The Efficacy and Safety of Topical 0.1% Fluocinolone Acetonide in Combination with a Fractional Erbium Yag Laser vs Topical 0.1% Fluocinolone Acetonide Alone for The Treatment of Scalp Psoriasis: A Randomized, Split-Scalp and Pilot Study

Kittikun Ngamudomkiat[*, 1], Punyaphat Sirithanabadeekul[2], Voraphol Vejjabhinanta[3]

[1]Division of Dermatology, Chulabhorn International College of Medicine, Thammasat University, Pathum Thani, Thailand
[2]Chulabhorn International College of Medicine, Thammasat University, Pathum Thani, Thailand
[3]Institute of Dermatology, Rajvithi Road, Phayathai, Bangkok, Thailand
[*]Corresponding author: Email address: dermsx@outlook.com

Abstract

Topical corticosteroids are the most common treatment for psoriasis. Fluocinolone acetonide is a medium potency corticosteroid that can reduce adverse effects from high potency steroids used. However, the thicken and hard skin from the hyperproliferation of the skin can block the entrance of a topical agent into the lesion site. The use of laser may be able to increase the transdermal absorption of topical fluocinolone acetonide for the treatment of scalp psoriasis. This study aimed to evaluate the efficacy of topical 0.1% fluocinolone acetonide gel in combination with a fractional Erbium YAG laser compare to topical 0.1% fluocinolone acetonide alone for the treating of scalp psoriasis. A 3-week, pilot study was conducted on 13 volunteers. Patients with psoriasis with at least mild severity, aged >18 years were enrolled. They were treated with fractional Erbium YAG laser and topical 0.1% fluocinolone acetonide gel applied once daily on the same site of lesion compare with received topical 0.1% fluocinolone acetonide gel alone apply once daily on another site of the lesion. The patients were followed up for 1 week to evaluate clinical symptoms by a physician and patient outcome measurement. Thirteen participants with a mean (SD) age of 52 years and at least mild severity were enrolled in the study. Compared to baseline, lesions were significantly improved in erythema, induration, and desquamation from the combination treatment and fluocinolone acetonide monotherapy although there were no statistically significant differences. Combining 0.1% fluocinolone acetonide and 0.1% fluocinolone acetonide with fractional Erbium YAG laser is an effective and safe treatment option for patients with scalp psoriasis. No statistically significant difference between the two groups. This study can assume that the use of 0.1% fluocinolone acetonide only has good affinity and penetration enough in the treatment of scalp psoriasis.

Keywords: *Scalp psoriasis, Fluocinolone acetonide, Fractional Erbium YAG laser*

1. Introduction

Psoriasis of the scalp is highly visible and has been found to have an impact on the quality of life of patients, their appearance can be only localized scales or can manifest as widespread with hyperkeratotic plaques. Scales can extend visibly beyond the hair margins and involve the face, neck, and ears. Patients with scalp involvement might experience intense itching.

The current mainstay of treatment is topical preparations that consist of an active ingredient within many formulations. The most important active ingredients available for scalp psoriasis are corticosteroids (van de Kerkhof et al, 2001). Numerous preparations that are available for the treatment of psoriasis of the scalp contain high-potency steroids, such as betamethasone dipropionate lotion or clobetasol propionate solution; both of these steroids are classified as superpotent (Class 1 steroids) (Pauporte et al, 2004). Currently, we have many studies which use low or medium potent steroids for the treatment of moderate to severe scalp psoriasis (such as triamcinolone acetonide, desoximetasone, hydrocortisone, and fluocinolone acetonide) and can reduce adverse effects from high potency steroid used.

Fluocinolone acetonide is a low-to-medium potent corticosteroid that has anti-inflammation, anti-hyperproliferation, immunosuppressive and vasoconstrictive effects that can directly resolve the pathogenesis

of psoriasis. In addition, fluocinolone acetonide has a fluorine group in its structure more than triamcinolone acetonide which can increase their affinity and penetration of the drug. Currently we have fluocinolone acetonide only concentrations 0.01% cream and 0.025% cream & ointment (synalar). Both concentrations had a high recurrent rate and less efficacy from the previous study, thus we decide to use 0.1% fluocinolone acetonide in our study.

Thickening and hardening from the hyperproliferation of the skin block the entrance of topical agents into the lesion site. Laser energy can changes the molecular arrangement of the tissue, thereby forming a dense channel and increasing the drug penetration rate. Er:YAG laser is a good method for enhancing transdermal absorption of both lipophilic and hydrophilic drugs (Li et al, 2007).

In addition, fluocinolone acetonide is fluoroginated steroid (have a fluorine group in its structure at C6 and C9) that increases its affinity and penetration of the drug. From the overall properties of this steroid, we decide to use 0.1% fluocinolone acetonide gel in this study. Topical fluocinolone 0.1% in combination with a fractional Erbium YAG laser can resolve excessive adverse effects from high potency steroids and increase transdermal absorption of the topical drug in the treatment of scalp psoriasis.

In this study, we would like to evaluate the efficacy of topical 0.1% fluocinolone acetonide gel in combination with a fractional Erbium YAG laser for the treatment of scalp psoriasis. Fluocinolone acetonide 0.1% gel will be applied to the whole lesion and a fractional Erbium YAG laser will be applied on one side, randomly. For outcome measurement, we use The Psoriasis Scalp Severity Index (PSSI) and The Patient's Global Assessment of scalp psoriasis (PGA) to evaluate the clinical efficacy and use the Visual Analogue Scale (VSA) to evaluate the improvement of quality of life.

2. Objective

1) To evaluate the efficacy of topical 0.1% fluocinolone acetonide in a combination with a fractional Erbium YAG laser for the treatment of scalp psoriasis

2) To evaluate the patient's satisfaction with topical 0.1% fluocinolone acetonide in a combination with a fractional Erbium YAG laser for the treatment of scalp psoriasis

3) To evaluate the adverse effect of topical 0.1% fluocinolone acetonide in a combination with a fractional Erbium YAG laser for the treatment of scalp psoriasis

3. Methodology

3.1 Hypothesis

The Used of topical 0.1% fluocinolone acetonide in combination with a fractional Erbium:YAG laser show a superior significance of clinical improvement than the use of topical 0.1% fluocinolone acetonide alone in the treatment of scalp psoriasis.

3.2 Conceptual framework

The conceptual framework of this study was shown in Figure 1.

A. Study design

An observational study to evaluate the effectiveness and adverse effect of topical 0.1% fluocinolone acetonide in combination with a fractional Erbium:YAG laser vs topical 0.1% fluocinolone acetonide for the treatment of scalp psoriasis in men or women aged >18years old. The study was conducted at the outpatient dermatology clinic of Thailand Tobacco Monopoly Hospital. This study was approved by the Human Ethics Committee of Thammasat University.

B. Study Participants

There are various guidelines for choosing an appropriate sample size for a pilot study, such as 12 participants per group. Steven A. Julious et al. studied a Sample size of 12 per group rule of thumb for a pilot study (Julious et al., 2005). Thus, in this study, we decide to choose at least 12 participants per group (from data from our literature reviews). A total of 13 patients are recruited for this pilot study.

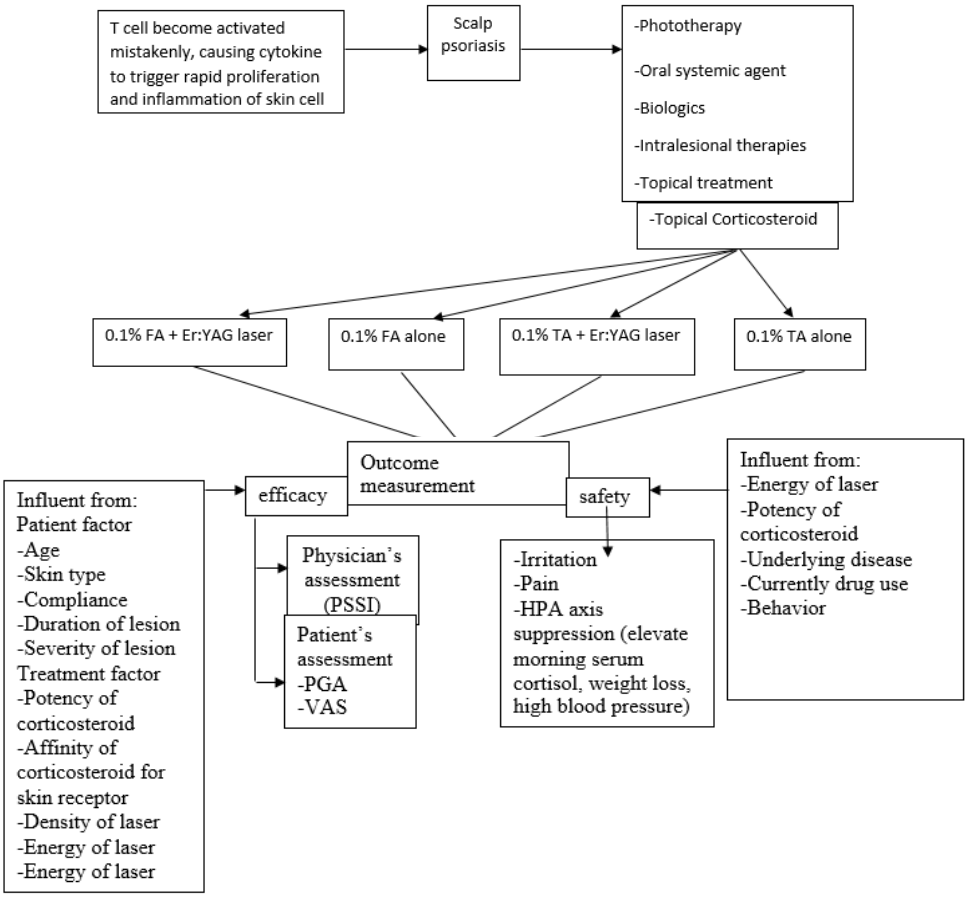

Figure 1 Conceptual framework

Thirteen males and females aged 38 to 76 years with Fitzpatrick skin Types III to V, who have been diagnosed with psoriasis >=6 months' duration with clinical diagnosis: Patients who have dry flaky lesions and well-demarcated plaques with any supporting diagnosis- personal or family history of psoriasis or confirmed or suspected psoriasis on the other parts of the body (trunk and limb, especially on the extensor surface of the extremities). At least mild psoriasis on lesions (defined by the Psoriasis Scalp Severity Index (PSSI) score >6, >=10% of the scalp surface area affected) were enrolled in the study.

In this study, we use simple random sampling for draw lot to see which site of lesion (left or right) would get a combination with drug and laser (0.1% fluocinolone acetonide with fractional Erbium YAG laser-treated group) or drug alone (0.1% fluocinolone acetonide alone –treated group) in individual patients. In patients who have clearly discrete lesions, we divide one site to be the right side and another site to be the left side. In the patient who has spreading lesions, we divide the symmetry of the lesion through the midline of the head in the sagittal plane. In the patient who has one lesion or lesion with a large area, we divide the symmetry of the lesion through the midline of the lesion in the sagittal plane.

Subjects were asked to avoid any topical treatment on lesions during the study. The exclusion criteria are subjects with any topical treatment on scalp psoriasis in the past 2 weeks or oral systemic medication for psoriasis 3 months prior to the start of the study, with the presence of seborrhoeic dermatitis or other inflammatory or connective tissue diseases that could interfere with the evaluation of psoriasis, pregnant and lactating women.

C.Methods

In this study, we separate the lesion into two sides (patient will be separated the lesion half to half in each person -left and right) for participants and received the treatment (drug alone or laser& drug) randomly. On the first side, participants received 0.1% fluocinolone acetonide (1 to 4 g per day) with fractional Erbium YAG laser while on the second site, participants received 0.1% fluocinolone acetonide (1 to 4 g per day) once daily, randomly. Also, the topical drug will apply for 2 weeks at the lesion, while a fractional laser will apply once a week at weeks 0 and 1. At the end of 2 weeks, treatment will stop and then follow up 1 week later for clinical symptoms by outcome measurement (Figure 2). Along with prescribing non-medical shampoo apply adequately once daily. Other topical applications or cosmetic products that will affect the result will be prohibited throughout the study. The use of 2940 nm Er:YAG (Fotona XS Dynamis, Slovenia) promoted the absorption of topical drugs for psoriasis. Er:YAG laser treatment parameters were as follows: Er:YAG fractional laser with the 50-μm energy depth (Li et al, 2007).

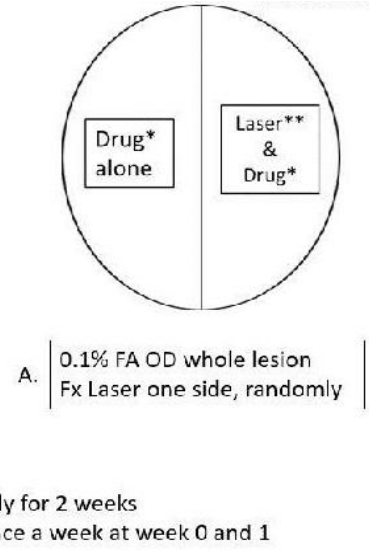

Figure 2 Protocol of receiving treatment

D.Assessment

The Psoriasis Scalp Severity Index (Frez et al., 2014) score is 0-72, the Patient's Global Assessment of scalp psoriasis scoring and visual analog scale for the clinical evaluation and photo recording will be conducted with each subject before starting the study, and at the last session of follow up visit by using a digital camera (Nikon d50, Nikon Corporation, Tokyo, Japan).

Photographic documentation is used by identical camera settings, lighting, and fixed patient positioning will be obtained. The distance and angle between the patient and the camera will be fixed. Flash lamps will be placed in fixed positions to the camera to ensure those all parts of the hand will be under controlled light. Two blinded dermatologists will assess the clinical assessment in each patient after treatment. Patients will be asked and observed about the sign of irritation (erythema, scaling, burning, pruritus), skin atrophy (telangiectasia, thinness, shininess, striae, bruising), HPA axis suppression, and any abnormal symptom of the skin from the treatment before and after each session.

4. Results

4.1 Results

The demographic data were analyzed using standard descriptive statistics. A total of 13 female and male subjects with a mean age of 51.92 years were included and completed the study (Table 1).

Table 1 Baseline Demographic data: Statistical analyses

Statistics data	Statistics data
Age	51.92 ± 12.05
Sex	
Female	2 (15.4%)
Male	11 (84.6%)
Hypertension	3 (23.1%)
Diabetes Mellitus	2 (15.4%)
Time since	36.46 ± 18.06
Duration	15.46 ± 13.1
Presence body	12 (92.3%)
Severity	
mild	3 (23.1%)
moderate to severe	10 (76.9%)
Weight	71.35 ± 14.57
Weight loss	0 (0%)
Systolic blood pressure	130.38 ± 11.5
Diastolic blood pressure	73.46 ± 12.55
hyper/hypotension (during procedure)	0 (0%)

Erythema, Induration, and Desquamation

At baseline, the mean erythema scores, mean induration scores, and mean desquamation scores were not significantly different between both treatment groups. First, among groups treated with 0.1% fluocinolone acetonide with fractional Erbium YAG laser (combine-treated group), the mean (SD) baseline of erythema scores was 1.69, decreasing to 1.12 after 3 weeks while the mean baseline of erythema scores for 0.1% fluocinolone acetonide group (FA-treated group) was 1.73, decreasing to 0.96 after 3 weeks. ($P<0.001$) Second, among groups treated with the combine-treated group, the mean (SD) baseline of induration scores was 1.65, decreasing to 0.69 after 3 weeks while the mean baseline of induration scores for the FA-treated group was 1.58, decreasing to 0.85 after 3 weeks. ($P<0.001$) Third, among groups treated with the combine-treated group, the mean (SD) baseline of desquamation scores was 2.35, decreasing to 1.12 after 3 weeks while the mean baseline of desquamation scores for the FA-treated group was 2.42, decreasing to 1.19 after 3 weeks ($P<0.001$). Comparing between groups, there is no difference in erythema, induration, and desquamation treatment efficacy between 0.1% fluocinolone acetonide with fractional Erbium YAG laser (combine-treated group) and 0.1% fluocinolone acetonide groups. ($P>0.05$) (Table 2).

Both groups have lesser erythema, induration, and desquamation compared to their baseline significantly but it does not show superior significance between the 0.1% fluocinolone acetonide with fractional Erbium YAG laser and 0.1% fluocinolone acetonide groups (Figure 3).

Area involvement of scalp psoriasis

At baseline, the area involvement of scalp psoriasis was not significantly different between both treatment groups. Among patients treated with 0.1% fluocinolone acetonide with fractional Erbium YAG laser, the mean (SD) area involvement was 4, decreasing to 3.77 and the mean baseline of area involvement for 0.1% fluocinolone acetonide groups was 4, decreasing to 3.77 ($P<0.05$). Patients treated with both groups have lesser area involvement compared to their baseline significantly but it does not show superior significance between the 0.1% fluocinolone acetonide with fractional Erbium YAG laser and 0.1% fluocinolone acetonide groups ($P>0.05$).

Table 2 Change of erythema, induration, and desquamation from baseline to 3 weeks (Paired t-test); 0.1% fluocinolone acetonide with fractional Erbium YAG laser vs 0.1% fluocinolone acetonide

Variables /Visit	Laser+drug			Drug alone			p-value	
	Mean ± SD.	Mean change ±SD.	p(a)	Mean ± SD.	Mean change ±SD.	p(b)	Mean	Mean change
Erythema (0-4)								
Baseline	1.69 ± 0.33	Ref.	1	1.73 ± 0.39	Ref.	1	0.787	Ref.
Visit 1	1.31 ± 0.33	-0.38 ± 0.36	0.002	1.35 ± 0.38	-0.38 ± 0.36	0.002	0.783	1
Visit 2	1.04 ± 0.38	-0.65 ± 0.55	0.001	1.04 ± 0.32	-0.69 ± 0.43	<0.001	1	0.846
Visit 3	1.12 ± 0.36	-0.58 ± 0.49	0.001	0.96 ± 0.32	-0.77 ± 0.48	<0.001	0.263	0.326
Induration (0-4)								
Baseline	1.65 ± 0.43	Ref.	1	1.58 ± 0.4	Ref.	1	0.640	Ref.
Visit 1	1.27 ± 0.6	-0.38 ± 0.36	0.002	1.15 ± 0.55	-0.42 ± 0.4	0.002	0.615	0.800
Visit 2	0.81 ± 0.48	-0.85 ± 0.47	<0.001	0.85 ± 0.43	-0.73 ± 0.39	<0.001	0.831	0.503
Visit 3	0.69 ± 0.38	-0.96 ± 0.43	<0.001	0.85 ± 0.47	-0.73 ± 0.33	<0.001	0.372	0.139
Desquamation (0-4)								
Baseline	2.35 ± 0.83	Ref.	1	2.42 ± 0.84	Ref.	1	0.816	Ref.
Visit 1	1.54 ± 0.63	-0.81 ± 0.6	<0.001	1.5 ± 0.58	-0.92 ± 0.49	<0.001	0.872	0.596
Visit 2	0.88 ± 0.85	-1.46 ± 0.8	<0.001	1.04 ± 0.72	-1.38 ± 0.68	<0.001	0.622	0.795
Visit 3	1.12 ± 0.89	-1.23 ± 0.88	<0.001	1.19 ± 0.83	-1.23 ± 0.86	<0.001	0.822	1

Note: P(a) = p-value from comparing mean (SD) of erythema, induration, and desquamation between baseline and following visit of laser + drug group, P(b) = p-value from comparing mean (SD) of erythema, induration, and desquamation between baseline and following visit of drug alone group, P-value= p-value from comparing mean (SD) of erythema, induration and desquamation between laser + drug group and drug alone group

The improvement of Psoriasis Scalp Severity Index (PSSI)

Among 0.1% fluocinolone acetonide with fractional Erbium YAG laser-treated patients, the mean (SD) baseline of Psoriasis Scalp Severity Index (PSSI) was 23.23 as shown in Table 3. After 3 weeks of treatment, the mean (SD) baseline of Psoriasis Scalp Severity Index (PSSI) was 10.77 (P=0.001). Moreover, among 0.1% fluocinolone acetonide–treated patients, the mean (SD) baseline of Psoriasis Scalp Severity Index (PSSI) was 23.27. After 3 weeks of treatment, the mean (SD) baseline of Psoriasis Scalp Severity Index (PSSI) was 11.27 (P<0.001). Both treatment groups have significant improvement in the Psoriasis Scalp Severity Index (PSSI), but it does not show superior significance between both groups (P>0.05) as shown in Figure 4**.**

Patient's measurement

PGA score range from 0 to 4 (0=clear ,1= very mild, 2= mild, 3= moderate, 4= severe). In the 0.1% fluocinolone acetonide with fractional Erbium YAG laser-treated patients, the mean PGA score showed a reduction from 3.15 at baseline to 1.23 at week3 with statistically significant ($p \leq 0.001$). In the 0.1% fluocinolone acetonide–treated patients, the mean PGA score showed a reduction from 3.15 at baseline to 1.23 at week3 with statistically significant ($p \leq 0.001$) (Figure 4). However, the statistic showed no significant difference when compared between the two groups ($p > 0.05$). Visual Analogue Scale (VAS) range from 0 to 10 (0 = normal/ no symptom, 10 = the worst symptom). In the 0.1% fluocinolone acetonide with fractional Erbium YAG laser-treated patients, the mean VAS score showed a reduction from 6.85 at baseline to 1.85 at week3 with statistically significant ($p \leq 0.001$) (Figure 6). In 0.1% fluocinolone acetonide–treated patients, the mean VAS score showed a reduction from 6.85 at baseline to 1.92 at week 3 with statistically significant ($p \leq 0.001$). However, the statistic showed no significant difference when compared between the two groups ($p > 0.05$).

Table 3 The improvement of the Psoriasis Scalp Severity Index (PSSI) at baseline, week1, week2, week3 (Pair t-test); 0.1% fluocinolone acetonide with fractional Erbium YAG laser vs 0.1% fluocinolone acetonide.

Variables /Visit	Laser+drug			Drug alone			p-value	
	Mean ± SD.	% Mean change ±SD.	P(a)	Mean ± SD.	% Mean change ±SD.	P(b)	Mean	Mean change
PSSI (0-72)								
Baseline	23.23 ± 12.11	Ref.	1	23.27 ± 11.84	Ref.	1	0.994	Ref.
Visit 1	15.19 ± 8.24	-32.41 ± 16.26	0.001	14.81 ± 8.07	-35.65 ± 16.19	<0.001	0.905	0.615
Visit 2	8.92 ± 6.55	-58.81 ± 21.82	<0.001	9.62 ± 6.66	-57.74 ± 19.33	<0.001	0.792	0.896
Visit 3	10.77 ± 7.54	-50.04 ± 24.08	0.001	11.27 ± 7.69	-49.59 ± 21.9	<0.001	0.868	0.961

Note: P(a) = p-value from comparing mean (SD) of PSSI between baseline and following visit of laser + drug group, P(b) = p-value from comparing mean (SD) of PSSI between baseline and following visit of drug alone group, P-value= p-value from comparing mean (SD) of PSSI between laser + drug group and drug alone group

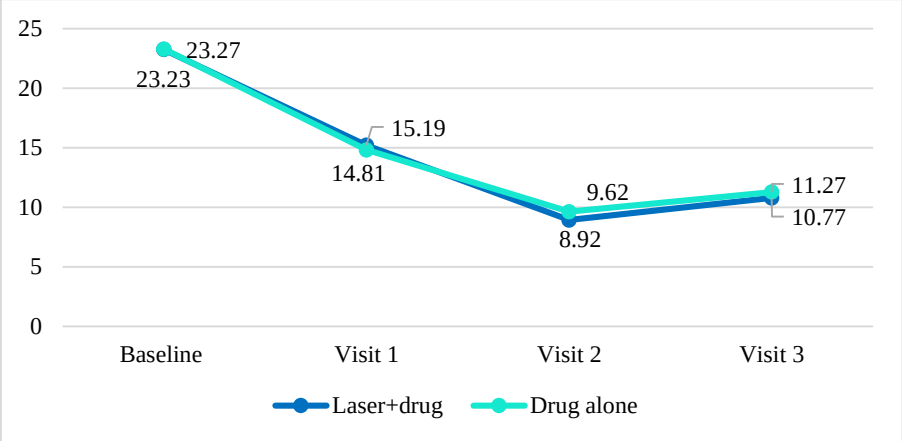

Figure 3 Mean of the Psoriasis Scalp Severity Index (PSSI) at baseline, week1, week2, week3 (Pair t-test); 0.1% fluocinolone acetonide with fractional Erbium YAG laser vs 0.1% fluocinolone acetonide.

There was no other side effect of skin (skin atrophy, hypertrichosis, telangiectasia, signs of infection) and a sign of Cushing syndrome in all patients. There was not any sign of suppression of the hypothalamic-pituitary-adrenal axis in our study. No other adverse reactions were reported in this study

4.2 Discussion

Scalp psoriasis is a common dermatologic disorder affecting individuals of all ages. It is an immune-mediated skin condition, resulting in over-proliferation of skin cells and the development of scaly plaques, characterized by areas of red, raised plaques, and scaling on the scalp. The goal of treatment is to use drugs or instruments to resolve the cause of scalp psoriasis, reduce the patient's symptoms and improve quality of life. T-cells become activated mistakenly, in turn causing cytokines in many pathways to trigger rapid proliferation of skin cells and inflammation (Renton, 2014). Topical fluocinolone acetonide is low to medium potent corticosteroid. It has properties of anti-inflammation, anti-hyperproliferation, immunosuppressive and vasoconstrictive effect that can resolve the pathogenesis of psoriasis. Moreover, fluocinolone acetonide has a fluorine group in its chemical structure that can increase its affinity and penetration of the drug. Topical corticosteroids are the most common treatment for psoriasis. However, the thickening and hardening from the hyperproliferation of psoriasis's skin can block the entrance of topical agents into the lesion site.

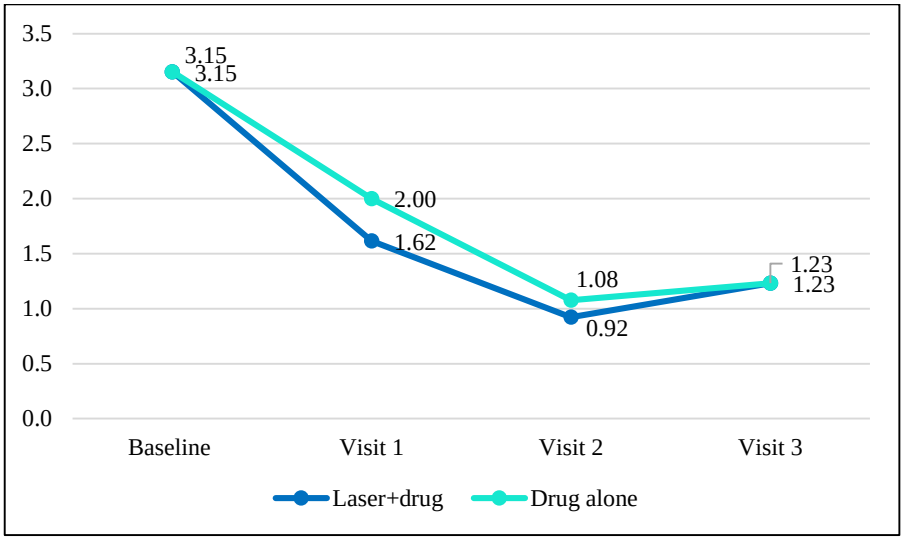

Figure 4 Mean of the Patient's Global Assessment of scalp psoriasis (PGA) at baseline, week1, week2, week3 (Pair t-test); 0.1% fluocinolone acetonide with fractional Erbium YAG laser vs 0.1% fluocinolone acetonide.

Laser-assisted transdermal drug delivery has been studied frequently in recent years. Laser penetration deep into the dermis or subcutaneous layer to transmit drugs with large molecular weight (as corticosteroids). Erbium YAG laser is associated with fast healing times and fewer side effects, because of superficial depth, decreased ablation, and less residual thermal damage (Tannous, 2007). Erbium YAG laser can form a dense channel and may increase drug penetration rate in scalp psoriasis treatment. This is the first randomized controlled trial study to evaluate the efficacy of the combination of topical 0.1% fluocinolone acetonide plus fractional Erbium YAG laser and compare it with topical 0.1% fluocinolone acetonide alone in the treatment of scalp psoriasis.

Moreover, both therapies of 0.1% topical fluocinolone acetonide plus fractional Erbium YAG laser and 0.1% topical fluocinolone acetonide showed a decrease in erythema, induration, and desquamation when compared with the baseline with statistically significant. This may be due to topical fluocinolone acetonide, which is a topical corticosteroid that can be the standard treatment of scalp psoriasis. A fluorinated steroid is flunisolide in which the hydrogen at position 9 is replaced by fluorine. The fluorine substitution at position 9 in the steroid nucleus greatly enhances its activity more than other drugs in the same potency (eg. triamcinolone, hydrocortisone) (Thongprasom, 2017). Fluocinolone acetonide topical oil for scalp psoriasis, studied by M Pauporte et al. They use 0.01% FA ointment once daily compared with vehicle base once daily for 3 weeks. The FA-treated group had a good or better improvement (three-point scale) from baseline

compared with the vehicle-treated group, both on day11 (58% vs 27%) and on day21 (83% vs 36%). But the recurrent rate was high after stopping treatment for 1 week (remain 36% vs 16%) (Pauporte et al, 2004). This suggested that FA helps reduce symptoms of scalp psoriasis.

According to the result, erythema, induration, and desquamation score in the combination group (FA plus fractional Erbium YAG laser) were slightly better than the drug alone group (FA alone) at week 3. This can indicate that in terms of dermatologist opinion, fractional Erbium YAG laser can use be laser-assisted transdermal by laser penetration deep into the epidermis and dermis to transmit topical corticosteroid and may can help for slightly resurfacing at the thickening plaque of scalp psoriasis but the study was no statistically significant difference between two groups ($P<0.05$).

This study mainly evaluated the efficacy of treatment by the Psoriasis Scalp Severity Index (PSSI). The result of the Psoriasis Scalp Severity Index (PSSI) showed statistically significant improvement in every visit compared to the baseline in both treatments. The result showed that both treatment groups (topical FA plus Erbium YAG laser and topical FA alone) were effective treatments for scalp psoriasis, reducing the symptoms of scalp psoriasis compared to baseline. However, it does not show superior significance between both groups ($P>0.05$). This may be due to the good affinity and penetration of fluocinolone acetonide in both groups, there was no statistically significant difference between them. However, in this study we use the energy depth of fractional Erbium YAG laser is 50 µm to penetrate stratum corneum, epidermis, and a minimal part of upper dermis on lesions while the treatment area in this study was scalp, whereas follicular penetration allows a rapid and direct transport into infundibulum region where penetration into the living tissue is facilitated by reduced barrier properties (Liu et al., 2011). A greater difference in PSSI may show if the study changes the energy of the laser or the location of the psoriatic lesion or has a larger group of patients or longer study period.

From a previous study, 0.01%FA has a high recurrent rate after stopping treatment for 1 week (decrease amount 40% of improvement rate) (Pauporte et al, 2004). In our study at the end of 2 weeks, treatment will stop and then follow up 1 week later. Among 0.1% fluocinolone acetonide with fractional Erbium YAG laser-treated patients, the mean (SD) of Psoriasis Scalp Severity Index (PSSI) at 2 weeks was 8.92. After 3 weeks of treatment, the mean (SD) baseline of Psoriasis Scalp Severity Index (PSSI) was 10.77 (an increasing amount of 20.7% of mean change). Moreover, among 0.1% fluocinolone acetonide–treated patients, the mean (SD) of Psoriasis Scalp Severity Index (PSSI) at 2 weeks was 9.62. After 3 weeks of treatment, the mean (SD) baseline of Psoriasis Scalp Severity Index (PSSI) was 11.27 (an increasing amount of 17.1% of mean change). From this result, the recurrent rate was low in both groups when stopped treatment for 1 week. In terms of the Patient's Global Assessment of scalp psoriasis (PGA) and Visual Analogue Scale (VAS), all subjects were evaluated after the treatment period (week3) compared to baseline. The result revealed a statistically significant decrease in scores in both groups ($P<0.05$). This indicated that all subjects have a better quality of life after finished both treatments. Although when comparing the two groups, there were no statistically significant differences from the baseline to week 3. Regarding the side effects, all subjects have no problems were seen with skin atrophy or telangiectasia attesting to safety associated with treatment using a 0.1% fluocinolone acetonide. Other side effects from the laser had only minimal pain and irritation after the laser. There is no Koebner phenomenon on the laser site (no psoriatic reaction; no increase in erythema, no increase in induration, no increase in desquamation, no increase in the area involved) at intermediate and 1 week after combination treatment. The theory in this condition may come from these two factors: First, the appropriate depth for laser-assist drug delivery, the energy depth of laser in our study is 50 µm that can penetrate stratum corneum, epidermis, and a minimal part of upper dermis on lesions. Our laser parameter can be laser-assist drug delivery to conduct topical triamcinolone acetonide (lipophilic) through the stratum corneum and epidermis (hydrophilic layer) to increase drug absorption. However, this energy depth of the laser is not enough for penetrating to all dermis. Thicker and harder skin than normal skin from pathology may be other reasons why our laser does not penetrate too much (minimal cell injury- no secondary dermal events) and not produce the Koebner phenomenon.

The second is an anti-inflammatory effect from corticosteroids. From the previous study, suspected pathogenesis of the Koebner phenomenon is related to dermal cells and processes such as cytokine (TNF), T

cells migration, B cells, autoantibodies, and keratinocyte proliferation. Fluocinolone acetonide is a corticosteroid that has anti-inflammation, anti-hyperproliferation, immunosuppressive, and can treat psoriasis related to T cell and inflammatory cytokine (TNF). During use, fluocinolone acetonide in psoriasis may inhibit or resolve the Koebner phenomenon in our patients.

Therefore topical 0.1% fluocinolone acetonide with fractional Erbium YAG laser and topical 0.1% fluocinolone acetonide alone can be used in scalp psoriasis treatment and not had any serious adverse events were observed during the study period.

5. Conclusion

In this randomized, split-site lesion, the double-blind study demonstrates that both treatments of 0.1% fluocinolone acetonide and 0.1% fluocinolone acetonide with fractional Erbium YAG laser are effective and safe treatment options for patients with scalp psoriasis. There was a statistically significant decrease in erythema, induration, and desquamation without serious adverse events after treatment. This study shows both treatments help reduce symptoms of scalp psoriasis and increase patient satisfaction in 2 weeks. Moreover, there was a low recurrence rate after stopping treatment for 1 week. However, the combination treatment of 0.1% fluocinolone acetonide with fractional Erbium YAG laser-treated group showed a minimal less mean induration and desquamation score than the 0.1% fluocinolone acetonide–treated group but no statistically significant difference between two groups. This study can assume that the use of 0.1% fluocinolone acetonide only has good affinity and penetration enough in the treatment of scalp psoriasis and not had any serious adverse events. The limitation of this study is the small number of subjects and the limited period. Further studies with more subjects and a longer duration of follow-up should be performed and should study in another parameter of fractional Erbium YAG laser and another location of the psoriatic lesion to validate those possible hypotheses.

6. Reference

Frez, M. L. F., Asawanonda, P., Gunasekara, C., Koh, C., Loo, S., Oon, H. H., et al. (2014). Recommendations for a patient-centered approach to the assessment and treatment of scalp psoriasis: a consensus statement from the Asia Scalp Psoriasis Study Group. *Journal of Dermatological Treatment, 25*(1), 38-45.

Julious, S. A. (2005). Sample size of 12 per group rule of thumb for a pilot study. Pharmaceutical Statistics. *The Journal of Applied Statistics in the Pharmaceutical Industry, 4*(4), 287-291.

Li, R., Zhou, J., Su, H., Wang, M., Wang, Y., Xiao, S., et al. (2017). 2940-nm Er: YAG fractional laser enhanced the effect of topical drug for psoriasis. *Lasers in medical science, 32*(6), 1393-1397.

Liu, X., Grice, J. E., Lademann, J., Otberg, N., Trauer, S., Patzelt, A., et al. (2011). Hair follicles contribute significantly to penetration through human skin only at times soon after application as a solvent deposited solid in man. *British journal of clinical pharmacology, 72*(5),768-774.

Pauporte, M., Maibach, H., Lowe, N., Pugliese, M., Friedman, D., Mendelsohn, H., et al. (2004). Fluocinolone acetonide topical oil for scalp psoriasis. *Journal of dermatological treatment, 15*(6), 360-364.

Renton, C. (2014). Diagnosis and treatment of adults with scalp psoriasis. *Nursing Standard, 28*(26), 35-39. doi: 10.7748/ns2014.02.28.26.35.e8335

Tannous, Z. (2007). Fractional resurfacing. *Clinics in dermatology, 25*(5), 480-486.

Thongprasom, K. A. (2017). A Review of the Effectiveness and Side-Effects of Fluocinolone Acetonide 0.1% in the Treatment of Oral Mucosal Diseases. *Acta Stomatologica Croatica, 51*(3), 240-247.

van de Kerkhof, P. C., Franssen, M. E. (2001). Psoriasis of the scalp. *American journal of clinical dermatology;2*(3), 159-65.