ORIGINAL ARTICLE

Efficacy of Aloe Vera Gel in the Treatment of Vulval Lichen Planus

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ABSTRACT

Objective: To compare the efficacy of aloe vera gel and placebo in the topical management of vulval lichen planus.
Study Design: Randomized, double-blind, placebo-controlled trial.
Place and Duration of Study: Department of Dermatology, Isra University Hospital, Hyderabad, from January 2007 to January 2008.
Methodology: Thirty-four female patients were randomized into two groups to receive aloe vera gel or placebo for local application for 8 weeks. Clinical data and treatment response was graded according to Thongprasom criteria. Z-test was used for comparing response between the groups.
Results: Thirty-four consecutive patients participated in the study. We found erosive and ulcerative lesions in 83% and 17%, respectively. The most common site of vulval lichen planus was the labia minora. Fourteen (82%) out of 17 patients treated with aloe vera had a good response i.e. clinically improved by at least 50% after 8 weeks of treatment, while one (5%) of 17 placebo-treated patients had a similar response ($p < 0.001$). Furthermore, one patient (5%) treated with aloe vera had a complete clinical remission. No side-effects were found in both groups.
Conclusion: Aloe vera gel was a safe and effective treatment for patients with vulval lichen planus.

Key words: *Aloe vera. Vulva Lichen planus.*

INTRODUCTION

Vulval lichen planus is a chronic inflammatory disorder of mucosal surfaces. There are flares and partial remission but no tendency for complete remission. Vulval lichen planus is quite common, affecting 1-2% of the population. Vulval lichen planus, unlike cutaneous lichen planus, is usually recalcitrant to treatment.[1,2] Prevalence of vulval lichen planus is still unknown, but there is evidence to suggest that it is immunologically mediated. Presentation of vulval lichen planus can be variable, patients typically presents with marked mucosal fagility, erythema and agglutination of labia majora, labia minora and vaginal orifice, but the most common site of involvement is labia minora.[3,4]

Vulval lichen planus is classified into three clinical types: white reticular, atrophic/erosive and ulcerative. The classical lesions consist of reticulated papules with violaceous discolouration, but hypertrophic, ulcerative and erosive forms can also occur. The disease causes lot of pruritus and dyspareunia, which seriously affects patients' quality of life. However, a minority of patients may be asymptomatic or have minimal symptoms.[5-7]

Several topical and systemic treatments are available for patients with vulval lichen planus but therapeutic responsiveness may differ.[8]

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Received April 9, 2008; accepted September 2, 2008.

Aloe Vera (AV) is a cactus-like plant that belongs to the Liliaceae family; it is species of *aloe*, native to northern Africa. Some cosmetic and medicinal products are made from the mucilaginous tissue in the centre of the *Aloe vera* leaf, which is called aloe vera gel. Researchers at the University of Miguel Hernandez in Alicante, Spain, have developed an aloe vera gel, which is tasteless, odourless and colourless.[10] The pharmacological actions of aloe vera include anti-inflammatory, antibacterial, antiviral and antifungal properties, and hypoglycaemic effects. *Aloe vera* has been used externally to treat various skin conditions such as cuts, burns and eczema.[11]

To the best of our knowledge, there has been only one case report of lichen planus that successfully responded to topical aloe vera,[12] but there has been no study comparing aloe vera gel and placebo in the treatment of vulval lichen planus.

The objective of this study was to compare the efficacy of topically applied aloe vera gel and placebo for the treatment of vulval lichen planus.

METHODOLOGY

It was a randomized, double-blind, placebo-controlled clinical trial carried out from January 2007 to January 2008 at the Department of Dermatology, Isra University Hospital, Hyderabad, after approval from hospital ethics committee and all patients gave verbal informed consent.

Inclusion criteria was all those patients who presented clinically with vulval lichen planus. Exclusion criteria

being pregnant women and any treatment taken during last 4 weeks for vulval lichen planus.

The aloe vera gel was prepared by Nature Bounty, USA, imported by Sigma Pharma, Pakistan. It consists of 100% aloe vera gel, triethanolamine, tocopheryl acetate, carbomer 940, tetrasodium ETDA. The placebo contained simple liquid paraffin. The study medications were packed in identical jars and code of the jars were kept at the Department of Dermatology till completion of the study.

Patients were randomly divided into two groups, group-A of patients received aloe vera gel, whereas group-B of patients received placebo. Patients were, thereby, instructed to apply the medication twice daily and were prohibited from using any emollient during the study. Each patient was examined at the beginning of treatment, and then after 2, 4, 6 and 8 weeks of therapy.

The clinical data were scored according to the criteria used by Thongprasom *et al.*[13] that included (0) for no lesion; (1) for mild white striae, no erythematous area; (2) for white striae with atrophic area < 1 cm; (3) for white striae with atrophic area > 1 cm; (4) for white striae with erosive area < 1 cm and (5) for white striae with erosive area > 1 cm or ulcerative lesion.

Treatment response was also graded according to Thongprasom *et al.*[13]; Good when scores decreased by 50% from baseline, poor when scores decreased by < 50% from baseline, and as no response when the lesions were unchanged.

Z-test for two-way hypothesis testing was used to compare the responses between the groups with significance at $p < 0.05$.

RESULTS

Thirty-four patients completed the study. There were no significant differences between the two groups with regard to age and clinical scores at baseline. The mean age of patients in group-A was 50 years and same was in group-B. The mean duration of the disease before participating in the study was 14 months in group-A and 16 months in group-B. There were atrophic and erosive lesions in 28 patients (82%, 15 in group-A and 13 in group-B), ulcerative lesions in 6 patients (18%, 4 in group-A and 2 in group-B) and reticular lesions in all patients.

The most common site of involvement was inner and outer side of labia minora in 27 patients (80%), followed by inner aspect of labia majora (7 patients, 20%).

Five of 34 patients also had cutaneous lichen planus. Regarding clinical signs at the end of therapy, one of the 17 patients in group-A had complete response, while none of the patients in group-B had complete remission. Improvement of the lesions by a decrease of the clinical scores by 50% (good response) was noted in 14 patients (82%) in the group-A and one patient (4%) in the group-B ($p < 0.001$). Thirteen patients (48%) in the group-B had poor response (improvement of < 50% from baseline), whereas 2 patients (7%) in group-A exhibited such a response. No change of the lesions after 8 weeks of therapy was observed in one patient (4%) in group-A and 13 patients (48%) in group-B ($p < 0.001$, Table I).

No side-effects were recorded in both groups.

Table I: Comparison of clinical response in both groups of patients.

Response	Aloe vera (n=17)	Placebo (n=17)
Complete response	1 (4%)	0 (0%)
Good response	14 (82%)	1 (4%)
Poor response	2 (7%)	13 (48%)
No response	1 (4%)	13 (48%)

DISCUSSION

Vulval lichen planus is a unique chronic inflammatory mucous membrane reaction, it can occur with or without cutaneous lichen planus, 55-65% of patients with cutaneous lichen planus can develop vulval lichen planus, generally in the sixth decade. Current treatments for vulval lichen planus are aimed at alleviating itching and eliminating the lesions. Many treatments have been tried but there is a lack of strong evidence supporting their efficacy.[2,5,7]

Even though no therapy of vulval lichen planus is curative, clinical relief can be achieved in the majority of patients with topical treatment such as corticosteroids, cyclosporine, retinoic acid, pimecrolimus and tacrolimus. Many systemic agents have also been used in the treatment of vulval lichen planus, e.g. acitretin, azathioprine, dapsone and systemic corticosteroids. Concomitant use of several medicines is usually required to achieve beneficial results.[2]

Vulval lichen planus is a T cell-mediated disease in which cytotoxic CD8+T cells trigger apoptosis of vulval epithelial cells. Upregulation of intercellular adhesion molecules and cytokines secreted by activated lymphocytes and keratinocytes such as interleukin IL-2, IL-4, IL-10 and Tumour Necrosis Factor (TNF) can play a role in the pathogenesis of lichen planus.[6,9]

Aloe vera can inhibit the inflammatory process by its interfering action on the arachidonic acid pathway via cyclooxygenase.[14,15] Recent data suggest that it has anti-bacterial, anti-fungal and anti-viral properties.[16,18] Aloe vera also has anti-inflammatory effects by the reduction of leucocyte adhesion and tumour necrosis factor level.[17]

After a review of the literature, only one case report was found about aloe vera gel in the treatment of lichen planus. Hayes described a 52-year-old woman who developed cutaneous lichen planus on her hands.[12] The treatment commenced with applying 75% AV cream on the hands. No other antimicrobial or steroid agent was used. After 4 weeks, the hand lesions showed slight improvement.

In this study, the effect of aloe vera gel on vulval lichen planus was significantly better than that of placebo. The results showed decrease in clinical signs. No side effects were noted and aloe vera gel was generally well-tolerated.

CONCLUSION

Aloe vera gel was a safe and effective treatment for inducing remission in vulval lichen planus.

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