A Comparative Study in Efficacy and Safety of 0.1% Tacrolimus and 0.05% Clobetasol Propionate Ointment in Discoid Lupus Erythematosus by Modified Cutaneous Lupus Erythematosus Disease Area and Severity Index

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Objective: *To compare the efficacy and safety between 0.1% Tacrolimus ointment twice a day and 0.05% clobetasol propionate.*
Material and Method: *Twenty-one Thai patients 18 to 60 years old with DLE lesions on both right and left sides of the body, without SLE, were included in the present study. Each patient was randomly allocated to determine the use of one side for twice-daily 0.1% topical tacrolimus ointment and the other side for once-daily 0.05% clobetasol propionate ointment for six weeks. Clinical outcomes were evaluated by Modified Cutaneous Lupus Erythematosus Disease Area and Severity Index (CLASI) and global assessment score for patient efficacy evaluation.*
Results: *Disease activity score were significantly decreased from baseline in both groups but clobetasol had better efficacy ($p < 0.05$). No significant change in disease damage score between the two groups. Both drugs were well tolerated. Transient pruritus and burning sensation were found in the tacrolimus group. Telangiectasia and acneiform eruption were found in the clobetasol group.*
Conclusion: *The present study proved the efficacy of twice-daily tacrolimus and once-daily clobetasol treatment for DLE lesion. Clobetasol has significantly higher efficacy and tacrolimus may be an alternative treatment.*

Keywords: *Discoid lupus erythematosus, Tacrolimus ointment 0.1%, Clobetasol propionate ointment 0.05%, CLASI*

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Discoid Lupus Erythematosus (DLE), an autoimmune inflammatory skin disorder, is the most common form of chronic cutaneous lupus erythematosus according to Gilliam classification of lupus erythematosus specific skin disease. DLE is found in all races and in about 15 to 30% of systemic lupus erythematosus (SLE) patient. Most of the patients are 20 to 40 years old and are female predominant in ratio of 3:2 to 3:1. The standard treatments of DLE compose of sun avoidance, regular use of broad-spectrum sunscreen, superpotent topical steroid (such as 0.5% clobetasol proprionate ointment) and oral antimalarial drugs[1]. Although topical steroid have anti-inflammatory and immunosuppressive effect, which inhibit chemotaxis and inflammatory cytokine production, it causes skin atrophy, telangiectasia, and increase opportunistic infections when used for a long time. Once-daily application of superpotent topical steroid is as beneficial as twice-daily application and may decrease the risks of side effects, tachyphylaxis, the cost of treatment and improve the patient's compliance[2]. Topical tacrolimus should be an alternative treatment to avoid such side effects. Topical tacrolimus, one of calcineurin inhibitors, has inhibitory effect on T-cell activation and inflammatory cytokine production [Interleukin (IL)-2, IL-3, IL-4, IL-12, Tumor necrotic factor and Interferon-gamma] by inhibiting NF-kB activation pathway[3]. There were many reports in efficacy of topical tacrolimus in DLE treatment, but most of them had fewer case report, no control group, and lack of standardized measurement. The aim of the present study was to compare the efficacy and safety between 0.1%Tacrolimus ointment twice a day, which is an alternative treatment and

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0.05% clobetasol propionate ointment once-daily, which is the standard treatment of DLE by using Modified Cutaneous Lupus Erythematosus Disease Area and Severity Index (CLASI).

Material and Method

Patient selection

Twenty-five patients between 18 and 60 years old with DLE lesions on both right and left sides of their body that came for consultation at the outpatient department of the Institute of dermatology between December 2008 and April 2010 and could be regularly followed up were included in the present study. DLE was diagnosed by clinical examination and histopathology, which was supported by direct immunofluorescence finding. All patients were worked up for SLE by the American College of Rheumatology classification criteria, if found present would be excluded. The authors also excluded patients under treatment with topical steroid, topical calcineurin inhibitor, oral antimalarial and immunosuppressive drugs four weeks prior to the present study, pregnancy, lactation, patients with a history of allergy to any active ingredients or any components of topical steroid and calcineurin inhibitor, or patients with a history of skin cancer and malignancy of any organs from the study.

Study design

The authors conducted a randomized, double-blind bilateral comparative study. The present study was approved by the local medical ethics committee. After written informed consent, the DLE lesions of each patient were divided into right and left side by mid imaginary line. The authors used modified CLASI to evaluate activity and damage score of DLE lesion on each side and took digital photograph for all lesions before the present study. However, lesion on scalp, mucous membrane, and score of alopecia were not included because of inappropriate vehicle to use in these areas. The authors randomly allocated each patient by head or tail coin to determine the use of which side is for 0.1% topical tacrolimus ointment (supported by Protopic® ointment 0.1%, Astellas, New York, USA) use and which side is for 0.05% clobetasol propionate ointment (Dermovate® ointment 0.05%, GlaxoSmithKline, UK). The authors designed twice a day use, in the morning and evening, for tacrolimus. For clobetasol, the authors allowed the patients to use the real drug in the evening and vehicle (Vaseline ointment, Institute of Dermatology, Bangkok, Thailand) in the morning. Both drugs and vehicle were similar in characteristic, color and packaging with label as to which side it must be used. Patients were given strict instructions to use each drug continuously to the assigned side in the morning and evening by using only one cotton swab for each side per day for six weeks. After drug application to all DLE lesions on each side was done, they have to use sunscreen (supported by Spectraban® SPF60, Stiefel, TH) all over the sun exposed area in the morning, and strictly avoid sun exposure during the day.

Assessments

All patients were evaluated at second, fourth, and sixth week after treatment and four week after end of treatment by digital photography of all DLE lesions and asked about side effects on each side. For efficacy evaluation, dermatologist blindly evaluated activity and damage score by modified CLASI on digital photograph. Disease activity score is the sum of erythema score (0-absent, 1-pink; faint erythema, 2-red, 3-dark red; purple/violaceous/crusted/hemorrhage) and scale/hypertrophy score (0-absent, 1-scale, 2-verrucous hypertrophy) of all anatomic location (ears, nose include malar area, rest of face, V-area neck frontal, posterior neck and/or shoulder, chest, abdomen, back and buttock, arms, hands, legs, feet). Disease damage score is the sum of dyspigmentation score (0-absent, 1-dyspigmentation) and scarring/atrophy/panniculitis score (0-absent, 1-scarring, 2-severely atrophic scarring or panniculitis) of the same in all anatomical area as activity score. For dyspigmentation score, if it will last for at least 12 months, the score is doubled.

The authors used global assessment score for patient efficacy evaluation. The patient evaluated each side for 0 to 4 level of improvement score compared with before study (0-not improved, 1-mild improved 1 to 25%, 2-moderate improved 26 to 50%, 3-marked improved 51 to 75%, and 4-exellent improved 75 to 100%).

Statistical analysis

Mean value of change in disease activity, damage score of modified CLASI and global grading score for tacrolimus treated side and clobetasol treated side were compared before and after six weeks of treatment and compared with each other using Wilcoxon Signed-Rank Test by SPSS 16 program for Window XP. A p-value of less than 0.05 was considered statistically significant.

Results

Twenty-five patients were enrolled in the present study but only twenty-one patients completed (Table 1). There were ten male and eleven female patients. Mean ± SD age was 39.19 ± 11.44 year (range from 18 to 60 years old). The mean onset of DLE development was 28.61 months (range from 3 months to 7 years). According to classification of DLE that are localized and generalized as the lesion involved only above the neck or both above and below the neck, respectively. Twelve patients (57.14%) were localized DLE and nine patients (42.86%) were generalized DLE. Seven patients (33.33%) had never received any treatment before. Twelve patients (57.14%) had used topical steroid and one patient (4.76%) had been injected with intralesional steroid. Six patients (28.57%) had received oral antimalarial treatment. None of them had received topical tacrolimus, systemic steroid, or immunosuppressive drug. All patients who were on medical treatment were advised to stop the treatment for four weeks before the present study. One patient (4.76%) had lymphopenia (total lymphocyte count less than 1,500 cell/mm3 for two or more occasions). None of them had anemia, thrombocytopenia, or proteinuria. Eight patients (38.09%) had positive low titer (less than 1:320), and five patients (23.81%) had positive high titer (more than1:320) of antinuclear antibody. None of them had positive anti-dsDNA or antiphospholipid antibody. Patients who withdrew from the present study were excluded from the data. Three of them, two male and one female, dropped out because of loss to follow-up with unknown reason. Another female patient was excluded from study at four week after treatment because of the development of SLE. Mean/median disease activity score of tacrolimus treated side before treatment was 6.24/6.00 and mean/median damage score was 5.24/4.00. For clobetasol treated side, mean/median disease activity score was 6.14/5.00 and mean/median damage score was 5.14/4.00 before treatment (Fig. 1, 2).

Table 1. Demographic data (n = 21)

Characteristic	Number of patient (%)
Age (year)	
Mean (SD)	39.19 (11.44)
Median (range)	42 (18-60)
Sex	
Male	10 (47.62)
Female	11 (52.38)
Onset of DLE	
Less than 1year	6 (28.57)
1-5 year	14 (66.66)
More than 5 year	1 (4.76)
Type of DLE	
Localized DLE	12 (57.14)
Generalized DLE	9 (42.86)
Previous treatment	
None	7 (33.33)
Topical steroid	12 (57.14)
Intralesional steroid	1 (4.76)
Oral antimalarial drug	6 (28.57)

DLE = discoid lupus erythematosus

Efficacy evaluation

Disease activity score

After six weeks of treatment, the mean activity score of tacrolimus treated side was decreased significantly to 2.71 [changing score = 3.52, $p < 0.001$,

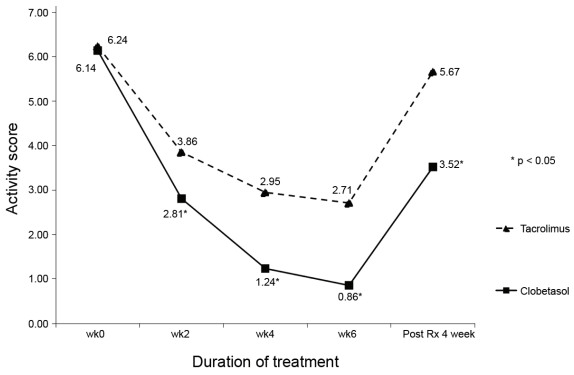

Fig. 1 Mean activity score (n = 21)
* $p < 0.05$, clobetasol had significantly decrease in mean activity score more than tacrolimus

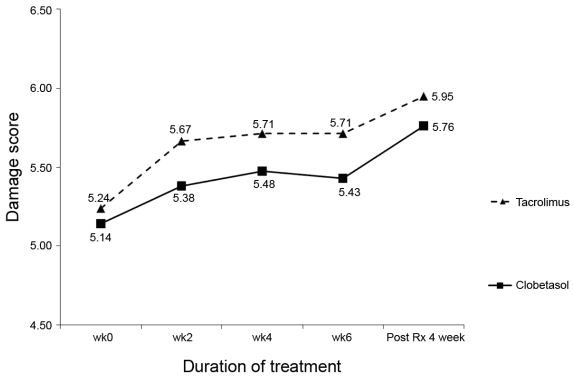

Fig. 2 Mean damage score

Table 2. Mean change in activity, damage and patient evaluation score

	Mean change [95% CI] (p-value)			
	wk0-wk2	wk0-wk4	wk0-wk6	wk0-post Rx 4 week
Tacrolimus				
Activity score	2.38 [1.31-3.45] (<0.001)	3.28 [1.90-4.67] (<0.001)	3.52 [2.17-4.88] (<0.001)	0.57 [-0.68-1.83] (0.45)
Damage score	-0.43 [(-0.9)-0.04] (0.07)	-0.48 [(-0.92)-(-0.03)] (0.04)	-0.48 [(-1.03)-0.07] (0.09)	-0.71 [(-1.22)-(-0.21)] (0.01)
Patient score	-1.05 [(-1.41)-(-0.68)] (<0.001)	-1.71 [(-2.31)-(-1.12)] (<0.001)	-2.00 [(-2.63)-(-1.37)] (<0.001)	-1.48 [(-2.11)-(-0.84)] (0.001)
Clobetasol				
Activity score	3.33 [2.31-4.54] (<0.001)	4.90 [3.18-6.63] (<0.001)	5.29 [3.48-7.10] (<0.001)	2.62 [0.72-4.52] (0.009)
Damage score	-0.24 [(-0.48)-0.01] (0.06)	-0.33 [(-0.63)-(-0.03)] (0.03)	-0.29 [(-0.61)-0.04] (0.08)	-0.62 [(-1.08)-(-0.15)] (0.01)
Patient score	-1.62 [(-2.03)-(-1.30)] (<0.001)	-2.40 [(-2.90)-(-1.96)] (<0.001)	-2.93 [(-3.48)-(-2.42)] (<0.001)	-2.27 [(-3.01)-(-1.56)] (<0.001)

95% CI = 2.17-4.88] and clobetasol treated side also decreased significantly to 0.86 [changing score = 5.29, p < 0.001, 95% CI = 3.48-7.10] (Table 2). When the authors compared the results of both drugs at 6 weeks after treatment, clobetasol had significantly decreased in median activity score more than tacrolimus [p = 0.002, 95% CI = (-4.44)-(-0.99)] as show in case No. 5 (Fig. 4) and 11 (Fig. 5).

Disease damage score

There were no significant changes of mean damage score of tacrolimus treated side [changing score = -0.48, p = 0.09, 95% CI = (-1.03)-0.07] and clobetasol treated side [changing score = -0.29, p = 0.08, 95% CI = (-0.61)-0.04] at six weeks after treatment (Table 2). No significant change of median damage score when both drugs were compared at 6 weeks after treatment (p = 0.273).

Patient efficacy evaluation

For tacrolimus treated side, the mean patient efficacy evaluation score showed moderate improvement (26-50% improvement) at six weeks after treatment [changing score = -2.00, p < 0.001, 95% CI = (-2.63)-(-1.37)] and good improvement (51-75% improvement) for clobetasol treated side [changing score = -2.93, p < 0.001, 95% CI = (-3.48)-(-2.42)] (Table 2). Clobetasol had significantly improved in median global assessment score at six weeks after treatment as compared to tacrolimus [p = 0.001, 95% CI = (-1.44)-(-0.46)] (Fig. 3).

Safety evaluation

Ten patients (47.62%) had complained of temporary burning sensation at tacrolimus treated side that disappeared without stopping treatment. After six weeks treatment, seven patients (33.33%) had developed telangiectasia and one patient (4.76%) had acneiform eruption at clobetasol treated side but all of these disappeared at four weeks after stopping treatment.

Discussion

Tacrolimus is an immunomodulatory drug belonging in calcineurin inhibitor family together with pimecrolimus and cyclosporine. It was isolated

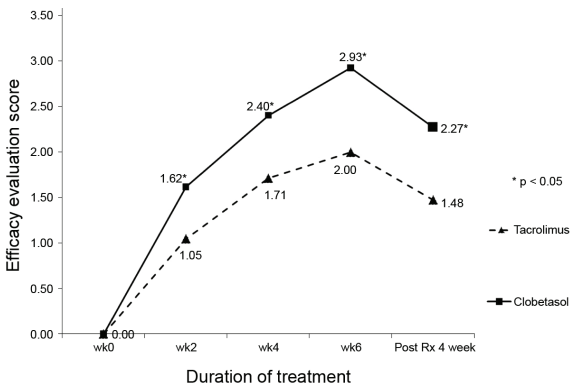

Fig. 3 Mean patient efficacy evaluation score
*p < 0.05, clobetasol had significantly improve in mean patient efficacy evaluation score more than tacrolimus

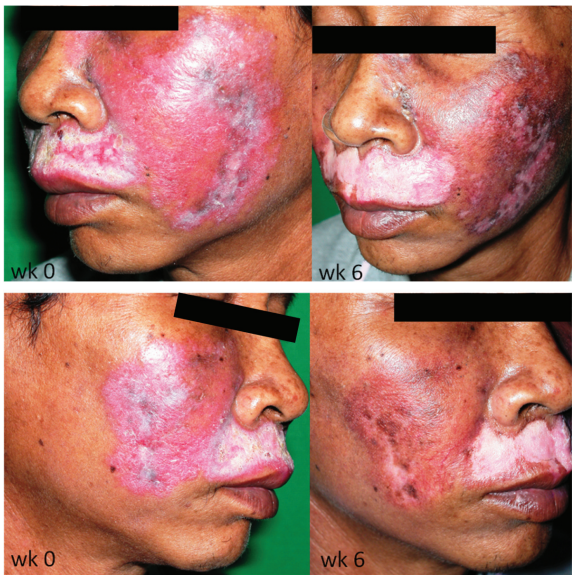

Fig. 4 Compare between tacrolimus (above) and clobetasol (below) treated side in case No. 5. Erythema and scale are decreased by both drugs but scarring and dyspigmentation still remain

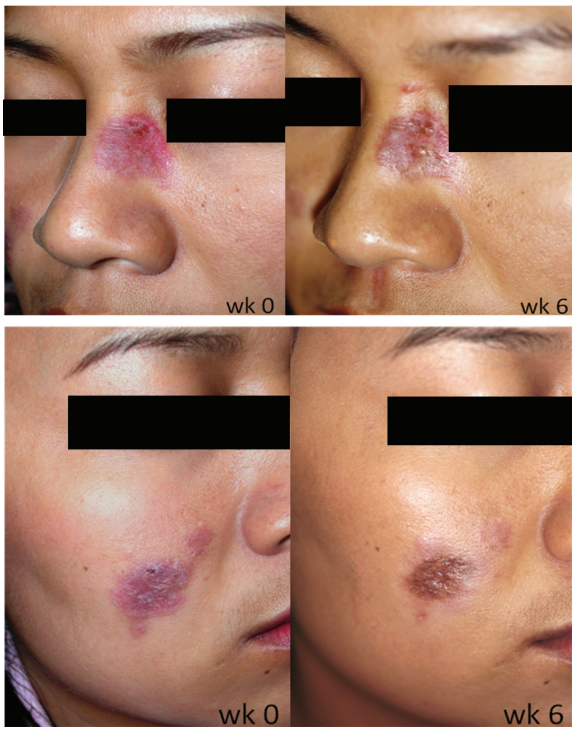

Fig. 5 Compare between tacrolimus (above) and clobetasol (below) treated side in case No. 11. Erythema and scale are decreased by both drugs but scarring and dyspigmentation still remain

from fungus *Streptomyces tsukubaensis* in 1984. The immunophillin receptor for both tacrolimus and pimecrolimus is macrophillin-12 (FK-506 binding protein-12). This drug/immunophilin complex binds to calcineurin and block its ability to dephosphorate nuclear factor of activated T cell, which is involved in cytokine, chemokine, and growth factor production after T cell activation. It exerts anti-inflammatory action the same as corticosteroid but without affecting the endothelial cells and fibroblasts, so it does not induce telangiectasia and skin atrophy[4]. In November 2000 the US FDA Dermatologic Committee approved tacrolimus ointment for the treatment of moderate to severe atopic dermatitis in children and adults[5] but it is also effective for the treatment of other chronic inflammatory skin diseases.

Several studies showed the efficacy of tacrolimus and pimecrolimus in treatment of cutaneous lupus erythematosus. Most of these studies were open, uncontrolled clinical trial with small number of cases and poor outcome measurement[6-12]. Singvahanont and Korkij had shown that the efficacy of twice daily 0.1% tacrolimus ointment in decreasing disease activity score of 21 DLE patients, evaluate by CLASI, was better than placebo by eight weeks in a randomized, placebo controlled, double-blind study[13]. Barikbin et al had shown in a randomized double-blind pilot study of 10 facial DLE treatment that the efficacy of twice daily treatment with pimecrolimus 1% cream is comparable with that of betamethasone valerate 0.1% cream[14]. Tzung, Liu and Chang had conducted a randomized, bilateral, double-blind study to compare the efficacy for four weeks facial cutaneous lupus erythematosus treatment in 18 patients (13 with malar rash of SLE, 4 with DLE and 1 with SCLE) between twice daily application of 0.1%tacrolimus ointment and 0.05% clobetasol propionate ointment[15]. They showed no significant difference in efficacy between tacrolimus and clobetasol in four weeks of treatment but 61% of patients developed telangiectasia on clobetasol side as early as the third week. In Tzung's study, microdermabrasion once a week was done before the treatment and outcome measure was based on only clinical feature. The present study was conducted to compare the efficacy between tacrolimus and clobetasol ointment without adjuvant treatment. The authors used CLASI to evaluate the treatment outcome because it was developed for clinical trial and has good validity and reliability[16-19].

The present study proved that tacrolimus had significantly shown efficacy in decreasing

disease activity score of DLE lesion at six weeks as compared to baseline. This can be explained by the anti-inflammatory effect of tacrolimus. However, tacrolimus has not shown significant change in disease damage score, which must be followed up for a longer period, and scaring is a permanent change. At four weeks after stopping treatment, the disease activity score increased but was lower than baseline. Disease damage score four weeks after stopping treatment was still rising as the disease progression. The patient efficacy evaluation showed moderate improvement after six weeks of treatment.

Clobetasol also had significant efficacy in decreasing the disease activity score at six weeks when compared to baseline due to its anti-inflammatory effect too. At four weeks after stopping treatment, the activity score increased again but was still lower than baseline. The same as tacrolimus, clobetasol has not shown significant change in disease damage score. The disease damage score also increased at four weeks after stopping treatment. The patient efficacy evaluation of clobetasol showed marked improvement after treatment, which was better than tacrolimus.

When the authors compared both drugs, at six weeks, once daily clobetasol was significantly better than twice daily tacrolimus in decreasing the disease activity score but not significantly different in damage score. The authors' result differs from Tzung's study[15] may be due to lack of adjuvant microdermabrasion before treatment. Tacrolimus has larger molecule than corticosteroid so it can penetrate lesser into the compact stratum corneum in DLE lesion[20,21]. Same as Tzung's study[15], the authors found that tacrolimus produce temporary, slightly burning sensation. When used continuously, this symptom spontaneously disappears. Although tacrolimus does not produce telangiectasia and acneiform eruption but it is higher cost of treatment (127.80 Baht/grams of tacrolimus vs. 7.72 Baht/grams of clobetasol). Both drugs were well tolerated by all the patients throughout the study.

Patient evaluation, that both drugs, can improve the DLE after six weeks of treatment, but clobetasol is more superior (marked improvement of clobetasol vs. moderate improvement of tacrolimus). This finding correlates with the efficacy in decreasing the disease activity score where clobetasol was better than tacrolimus.

In conclusion, the present study proved the efficacy of twice-daily tacrolimus and once-daily clobetasol treatment to DLE lesion. Clobetasol has significantly higher in efficacy and tacrolimus may be an alternative treatment.

Potential conflicts of interest

None.

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การศึกษาเปรียบเทียบประสิทธิภาพและผลข้างเคียงการรักษาผื่นDLE ด้วยยาทาขี้ผึ้ง 0.1% Tacrolimus และ 0.05% Clobetasol Proprionate ประเมินผลการรักษาด้วย Modified Cutaneous Lupus Erythematosus Disease Area and Severity Index

พรชัย โพธินามทอง, พัชรินทร์ จันทร์จำรัสแสง

วัตถุประสงค์: *เพื่อประเมินประสิทธิผลและความปลอดภัยของยาขี้ผึ้งทาโครลิมัส 0.1% ทาวันละ 2 ครั้ง เปรียบเทียบกับยาขี้ผึ้งโคลเบทาซอล โปรปิโอเนท 0.05% ทาวันละ 1 ครั้ง ในการรักษาผื่นดิสคอยด์ ลูปัส อิริทรีมาโทซัส*

วัสดุและวิธีการ: *ผู้ป่วยไทย จำนวน 21 ราย ที่มีอายุระหว่าง 18-60 ปี ที่มีผื่นดิสคอยด์ ลูปัส อิริทรีมาโทซัสที่ร่างกายทั้งสองข้างโดยไม่เป็น เอสแอลอี ได้ถูกคัดเลือกเข้าร่วมในการศึกษาครั้งนี้ ผู้นิพนธ์สุ่มให้ผู้ป่วยแต่ละรายทายาขี้ผึ้งทาโครลิมัส 0.1% วันละ 2 ครั้ง ที่ผื่นบนร่างกายซีกหนึ่ง และทายาขี้ผึ้งโคลเบทาซอล โปรปิโอเนท 0.05% ที่ผื่นบนร่างกายอีกซีกหนึ่งในช่วงเวลา 6 สัปดาห์ วัดการเปลี่ยนแปลงทางคลินิกของผื่นโดยใช้เครื่องมือวัดซึ่งดัดแปลงมาจาก Cutaneous Lupus Erythematosus Disease Area and Severity Index (CLASI) และให้ผู้ป่วยเป็นผู้ประเมินประสิทธิผลของยา*

ผลการศึกษา: *พบว่า ยาทั้งสองชนิด สามารถลดคะแนนตัวโรคที่กำลังดำเนินอยู่ได้อย่างมีนัยสำคัญเมื่อเทียบกับก่อน ให้การรักษา แต่ยาขี้ผึ้งโคลเบทาซอล โปรปิโอเนท 0.05% มีประสิทธิผลดีกว่า ($p < 0.05$) ไม่พบความแตกต่างในการลดคะแนนความเสียหายจากรอยโรคที่ยังคงอยู่หลังการรักษาและระหว่างยาทั้งสองชนิด ผู้ป่วยทนต่อการรักษาด้วยยาทั้งสองชนิดได้ดี พบอาการแสบคันชั่วคราวในผู้ป่วยที่ได้ยาขี้ผึ้งทาโครลิมัส 0.1% แต่พบหลอดเลือดฝอยที่ผิวหนังเพิ่มขึ้นและมีผื่นคล้ายสิวเกิดขึ้นในผู้ป่วยที่ได้ยาโคลเบทาซอล โปรปิโอเนท 0.05%*

สรุป: *การศึกษาวิจัยนี้พิสูจน์ให้เห็นถึงประสิทธิผลของการรักษาผื่นดิสคอยด์ ลูปัส อิริทรีมาโทซัส ด้วยยาทั้ง ทาโครลิมัส 0.1% ทาวันละ 2 ครั้ง และโคลเบทาซอล โปรปิโอเนท 0.05% ทาวันละ 1 ครั้ง ยาโคลเบทาซอล โปรปิโอเนท 0.05% มีประสิทธิผลดีกว่าอย่างมีนัยสำคัญทางสถิติ และทาโครลิมัส 0.1% ก็สามารถใช้เป็นทางเลือกในการรักษาได้*