

Egy prospektív, randomizált kettős-vak, 8 hetes klinikai összehasonlító vizsgálatban vizsgálták az Aloe Vera, és 0,1%-triamcinolon acetonidot enyhe - mérsékelt psoriasis vulgaris helyi kezelése során

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Absztrakt:

Aloe Vera-t (AV) használnak különböző bőrbetegségek kezelésére, így a psoriasis bőrbetegségben is, jó eredménnyel.

Ezen tanulmány célja, hogy összehasonlítsa az Aloe Vera (AV) hatásosságát és 0,1%-triamcinolon acetonid (FA)-ot **Az enyhe vagy közepesen súlyos Psoriasis Vulgaris helyi kezelésében.**

Módszerek:

Egy randomizált, összehasonlító, kettős-vak, 8 hetes vizsgálatot végeztek el. **Nyolcvan (80) beteget vizsgáltak.** Ez a nyolcvan beteg véletlenszerűen kapott Aloe Vera (AV) és 0,1% triamcinolon acetonidot –(TA) krémet.

A klinikai válaszokat értékelték, mérési módszerükben a válaszokat a Psoriasis Area Severity Index (PASI), és a Dermatology Life Quality Index (DLQI) segítségével mérték.

Eredmények:

8 hetes kezelés után az átlagos PASI- pontszám csökkent, 11,6-3,9 (-7,7) az Aloe Vera (AV) - csoportban és 10,9-4,3 (-6,6) a triamcinolon acetonid (TA) - csoportban. Csoportok közötti különbség 1,1 (95% konfidencia intervallum-2, 13, -0,16, P = 0,0237). DLQI az átlagos pontszám csökkent, 8,6-2,5 (-6,1) az AV csoport és 8,1-2,3 (-5,8) a Technikai csoportban.

Csoportok közötti különbség 0,3 (95% konfidencia intervalluma, -0,64, p = 0,5497). Nem volt

Következtetések:

Aloe Vera (AV) krém, hatásosabb lehet, mint 0,1%- triamcinolon acetonid (TA) krém!

Az Aloe Vera jobban csökkentette a klinikai tüneteket a pikkelysömör (Psoriasis Vulgaris) betegségben, azonban a két kezelés hasonló hatékonyságú az enyhe vagy középsúlyos Psoriasisos betegek életminőségének javításában.

ORIGINAL ARTICLE

A prospective, randomized clinical trial comparing topical aloe vera with 0.1% triamcinolone acetonide in mild to moderate plaque psoriasis

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Abstract

Background Topical aloe vera (AV) has been used to treat various skin conditions, including psoriasis, with good results.

Objectives This study aims to compare the efficacy of AV and 0.1% triamcinolone acetonide (TA) in mild to moderate plaque psoriasis.

Methods A randomized, comparative, double-blind, 8-week study was designed. Eighty patients randomly received AV or 0.1% TA cream and their clinical response were evaluated using the Psoriasis Area Severity Index (PASI) and the Dermatology Life Quality Index (DLQI).

Results After 8 weeks of treatment, the mean PASI score decreased from 11.6 to 3.9 (-7.7) in the AV group and from 10.9 to 4.3 (-6.6) in the TA group. Between-group difference was 1.1 (95% confidence interval -2.13, -0.16, $P = 0.0237$). The mean DLQI score decreased from 8.6 to 2.5 (-6.1) in the AV group and from 8.1 to 2.3 (-5.8) in the TA group. Between-group difference was 0.3 (95% confidence interval -1.18, -0.64, $P = 0.5497$). There was no follow-up period after the 8-week treatment.

Conclusions AV cream may be more effective than 0.1% TA cream in reducing the clinical symptoms of psoriasis; however, both treatments have similar efficacy in improving the quality of life of patients with mild to moderate psoriasis.

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Keywords

aloe vera, mild to moderate, psoriasis, triamcinolone acetonide

Conflicts of interest

None declared.

Introduction

Psoriasis affects between 1% and 3% of the world's population. Although it is generally considered a benign disorder because it does not cause mortality among those affected, it has a severe impact on quality of life. Various existing treatments for psoriasis have been optimized by enhancing their clinical efficacy and/or decreasing the occurrence of side effects. However, treatment management should be individualized, resulting in optimal treatment for each patient at the very first moment of consultation.

A variety of approaches are available for psoriasis therapy, ranging from topical medications for mild or moderate psoriasis to systemic agents and phototherapy for the severe form of the disease. Despite the importance of systemic agents and the advances represented by biologics, topical medications remain the mainstay for most psoriatic patients. Topical corticosteroids are important in the

management of psoriasis. In appropriate concentrations, they are generally effective and cosmetically acceptable, and are the treatment of choice for flexures and the genitalia where other medications may be an irritant. However, corticosteroid overuse may cause local side effects and, rarely, serious systemic problems.¹⁻³

Aloe vera (AV) is a perennial, succulent, cactus-like plant belonging to the family Liliaceae. AV secretes a clear, mucilaginous gel possessing diverse putative pharmacological activities, including anti-inflammatory effects, and is being used for various cosmetic and medicinal purposes.⁴⁻⁶ AV cream has been described as an effective treatment for psoriasis without any drug-related side effects when compared to placebo.⁷

Our purpose here was to compare the efficacy of topically applied AV and 0.1% triamcinolone acetonide (TA) for the treatment of psoriasis in a double-blind, randomized protocol.

Materials and methods

Study design

This study used a randomized, comparative, double-blind design. The study was carried out between October 2006 and September 2007. The sample size was calculated after checking relevant, related published articles. We used the PASS program for equivalent proportions with the following information – standard proportion = 0.7, experimental proportion = 0.75, type I error (α) = 0.05, type II error (β) = 0.2 – and determined 40 patients were needed for each group.

Study population

Patients with chronic plaque psoriasis were recruited from the Division of Dermatology, Srinagarind Hospital, Faculty of Medicine, Khon Kaen University, and were asked to participate in our study.

Entry criteria required a clinical diagnosis of psoriasis involving < 10% of the body surface and being at least 18 years of age. Exclusion criteria included pregnancy and known hypersensitivity to AV or corticosteroids. All patients had a 4-week washout of any topical treatment for psoriasis prior to receiving the study drugs. Systemic therapies, including phototherapy, were discontinued 4 weeks before the study.

Randomization, study medication and treatment

The patients were randomly assigned into either of two groups. Randomization was performed by using a simple random table. AV and 0.1% TA cream were prepared by the Faculty of Pharmaceutical Sciences, Khon Kaen University, and the AV cream consisted of 70% aloe mucilage. The study medication was packed in identical containers and the code was kept at the Faculty of Pharmaceutical Sciences until completion of the study.

The first group of patients received AV cream and the second group received 0.1% TA cream. The medication used was not revealed to either patients or their physicians. The patients were instructed to apply the medication twice daily and were prohibited to use any emollient during application.

Assessments

Each patient was examined at the beginning of treatment, and again after 2, 4 and 8 weeks of therapy. The severity of the disease was measured using the Psoriasis Area Severity Index (PASI) scoring method as described elsewhere.⁸

The primary outcome measure was the PASI, which was calculated at weeks 0, 2, 4 and 8. The range of the PASI is 0 to 72. The efficacy outcome was the change in PASI score from baseline to the measure at 8 weeks. The clinical findings were rated: 'complete response' (clear) when the PASI score at week 8 was 0; 'marked' when the PASI score was decreased \geq 75% (PASI 75); 'moderate' when the PASI score was decreased 50–74% (PASI 50); and 'slight' when the PASI score was decreased < 50% from the baseline. No response was indicated when the lesions showed no change after the end of therapy.

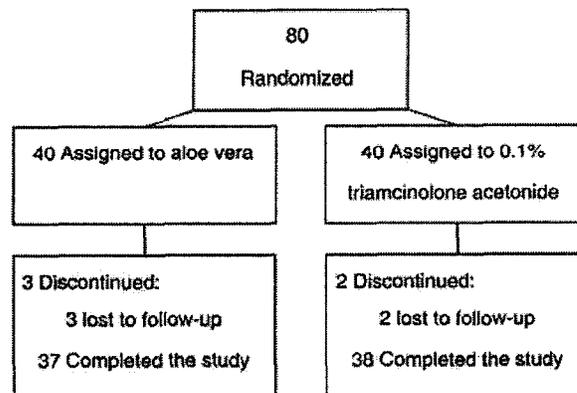


Figure 1 Flow chart of the study participants.

The secondary endpoint was evaluated by using the Dermatology Life Quality Index (DLQI).⁹ The patients completed the DLQI at baseline and after 2, 4 and 8 weeks of treatment.

Ethical considerations

The study was approved by the Ethics Committee of the Faculty of Medicine before the trial started and all patients gave written informed consent. The study was conducted in accordance with the ICH Guideline for Good Clinical Practice for the clinical testing of drugs, and the Declaration of Helsinki.

Statistical analysis

Comparison between groups was done using the *t*-test. Two-sided 95% confidence interval (CI) for the difference in response rates between the two treatment groups was calculated. A *P*-value of < 0.05 was needed for a result to be considered statistically significant.

Results

Study patients

Eighty consecutive patients (43 females, 37 males) were enrolled in this study. Five patients were lost during follow-up, three in the AV group and two in the TA group (Fig. 1). Demographics and clinical characteristics are presented in Table 1. There were no significant differences between the two groups in terms of age, sex, mean DLQI scores and mean PASI scores at baseline. The mean duration of the disease before participating in the study was 7.89 years in the AV-treated group and 6.42 years in the TA-treated group. The sites of the lesions that were used in the study for both groups are presented in Table 2.

Efficacy analysis: primary endpoint

After 8 weeks of treatment, no patient experienced complete clearance of psoriasis in either group. Six patients (16.2%) in the

Table 1 Baseline demographics and disease parameters

	Aloe vera (n = 37)	0.1% Triamcinolone acetonide (n = 38)
Age (years)		
Mean \pm SD	43.4 \pm 11.2	44.2 \pm 13.0
Range	27–65	23–71
Gender, n (%)		
Male	17 (54.1)	19 (50)
Female	20 (45.9)	19 (50)
Previous treatments, n		
Topical only	25	28
Ultraviolet B	9	7
Methotrexate	5	3
Acitretin	1	2
PASI score week 0, mean \pm SD	11.6 \pm 2.9	10.9 \pm 3.1
DLQI score week 0, mean \pm SD	8.6 \pm 1.7	8.1 \pm 1.8

DLQI, Dermatology Life Quality Index; PASI, Psoriasis Area Severity Index; SD, standard deviation.

AV group and four patients (10.5%) in the TA group achieved a PASI 75 by week 8 (Fig. 2). Twenty patients (54.1%) in the AV group achieved a PASI 50 compared to 25 (65.8%) in the TA group. Ten patients (27%) in the AV-treated group and nine (23.7%) in the TA-treated group experienced a slight improvement in their lesions (PASI scores decreased < 50% from baseline) by week 8. There was no change observed in the lesions, even at the end of the therapy, in one patient (2.7%) receiving AV (Fig. 3). The mean PASI score at baseline was 11.6 in the AV group and 10.9 in the TA group (difference 0.7, 95% CI -2.04, 0.66, $P = 0.3120$). After 8 weeks of treatment, mean PASI score was 3.9 (-7.7) and 4.3 (-6.6), respectively (difference 0.4, 95% CI -0.37, 1.28, $P = 0.2783$) (Fig. 4). The between-group difference in the adjusted means was 1.1 (95% CI -2.13, -0.16, $P = 0.0237$) (Table 3). AV cream was significantly superior to 0.1% TA cream with respect to the lesion as evaluated using the PASI score.

Efficacy analysis: secondary endpoint

The impact of psoriasis on patients' quality of life was assessed using the DLQI. The mean DLQI scores decreased in both treatment groups throughout the course of the study, but in comparison with baseline there was no significant difference between the two

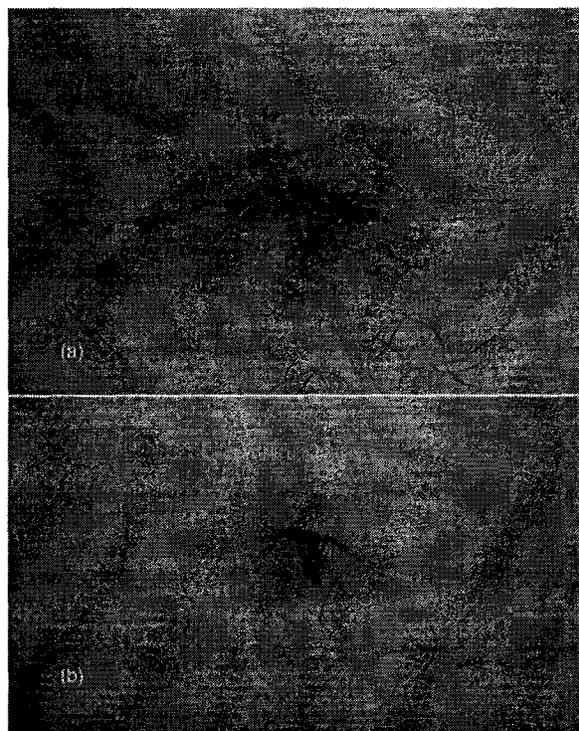


Figure 2 (a) Psoriatic lesions on umbilicus; (b) marked improvement after an 8-week treatment with aloe vera cream.

groups after 8 weeks of treatment. The patients in the AV group had a mean DLQI score of 8.6 at baseline, decreasing to 2.5 after 8 weeks of treatment (a drop of 6.1). The TA group showed a DLQI score decrease from 8.1 at baseline to 2.3 at week 8 (a drop of 5.8) (Fig. 5). The between-group difference in adjusted means was 0.3 (95% CI -1.18, -0.64, $P = 0.5497$) (Table 3).

Side effects

No serious side effects were recorded in either group. Six patients receiving AV cream experienced stinging and itching at the lesions, mostly within the first week after topical application. All adverse effects were reversible after receiving supportive treatment with antihistamines. No significant complaint was reported by the patients who received 0.1% TA cream.

Table 2 Location of the lesions

Agent	Number of patients	Location of lesions (%)			
		Face	Trunk	Upper extremity	Lower extremity
Aloe vera	37	1 (2.7)	10 (27.0)	11 (29.7)	15 (40.5)
0.1% Triamcinolone acetonide	38	0	12 (31.6)	10 (26.3)	16 (42.1)
Total	75 (100)	1 (2.7)	22 (58.6)	21 (56.0)	31 (82.6)

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the AV-treated sites compared with 82.5% of the placebo-treated areas at week 4 ($P = 0.0197$). However, there was no difference in efficacy between AV and the placebo after 12 weeks.

Although contrary results were reported by two previous placebo-controlled studies,^{7,15} our study showed that AV cream was more effective than 0.1% TA cream after 8 weeks of treatment. In our study, a considerably lower percentage of patients in the AV group reached PASI 75, compare with the previous study.⁷ The average improvement in the PASI after 8 weeks was approximately 60.1% in the TA group and 66.1% in the AV group. In contrast to a previous study,⁷ no complete remission was observed in either of our groups; however, the between-group difference in adjusted means was statistically significant.

After 8 weeks of treatment, no significant difference was seen in the between-group difference in mean DLQI, indicating that the AV cream and the 0.1% TA cream were equally effective in improving patients' quality of life. The mean improvement in the DLQI scores of both groups was approximately 71%.

The side effects of AV cream were mild and they were controlled by using symptomatic treatment alone. Because there were only few and mild side effects, none of the patients withdrew from the study. AV cream may be appropriate for psoriasis that involves the face, genitalia and intertriginous areas, and may be used in certain populations, including children and the elderly, to prevent the occurrence of local or systemic adverse effects that can develop after prolonged use of corticosteroids.

Psoriasis is characterized by hyperproliferation and abnormal differentiation of keratinocytes and lymphocyte infiltration (mostly T lymphocytes). The T lymphocytes and the cytokines they release [interferon- γ , interleukin-2 and tumour necrosis factor- α (TNF- α)] appear to be important factors in lesion occurrence and persistence. TNF- α may promote psoriasis development in several ways, which include increasing proliferation of keratinocytes and augmenting the production of pro-inflammatory cytokines from T lymphocytes and macrophages, and of adhesion molecules from vascular endothelial cells. TNF- α is also a promoter of angiogenesis.³ AV has an anti-inflammatory activity and it is suggested that its inhibitory action on the arachidonic acid pathway is via cyclooxygenase.⁶ Recently, AV was found to reduce leucocyte adherence and TNF- α level in the anti-inflammatory process.^{16,17}

In conclusion, in this study we found that AV cream is more effective than 0.1% TA cream in terms of lowering patients' PASI score. However, both treatments have a similar efficacy in improving patients' quality of life. Thus, AV cream can be con-

sidered a safe, alternative treatment for mild to moderate chronic plaque psoriasis.

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