application. After the treatment, the results obtained were statistically analyzed and tabulated. Research results indicate that applying Aloe vera topically is just as effective as using topical triamcinolone acetonide, suggesting that Aloe vera may be a preferable replacement due to its safety profile in comparison to 0.1% triamcinolone acetonide.

KEY WORDS: lichen planus, aloe vera, triamcinolone acetonide, OLP, AV.

INTRODUCTION

Lichen planus is a chronic inflammatory mucocutaneous disease where it appears as either white reticular plaque or erosive lesions with a prominent T-lymphocyte response in immediate underlying connective tissue. Erasmus Wilson initially documented this condition in 1869, labeling it as lichen planus—an outbreak of distinctive pimples characterized by their color, shape, and structure, isolated and grouped growth patterns, localized and persistent nature, and the melanin deposits they may leave upon resolution (Wilson, 1869). Oral Lichen Planus may manifest as reticular, papular, plaque like, erosive, atrophic, and bullous type (Eisen, 1999).

Preventing the lesion's malignant transformation and providing symptomatic relief are the primary goals of treatment for oral lichen planus. A variety of treatments have been proposed for OLP: topical or systemic corticosteroids, cyclosporine, retinoid, azathioprine, tacrolimus, photo-chemotherapy, and surgery.

Corticosteroids are the mainstay of OLP therapy because of their activity in dampening cell mediated immune activity and are administered topically, intra-lesional or systemically. In cases of extensive skin, genital, esophageal, or scalp involvement, systemic corticosteroids are employed, while intralesional or topical corticosteroids exhibit anti-inflammatory and immunosuppressive effects on the oral epithelium (Walia *et al*., 2022).

Triamcinolone acetonide, a synthetic corticosteroid, offers rapid relief from oral tenderness, pain, inflammation, and ulceration through its anti-inflammatory, anti-pruritic, and anti-allergic properties. Although triamcinolone acetonide 0.1% is the mainstay

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for treatment of oral lichen planus, it has its own side effects.

Primary issues associated with corticosteroids treatments include potential local and systemic side effects, such as fungal infections, dryness, adrenal suppression (prolonged usage), and the recurrence of lesions after discontinuation of the treatment. Hence, there is a demand for alternative approaches in managing OLP that pose fewer or no identified side effects.

Apart from the conventional drugs used, certain alternative mode of therapies have been tried in the management of oral lichen planus such as green tea (Agha-Hosseini *et al*., 2010), pursalane (Chainani-Wu *et al*., 2007), curcuminoids (Choonhakarn *et al*., 2008) and aloe vera (Surjushe *et al*., 2008). This original research selected aloe vera due to its antioxidative characteristics.

Aloe vera, of the Xanthorrhoeaceae family is a perennial green herb featuring vibrant yellow tubular flowers. The transparent, gelatinous substance obtained from the leaves of Aloe vera has been widely utilized in both pharmaceutical and cosmetic sectors. Aloe vera contains more than 75 different compounds, including vitamins (vitamin A, C, E, and B12), enzymes (i.e., amylase, catalase, and peroxidase), minerals (i.e., zinc, copper, selenium, and calcium), sugars (monosaccharides such as mannose-6-phosphate and polysaccharides such as glucomannans), anthraquinones (aloin and emodin), fatty acids (i.e., lupeol and campesterol), hormones (auxins and gibberellins), and others (i.e., salicylic acid, lignin, and saponins) (Surjushe *et al*., 2008). Various pharmacological effect of Aloe vera are anticancer effect, anti-inflammatory effect, antimicrobial & prebiotic effect, skin protection, cardioprotective effect, antidiabetic effect, digestive disease protection and bone protection (Fig. 1).

Aloe-emodin has demonstrated efficacy as an anticancer agent by triggering apoptosis in both mitochondria and endoplasmic reticulum, along with inhibiting metastasis and oxidative stress. Aloe vera hinders the cyclooxygenase pathway, leading to a reduction in prostaglandin E2 production from arachidonic acid, demonstrating its anti-inflammatory effects (Hutter *et al*., 1996).

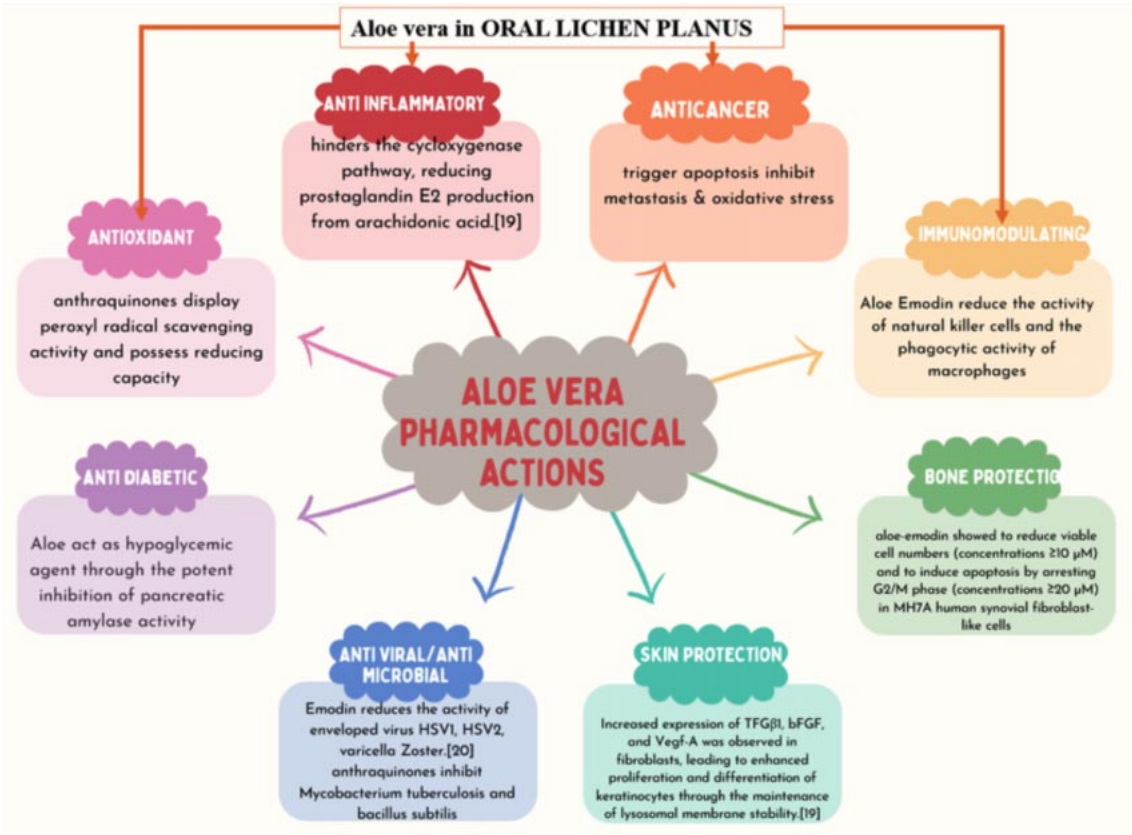

Fig. 1. Pharmacological actions of Aloe Vera and its mechanism of action in oral lichen planus.

In the context of melanoma, characterized by the malignant transformation of melanocytes, aloe-emodin demonstrated protective effects against metastatic human melanoma cells. These effects were realized through the decrease in cell proliferation, the stimulation of cell differentiation, and the augmentation of transamidating activity of transglutaminase (Surjushe *et al*., 2008). The antioxidative attributes of Aloe vera can be ascribed, at least in part, to anthraquinones and related compounds (at a concentration of 10 μM). These compounds display peroxyl radical scavenging activity and possess reducing capacity (Massoud *et al*., 2022).

Thus, aim of study is to evaluate the efficacy of aloe vera in management of burning sensation in OLP, and compare it with triamcinolone acetonide gel (0.1%).

MATERIAL AND METHOD

This comparative investigation was carried out on outpatients attending the dental outpatient department (OPD). The study involved 30 symptomatic oral lichen planus (OLP) patients of both genders. The participants encompassed clinically and histopathologically diagnosed cases of oral lichen planus, with individuals aged 20 years and above. Exclusion criteria included pregnant or lactating women and those already undergoing medication for lichen planus.

Symptomatic OLP patients, diagnosed clinically, underwent incisional biopsy under local anesthesia with their informed consent. After diagnosis, each patient received information about the condition, its premalignant potential, and details about the treatment. The 30 OLP patients were randomly divided into two groups, Group A and Group B, each comprising 15 patients. Group A exclusively received aloe vera gel applied twice daily to the lesions using a disposable cotton swab. Group B underwent topical application of 0.1% triamcinolone twice daily, administered with a disposable cotton swab. Follow-up assessments were conducted at 3 and 5 weeks (Tables I and II).

The effectiveness of Aloe vera and Triamcinolone Acetonide ointment in OLP patients was evaluated by assessing the burning sensation using the Tel Aviv-San Francisco (TASF) Scale (Table III).

Table I. Evaluation of burning sensation between group A and group B.

	GROUP	N	Mean	Standard Deviation	t
FIRST VISIT	Aloe vera	15	40.000	12.677	.661
	Triamcinolone acetonide	15	43.333	14.840	p=0.514 non significant
SECOND VISIT	Aloe vera	15	53.333	12.910	.296
	Triamcinolone acetonide	15	51.667	17.593	p=0.77 non significant
THIRD VISIT	Aloe vera	15	75.000	9.449	1.483
	Triamcinolone acetonide	15	68.333	14.840	p=0.153non significant

Table II. Evaluation of burning sensation between group A and group B in different visits.

	GROUP	N	Mean	Standard Deviation	T
DIFF 12	Aloe vera	15	-13.333	12.910	1.090
	Triamcinolone acetonide	15	-8.333	12.199	p=0.285 non significant.
DIFF 23	Aloe vera	15	-21.667	12.910	1.090
	Triamcinolone acetonide	15	-16.667	12.199	p=0.285 non significant.
DIFF 13	Aloe vera	15	-35.000	12.667	2.448
	Triamcinolone acetonide	15	-25.000	9.449	P=0.021 significant

Table III. Tel Aviv-San Francisco (TASF) Scale.

Stages	**Symptoms**
100	Asymptomatic
75	Low level of symptoms, does not interfere with usual daily activity
50	Symptoms interfere with regular daily activity
25	Sore and painful; greatly interferes with regular daily activity.
0	Impossible to live with the severe symptoms

RESULTS

The average age of the 30 patients enrolled in this study was 46.16 years. When examining the burning sensation during the initial visit, the mean value in the aloe vera group was 40.00 + 12.67, whereas in the triamcinolone acetonide group, it was 43.33 + 14.84. In the second visit, the mean value in the aloe vera group was 53.33 + 12.91, and in the triamcinolone acetonide group, it was 51.66 + 17.59. By the third visit, the mean value in the aloe vera group was 75.00 + 9.44, and in the triamcinolone acetonide group, it was 68.33 + 14.84.

The p-values, determined through unpaired t-tests for the first (Figs. 2 and 3), second, and third visits (Figs. 4 and 5), were 0.51, 0.77, and 0.15, respectively, suggesting non-significant differences in all three visits.

In comparing the variation in burning sensation between the first and second visits, the mean value in the aloe vera group was -13.33, while in the triamcinolone acetonide group, it was -8.33. The standard deviation in the aloe vera group was 12.91, and in the triamcinolone acetonide group, it was 12 (Sánchez *et al*., 2020). The associated p-value was 0.28, indicating a lack of significance. Similarly, when assessing the difference between the second and third visits, the mean value in the aloe vera group was -21.66, and in the triamcinolone acetonide group, it was -16.66. The standard deviation in the aloe vera group was 12.91, and in the triamcinolone acetonide group, it was 12 (Sánchez *et al*., 2020). Once again, the p-value was 0.28, signifying non-significance.

However, when examining the variation in burning sensation between the first and third visits, the mean value in the aloe vera group was -35.00, and in the triamcinolone acetonide group, it was -25.00. The standard deviation in the aloe vera group was 12.67, and in the triamcinolone acetonide group, it was 9.44. The p-value was 0.02, indicating statistical significance.

Fig. 2. First visit of the patient A with reticular lichen planus: Erythematous area with Wickhams striae.

Fig. 3. Third visit of the patient A after 5 weeks: Complete resolution of erythematous area and reduction in the Wickhams striae after the application of Aloe vera gel two times daily.

Fig. 4. First day visit of the patient B with reticular lichen planus.

Fig. 5. Third visit of the patient B after 5 weeks with complete resolution of the lesion after the application of aloe vera gel two times daily.

DISCUSSION

Oral lichen planus is a long protracted chronic disease with periods of exacerbations and remissions (Eisen, 1999). Current therapeutic approaches primarily focus on relieving pain, burning sensations, and eliminating lesions. However, the recalcitrant and aggressive nature of the disease complicated the condition leading to stress and morbidity among patients. While topical corticosteroids, cyclosporine, retinoic acid, or tacrolimus can provide pain relief for the majority, systemic drugs like acitretin, systemic corticosteroids, and azathioprine are reserved for recalcitrant lesions (Chan *et al*., 2000).

Topical and systemic corticosteroids have traditionally been the mainstay in OLP management, but their variable therapeutic responses and associated side effects such as fungal infection, adrenal suppression, bad taste, dry mouth and systemic absorption necessitate alternatives with fewer or no known adverse effects (Thongprasom & Dhanuthai, 2008).

The use of plants as medicine to treat diseases is almost universal and has been practiced since many years. One such plant is Aloe vera (AV, Aloe barbadensis Miller), a member of Liliaceae family. It has anti- inflammatory, antibacterial, antiseptic, antiviral and antifungal properties (Surjushe *et al*., 2008). AV is widely used as a natural treatment and alternative therapy for various types of diseases such as radio dermatitis, psoriasis, genital herpes, wound healing, acne vulgaris and diabetes type 2 (Shelton, 1991). AV has also been explored for treating oral mucositis, aphthous stomatitis, and lichen planus. Previous studies have highlighted its healing, cosmetic, and nutritional benefits (Shelton, 1991). Motivated by these properties, our study aimed to compare the efficacy of topical Aloe vera and triamcinolone acetonide (TA) in managing burning sensations in OLP patients.

The age range of the patients for the current study was above 20 year and the mean age of patients was 46 (Surjushe *et al*., 2008). Thus, OLP was more prevalent in 4th decade of life in our study, which is lower than the mean age reported in central China (50.4years), UK (52.0 years), Spain (56.4years) and Italy (56.7 years) (Bermejo-Fenoll *et al*., 2010). This divergence may be attributed to variances in ethnic composition and geographical factors when compared to earlier findings.

Patients in Group A received topical Aloe vera, while those in Group B were administered topical triamcinolone acetonide twice daily after meals, and regular follow-ups were conducted at 3 weeks and 5 weeks. The Tel Aviv-San Francisco (TASF) Scale and Clinical scores were lower in subsequent visits as compared to the initial visit.

Therefore, both the application of topical Aloe vera and triamcinolone acetonide demonstrated equal effectiveness in alleviating pain and burning sensations thus enhancing the clinical condition of patients with oral lichen planus. This may be ascribed to the anti-inflammatory properties of Aloe vera and the immunosuppressive effects of steroids. Corticosteroids primarily exert their effects by suppressing antigen-driven T-cell proliferation through inhibiting the release of interleukin-1 (IL-1) from monocytes. In contrast, Aloe vera hinders the inflammatory process through its interference with the arachidonic acid pathway via cyclooxygenase (Surjushe *et al*., 2008). Recent data also have suggested that Aloe vera has anti-inflammatory effects by the reduction of leukocyte adhesion and TNF-α level (Vogler & Ernst, 1999; Surjushe *et al*., 2008).

In our study, when comparing the burning sensation using the Tel Aviv-San Francisco (TASF) Scale, the mean value for the Aloe vera group at the 3rd visit was 75.00, whereas for the Triamcinolone group, it was 68.33. This indicates that Aloe vera exhibited a slightly more efficient reduction in burning sensation compared to Triamcinolone acetonide.

Reddy *et al*. (2012) conducted a randomized trial comparing Aloe gel and triamcinolone acetonide ointment in the treatment of oral lichen planus, involving 40 patients (23 males and 17 females). The participants were randomly assigned to two equal groups, receiving either Aloe vera gel or triamcinolone acetonide. Upon observation of clinical signs and symptoms after 8 weeks of therapy, it was established that Aloe vera gel proved more effective than triamcinolone acetonide in treating oral lichen planus. Nevertheless, in our investigation, both Aloe vera and triamcinolone acetonide demonstrated effectiveness in reducing the burning sensation associated with the lesions.

The amount of active ingredient in AV varies depending on the age of plants, growing, and harvesting conditions, parts of plants, and extraction methods (Choonhakarn *et al*., 2008). The topical Aloe vera gel used in over study had 100% aloe vera concentration.

The results of our study showed that topical Aloe vera alleviated symptoms of OLP without any side effects.

CONCLUSION

In conclusion, the outcomes derived from our study are promising, indicating positive results with the use of Aloe vera in patients with OLP. Nevertheless, given the limited sample size in our study, it is advisable to conduct further investigations on a larger scale with an extended follow-up period. Additionally, considering the exploration of oxidative stress markers and assessments of antioxidant enzyme levels at pre- and post-treatment stages may provide a deeper understanding of the role of antioxidants in managing this disease and the involvement of oxidative stress in its pathogenesis.

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RESUMEN: Se llevó a cabo un ensayo clínico aleatorizado para comparar la eficacia del gel de aloe vera y el acetónido de triamcinolona al 0,1% en el tratamiento del liquen plano oral sintomático. El estudio involucró una muestra de 30 pacientes (16 hombres y 14 mujeres) diagnosticados clínica e histopatológicamente con liquen plano oral, que fueron asignados aleatoriamente en dos grupos. A los pacientes del grupo A se les administró gel de aloe vera, mientras que los del grupo B recibieron acetónido de triamcinolona al 0,1% como aplicación local. Después del tratamiento, los resultados obtenidos fueron analizados estadísticamente y tabulados. Los resultados de la investigación indican que la aplicación tópica de Aloe vera es tan efectiva como usar acetónido de triamcinolona tópico, lo que sugiere que el Aloe vera puede ser un reemplazo preferible debido a su perfil de seguridad en comparación con el acetónido de triamcinolona al 0,1%.

PALABRAS CLAVE: liquen plano, aloe vera, acetónido de triamcinolona, OLP, AV.

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