

# Efficacy of a Thai Herbal Remedy in Patients with Mild Chronic Plaque Psoriasis: An Observer-Blinded Randomized, Standard Treatment-Controlled Trial

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**Background:** Psoriasis is a chronic non-infectious inflammatory skin disease caused by genetic and environmental predispositions. There is a Thai herbal remedy for psoriasis recorded in Wat Pho's marble inscriptions, consisting of *Dictyophora indusiate* Fisch, *Psilocybe cubensis* (Earle) Sing, and sesame oil.

**Objective:** To compare the efficacy and safety of a Thai herbal remedy as an alternative treatment to the standard treatment of 0.1% triamcinolone lotion in patients with mild chronic plaque psoriasis.

**Materials and Methods:** A randomized, split-body controlled design was conducted in 30 mild chronic plaque-type psoriasis patients with symmetrically distributed psoriasis rashes. Each patient was randomized to apply a Thai herbal remedy on a rash on one side of the body and 0.1% triamcinolone lotion on the other side, using the same dosage of twice daily for eight weeks. Efficacy was assessed at week 1, 2, 4, and 8 by the Targeted Area Score (TAS). The Self-Assessment Score (SAS) at week 8 was compared to the baseline. Safety was assessed through the interviews at each visit. Product satisfaction was evaluated by the visual analog scale (VAS).

**Results:** The TAS and SAS for erythema, desquamation, and induration decreased in both treatment groups, with no significant difference. However, product satisfaction in color ( $p=0.012$ ), odor ( $p=0.013$ ), and absorption ( $p=0.003$ ) were significantly higher in the 0.1% triamcinolone lotion group.

**Conclusion:** The present study showed that the Thai herbal remedy was safe and efficacious in treating chronic plaque-type psoriasis, therefore, can be used as an alternative treatment.

**Keywords:** Thai herbal remedy; Psoriasis; *Dictyophora indusiate* Fisch; *Psilocybe cubensis* (Earle) Sing; Sesame oil

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Psoriasis is a common chronic skin disorder with predisposing genetic and external environmental factors, resulting in skin inflammation and excessive growth of skin epithelial cells. Chronic plaque-type psoriasis is characterized by a well-demarcated erythematous plaque with an overlying silvery scale. The common locations of psoriasis are the scalp and bony-prominent areas. Apart from the

physical aspect of the disease, psoriasis also affects the patients psychologically and their quality of life. Plaque psoriasis tends to be mild to moderate severity. Typically, mild plaque psoriasis lesions involve no more than 10% of the body surface area.

The Clinical Practice Guideline for Psoriasis from the Dermatological Society of Thailand recommends topical corticosteroids such as 0.1% triamcinolone lotion, which is a medium-potency topical corticosteroids preparation for the treatment of mild plaque psoriasis, vitamin D analogs, tar, and dithranol such as Anthralin, as the standard treatment regimen for mild psoriasis patients with lesions involving less than 10% of the body surface area using the Psoriasis Area and Severity Index (PASI). Phototherapy or systemic therapies are recommended for those with more severe clinical symptoms or who do not respond to topical treatment<sup>(1)</sup>. Because psoriasis is a chronic disease, patients need to use medications for a long time. Many alternative

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medicines are necessary to avoid unfavorable long-term side effects of some treatments.

Herbal medicine has been increasingly used as the treatment for a variety of diseases worldwide. Thai herbal remedies from Wat Pho's marble inscription have been declared a world heritage by the United Nations Educational, Scientific and Cultural Organization (UNESCO)<sup>(2)</sup>. A combination of *Dictyophora indusiata* Fisch, which had an anti-inflammatory and immune-enhancer effect<sup>(3,4)</sup>, *Psilocybe cubensis* (Earle) Sing, which has psilocybin, an alkaloidal and 5-hydroxymethyl-2-furan-carboxylic acid, that is an antimicrobial, and sesame oil, which is a nutritional product with medicinal properties consists of multiple antioxidants, was recorded as potential Thai herbal remedy for psoriasis but has never been tested on the skin and no study in vitro<sup>(5)</sup>.

## Materials and Methods

### The Thai herbal remedy

Thai herbal remedy for psoriasis recorded in Wat Pho's marble inscriptions consists of 25% of *Dictyophora indusiata* Fisch, 25% of *Psilocybe cubensis* (Earle) Sing, and 50% of Sesame oil. The preparation is a brown-colored lotion. All herbs in the remedy complied with the in-house standard specifications tested at the Faculty of Pharmaceutical Science, Khon Kaen University, and the Faculty of Pharmacy, Mahasarakham University. In addition, the herbs were tested for specific microbial assays such as *Staphylococcus aureus*, *Clostridium* spp., and *Salmonella* spp., which had negative results. Furthermore, the results for heavy metal contamination tests, including arsenic, cadmium, and lead, were also negative. The tests for cadmium and lead were performed by the Department of Medical Sciences of the Ministry of Public Health.

Dosage was assessed by a safety study of 10 healthy volunteers. Briefly, using a provocative use test, 5 mL per 1 square inch skin surface area was applied on a designated area of the forearm twice a day for seven days. Then, the skin reactions were evaluated by a dermatologist immediately and after the first application at 15 and 30 minutes, Day 2, Day 3, and Day 7. Neither skin nor systemic reactions were observed in all healthy volunteers at all time points.

### Research design

The present study was conducted in accordance with the Good Clinical Practice Guidelines and

approved by the Institutional Ethics Committee of the Faculty of Tropical Medicine, Mahidol University (approved No. TMEC 18-008) and The Thai Clinical Trial Registry (No.201801225004). The study design was an open-label, dermatologist observer-blinded, randomized, and standard treatment-controlled trial that compared the efficacy and safety of a Thai herbal remedy with a 0.1% triamcinolone lotion, approved by the Thai Food and Drug Administration for medical use. The participants must wash out any topical treatment or systemic medication within the two weeks before the study period.

The participants with mild chronic plaque psoriasis who had symmetrically psoriasis rashes were simply randomized by an investigator (KC) to apply a Thai herbal remedy on a rash on one side of the body and 0.1% triamcinolone lotion on the other side. The dosage of both medications was 5 mL per 1 inch<sup>2</sup> skin surface area twice daily for eight weeks. To avoid cross-contamination, the patients were recommended to wash their hands before applying a Thai herbal remedy and 0.1% triamcinolone lotion. During the study period, patients did not use other topical medications.

### Sample size

A literature review of topical drug use in clinical trials was applied as the reference for appropriate sample size, randomized controlled trial for topical drugs in dermatology, within-person design. It is suggested that the split-body design could have fewer participants<sup>(6)</sup>. In a previous clinical trial, namely "Comparative Study of Tar and Betamethasone Valerate in Chronic Plaque Psoriasis", the sample size included 30 patients, with a 20% assumption of a loss to follow-up and withdrawals<sup>(7)</sup>. The formula for sample size calculation in the clinical trials was derived from a textbook of clinical research<sup>(8)</sup>, which resulted in 30 patients in the present study.

### Study participants

The mild chronic-plaque type psoriasis patients, aged over 18 years old, with symmetrically distributed rashes, who attended the Dermatology Outpatient Department, Hospital for Tropical Diseases, were enrolled. The exclusion criteria were pregnancy, receiving any topical treatments within two weeks, allergy to any herbal medicines, and immunodeficiency diseases.

### Efficacy and safety assessment

Efficacy was assessed by using the Targeted Area

Score (TAS), consisting of an individual assessment of erythema, desquamation, and induration. The scores ranged from 0 to 4 for each aspect. TAS was not related to the body surface area and was recorded at baseline, weeks 1, 2, 4, and 8. A clinical examination of both treated sides was performed by an experienced dermatologist (JD or SK), who were the blinded observers, to obtain the TAS. Self-Assessment Score (SAS) was recorded at baseline, and week 8 was performed by interviewing the patients individually. Lesions were graded in three aspects, including erythema, induration, and desquamation, with the following scores, 0=none, 1=slight, 2=moderate, 3=severe, and 4=very severe. Photographs of lesions on both sides were taken at each visit. In addition, local side effects were assessed at each visit by interviewing the patients about itching, burning, and pain on the lesion.

At the end of the present study, product satisfaction was evaluated at week 8 by VAS (1 to 10), focusing on skin moisture, color, odor, absorption, packaging, and easy-to-use.

### Statistical analyses

The intention-to-treat approach was used for statistical analyses. For TAS, SAS, and VAS outcomes, paired t-test and Fisher's exact test were applied. Statistical significance was considered if the p-value was less than 0.05. Continuous variables were described by mean and standard deviation, while discrete variables used proportion. All statistical analyses were conducted with IBM SPSS Statistics, version 27.0 (IBM Corp., Armonk, NY, USA).

### Results

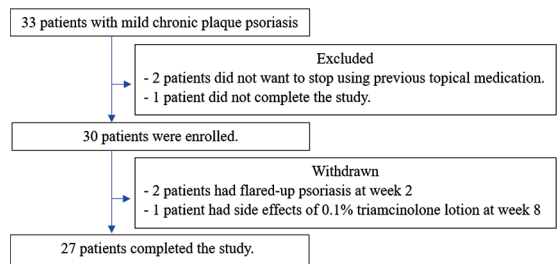
Overall, thirty-three patients diagnosed with chronic mild plaque psoriasis were screened into the present study, and three patients were excluded as two patients did not want to stop using previous topical medication, and one patient did not complete the study. Finally, 30 patients with chronic mild plaque psoriasis were included in the present study. The baseline characteristics of the patients are shown in Table 1.

During the study, two patients were withdrawn by the investigators at week 2 due to psoriasis flare-up, which required systemic therapy, and one patient stopped 0.1% triamcinolone lotion at week 8 due to redness and stinging side effects. Eventually, the intention-to-treat analysis included 27 patients, as shown in Figure 1.

**Table 1.** Baseline characteristics (n=30)

Characteristics	Value
Sex; n (%)	
Male	16 (53)
Female	14 (47)
Age (years)	
Mean±SD	47±2.35
Range	30 to 80
Disease duration (years)	
Mean±SD	10.5±0.70
Range	2 to 20
Previous treatments; n (%)	
Topical medication	27 (90)
Topical medication and MTX	2 (6)
Herbal medication	1 (3)
Lesion sites; n (%)	
Legs	15 (50)
Arms	7 (23)
Trunk	6 (22)
Scalp	1 (3)
Buttock	1 (3)
Smoking; n (%)	3 (10)
Alcohol intake; n (%)	3 (10)

SD=standard deviation; MTX=methotrexate



**Figure 1.** Flow diagram of the study.

### Efficacy

The baseline TAS for erythema, induration, and desquamation was not significantly different at 1.81±0.79, 1.59±0.93, and 1.85±0.86, respectively, in the Thai herbal remedy group versus 1.67±0.68, 1.52±0.85, and 1.70±0.82 in the 0.1% triamcinolone lotion group. At week 8, TAS was significantly reduced to 0.84±0.75 for erythema, 0.84±0.75 for induration, and 0.64±0.70 for desquamation in a Thai herbal remedy group and side versus 0.68±0.69, 0.92±1.04, and 0.60±1.12 in a 0.1% triamcinolone lotion group, as shown in Figure 2.

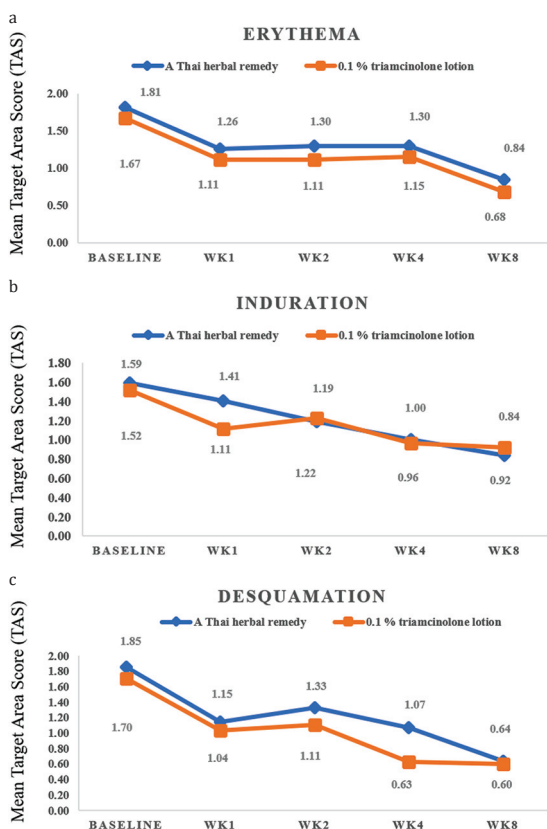
For efficacy assessment, psoriasis lesions at baseline were compared with the lesions at week 8. The results of TAS showed that for the 0.1%

**Table 2.** Efficacy assessment using TAS and SAS at week 8, compared to baseline

Assessment	Treatment	TAS; n (%)			SAS; n (%)		
		Better	Not better	p-value#	Better	Not better	p-value#
Erythema	A Thai herbal remedy	20 (74)	7 (26)	0.745	18 (67)	9 (33)	1.000
	0.1% TA lotion	22 (81)	5 (19)		17 (63)	10 (37)	
Induration	A Thai herbal remedy	17 (63)	10 (37)	0.372	18 (67)	9 (37)	0.577
	0.1% TA lotion	21 (78)	6 (22)		15 (56)	12 (44)	
Desquamation	A Thai herbal remedy	21 (78)	6 (22)	1.000	19 (70)	8 (30)	1.000
	0.1% TA lotion	22 (81)	5 (19)		19 (70)	8 (30)	

TAS=Targeted Area Score; SAS=Self-Assessment Score; TA=triamcinolone

# Fisher's exact test



**Figure 2.** (a) Mean erythema scores of two groups at baseline and each time point. (b) Mean induration scores of two groups at baseline and each time point. (c) Mean desquamation scores of two groups at baseline and each time point.

triamcinolone lotion group, the percentages of patients with better outcomes of erythema (81%) and desquamation (81%) were higher than induration (78%). For the Thai herbal remedy group, the better results of desquamation (78%) were higher than erythema (74%) and induration (63%). However, there was no significant difference between the

Thai herbal remedy and 0.1% triamcinolone lotion on each efficacy assessment by TAS (erythema:  $p=0.745$ ; induration:  $p=0.372$ ; and desquamation:  $p=1.000$ ). SAS at week 8 was also compared with the baseline and described as better or not better. For the lesions treated with 0.1% triamcinolone lotion, the percentages of patients with better results of desquamation was 70%, and was higher than erythema at 63% and induration at 56%. For the Thai herbal remedy, the percentages of better desquamation was 70% and was higher than erythema at 67% and induration at 67%. Notably, there were no significant differences between the two groups on each efficacy assessment by SAS (erythema:  $p=1.000$ ; induration:  $p=0.577$ ; and desquamation:  $p=1.000$ ), as shown in Table 2.

### Local side effects

Local side effects were assessed by the questionnaire interview of the patients at weeks 1, 2, 4, and 8. No adverse reactions such as itching, burning, or pain were reported, but the patients complained of the color of herbal medicine on their clothes after using Thai herbal remedies. However, one patient withdrawn from the study and was not included in the analysis because of erythema and a burning sensation at the 0.1% triamcinolone lotion site.

### Product satisfaction

At the end of the study, patients were interviewed using VAS. As a result, 0.1% triamcinolone lotion was significantly better than Thai herbal remedy in terms of color ( $p=0.012$ ), odor ( $p=0.013$ ), and absorption ( $p=0.003$ ) (Table 3).

Representative psoriasis lesions at different locations of the patients at baseline were compared with the lesions at week 8 after treatments (Figure 3, 4).



**Table 3.** Product satisfaction at the end of the study using VAS

Factors	A Thai herbal remedy; mean±SD	0.1% triamcinolone lotion; mean±SD	p-value@
Moisturized skin	4.46±0.962	4.00±1.388	0.152
Color	4.11±1.166	4.71±0.713	0.012*
Odor	3.71±1.272	4.36±0.911	0.013*
Adsorption	3.61±1.370	4.50±0.793	0.003*
Easy to use	4.39±0.994	4.61±0.737	0.246
Packaging	4.29±1.301	4.57±0.742	0.223

SD=standard deviation

@ paired t-test

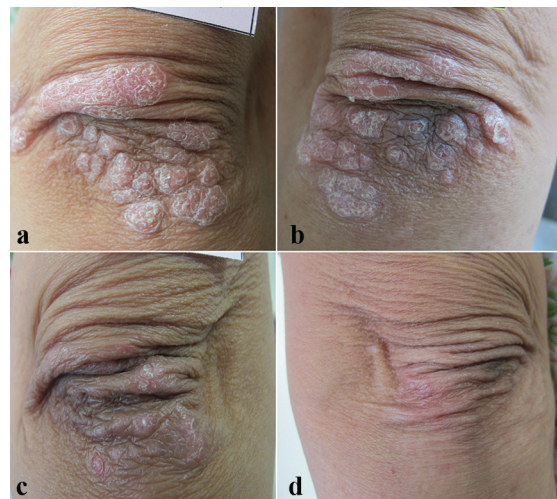
## Discussion

The present study is the first study of the Thai herbal remedy, consisting of *Dictyophora indusiate* Fisch, *Psilocybe cubensis* (Earle) Sing, and Sesame oil for the treatment of psoriasis. The results revealed the comparable efficacy of the Thai herbal remedy to the standard 0.1% triamcinolone lotion in reducing symptoms of erythema, desquamation, and induration in the treatment of psoriasis. *Dictyophora indusiate* Fisch extracts have antioxidant potential that leads to a significant anti-inflammatory effect, and effective collagen stimulation<sup>(9)</sup>. In addition, polysaccharides in the extracts enhance cell-mediated immunity through the regulation of immunomodulatory cytokines<sup>(10)</sup>. *Psilocybe cubensis* (Earle) Sing contains a high concentration of 5-hydroxymethyl-furan-2-carbaldehyde, which is effective in the antibacterial activity against *Staphylococcus aureus*<sup>(5)</sup>. Sesame oil has antioxidant mechanisms that lead to anti-inflammatory and immune-enhancer effects<sup>(11)</sup>. It also promotes wound healing and repairs of the skin barrier<sup>(12)</sup>. Psoriasis is a chronic immune-mediated inflammatory condition of skin and several other systems<sup>(1)</sup>. Therefore, it is possible that the anti-inflammatory, immune-enhancer, and antioxidant mechanisms contained in the herbal ingredients improve the skin lesion of psoriasis. Moreover, antibacterial action of *Psilocybe cubensis* (Earle) Sing may reduce secondary bacterial infection that could worsen psoriatic lesions.

There were studies on other Thai herbal remedies in the treatment of psoriasis. A randomized controlled trial study of the efficacy of *Gynura pseudochina* (GP) DC. var. *hispidula* Thv. ointment versus 0.1% TA cream in treating 25 patients with chronic plaque psoriasis who had lesions distributed equally on both sides of the body. TAS was assessed at baseline and weeks 1, 2, 3, and 4. Regarding the TAS for erythema and induration, the efficacy of the GP ointment could



**Figure 3.** Lesions of a 51-year-old male patient with psoriasis for 10 years using a Thai herbal remedy at weeks 0 (a) and week 8 (c) compared with using 0.1% TA lotion at week 0 (b) and week 8 (d).



**Figure 4.** Lesions of a 55-year-old female patient with psoriasis for 10 years using a Thai herbal remedy at weeks 0 (a) and week 8 (c) compared with using 0.1% TA lotion at weeks 0 (b) and 8 (d).

be observed as early as the first week of treatment.

Additionally, the GP ointment demonstrated similar efficacy to that of 0.1% TA cream, which demonstrated equivalent reduction of erythema, scaling, and induration on both treated sides. Safety showed similar side effects from both treatments such as yellowish staining, which could be washed off with water. Moreover, 12% of the lesion treated with 0.1

TA cream had hypopigmentation<sup>(13)</sup>. Consistent with the present study, both Thai herbal remedies, the GP ointment, and the combination of *Dictyophora indusiata* Fisch, *Psilocybe cubensis* (Earle) Sing, and sesame oil, could rapidly alleviate redness from the first week of treatment. Additionally, Thai herbal remedies also contain some anti-inflammatory effects. However, the undesirable side effects of both Thai herbal remedies were color staining on the clothes.

There have been several clinical trials using topical cannabidiol in the treatment of psoriasis. In a dual-center randomized placebo-controlled study of topical cannabidiol (CBD)-based treatment for psoriasis, the study design was split-body and double-blind, which included 51 mild plaque-type psoriasis patients. The patients were assigned to apply 2.5% CBD ointment and placebo and followed-up at weeks 2, 4, 8, and 12 for PASI score evaluation. The results indicated that 2.5% CBD ointment could significantly reduce PASI scores. As for safety, the observed adverse events were unlikely due to CBD. Preliminary clinical evidence suggested that topical CBD application may be effective for treating psoriasis and other inflammatory conditions<sup>(14)</sup>. Though CBD and a Thai herbal remedy for psoriasis treatment tend to have favorable responses and could potentially be a novel therapeutic option for psoriasis, systemic side effects should be further studied for extensive use of the medicines on the whole body.

Product satisfaction, in terms of moisture, easy to use, and packaging, of Thai herbal remedy was not significantly different from 0.1% triamcinolone lotion, but not for the color, odor, and drug absorption. Future studies to improve the product satisfaction of Thai herbal remedies should be implemented without compromising their efficacy and safety. In a previous study, the application of the black sesame meal scrub cream was acceptable for its moisture. Therefore, future studies on product development and stability of Thai herbs are essential to increase satisfaction<sup>(15)</sup>. Traditional Thai medicine may be an alternative psoriasis treatment, particularly with some specific herbs. The management guidelines incorporating Thai Herbal Remedy for psoriasis treatment may also reduce the extensive use of steroids.

The limitation of the study was that Thai Herbal Remedy was applied on a small and selective area of psoriasis rash. Therefore, possible systemic side effects could not be evaluated. Moreover, three psoriasis patients could not control the disease symptoms. As a result, the data were obtained from

27 psoriasis patients for statistical analysis, thus compromising the statistical test's power. Studies in the future with whole-body treatment, longer follow-up, and monitoring side effects should be evaluated.

## Conclusion

The combination of Thai herbs in the present study was a novel Thai herbal remedy for psoriasis treatment. The results tended to have comparable efficacy to 0.1% triamcinolone lotion in reducing erythema, induration, and desquamation symptoms. Moreover, side effects or drug reactions of a Thai herbal remedy were not observed, which may imply their safety.

## What is already known on this topic?

A Thai herbal Remedy can relieve some symptoms of chronic plaque psoriasis.

## What this study adds?

Future studies on the dosage and duration of Thai herbal remedies in psoriasis treatment should be increased to enhance clinical response and improve the products in terms of color, smell, and drug absorption.

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## Conflicts of interest

The authors declare no conflict of interest.

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