A Randomised Controlled Trial of the Efficacy and Safety of 0.25% Desoximetasone Cream (Topoxy) Compared with 0.25% Desoximetasone Cream (Topicorte) for the Treatment of Scalp Psoriasis

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ABSTRACT

Objective: To compare the efficacy and safety of a generic desoximetasone cream (Topoxy) with the reference form, Topicorte, for the treatment of scalp psoriasis.

Methods: A randomised, double-blind, controlled study was conducted. Altogether, 105 patients with psoriasis lesions covering more than 10% of the scalp were randomised into three groups. The first, second and third groups received a placebo, Topoxy and Topicorte, respectively. The scalp psoriasis severities were assessed at weeks 0, 2, 4 and 8, using the Investigator Global Assessment (IGA) scale and Total Sign Score (TSS). The safety profiles of the products were assessed by the patients and physicians.

Results: Topoxy and Topicorte were significantly more effective than the placebo in achieving at least a two-grade improvement in the IGA score from baseline at weeks 2, 4 and 8, and there were no significant differences between Topoxy and Topicorte. The TSS of both creams were significantly lower than that of the placebo at weeks 2, 4 and 8. All patients tolerated well to the therapy.

Conclusion: Topoxy and Topicorte had comparable efficacies for scalp psoriasis. The medications were superior to the placebo in all parameters, and had a good safety profile.

Keywords: Desoximetasone cream; scalp psoriasis; topicorte; topoxy (Siriraj Med J 2020; 72: 371-379)

INTRODUCTION

Psoriasis is a chronic, immune-mediated, skin condition that is caused by an abnormal proliferation and differentiation of the epidermis. It affects 2%–3% of the global population, depending on the geographic area being studied.[1] Scalp psoriasis is found in up to 80% of psoriasis patients, and it proves to be troublesome and frustrating to most patients.[2] It is characterised by erythematous plaques with silvery scales that cause itching and discomfort.[3] Scalp psoriasis is generally hard to treat because the affected areas are mostly covered with hairs, which act as a physical barrier to topical medications.[2] The medications currently used to treat scalp psoriasis are topical corticosteroids, topical vitamin D analogues and tar shampoo.[4] Monotherapy with a topical steroid has proven to be acceptable for use as a short-term therapy

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for scalp psoriasis.[4] Topical moderate- to high-potency corticosteroids such as 0.05% clobetasol propionate, 0.25% desoximetasone, 0.1% betamethasone valerate and 0.05% betamethasone dipropionate are recommended for adult patients.[2] Cutaneous side effects of topical steroids on the scalp are rare.[5-7] Some of the reported adverse effects are skin discomfort, irritation, skin atrophy and telangiectasia.[8]

The topical corticosteroid desoximetasone is used for scalp psoriasis because of it has high efficacy with limited side effects.[9-11] Several formulations of the medication are available in the market. Topical 0.25% desoximetasone cream (Topicorte) is the reference form and is widely used. Recently, a generic formulation of the 0.25% desoximetasone cream, Topoxy, has been developed. However, Topoxy is relatively new, and its efficacy and safety have never been tested in a randomised control trial. Therefore, we conducted the present study to compare the efficacy and safety of 0.25% desoximetasone cream, Topoxy, with the reference form, Topicorte.

MATERIALS AND METHODS

Study design

A double-blinded, randomised, and placebo- and active comparator-controlled drug trial was conducted October 2016 to December 2018 at the Department of Dermatology, Faculty of Medicine Siriraj Hospital, Mahidol University. The trial was registered with ClinicalTrials.gov identification number NCT02749656. Patients were randomised into 3 groups using GraphPad Prism 5.00 for Windows (GraphPad Software, San Diego, CA). The first group received a placebo with tar shampoo; the second received Topoxy with tar shampoo; and the third was given Topicorte with tar shampoo. Patients were requested to apply the scalp cream twice daily with the recommended dosage of 1 ml or 3.5 grams of product per ten percent of total area of scalp affected and to use the tar shampoo regularly.

Subjects

This study enrolled 105 scalp psoriasis patients. The inclusion criteria were as follows: being over 18 years of age; having had a dermatologist give a diagnosis of scalp psoriasis with more than 10% of the scalp involved; and having mild to severe scalp psoriasis, according to the Investigator Global Assessment (IGA) scale, scoring a moderate-to-severe severity for at least one parameter out of redness, thickness or scaling.[12] The washout periods were 2 weeks for topical therapy; 2 weeks for phototherapy (narrow-band ultraviolet B or psoralen plus ultraviolet A); 4 weeks for oral systemic agents (methotrexate, acitretin and cyclosporine); and 6 months for biological agents. The exclusion criteria consisted of having a skin infection or skin atrophy on the scalp; currently receiving medications that might affect psoriasis (such as beta-blockers, antimalarial drugs or lithium); being pregnant or lactating; being unable to attend follow-up visits; having communication problems; or having a history of an allergic reaction or hypersensitivity to desoximetasone. The withdrawal or termination criteria comprised a patient being unwilling to continue to participate, missing more than 2 follow-up visits, or having an allergic reaction to the Topoxy or Topicorte cream. All patients gave their written informed consents prior to participating in the study.

Assessments

The scalp lesions were assessed by two dermatologists at weeks 0, 2, 4 and 8 using IGA, the Total Sign Score (TSS) and the area of scalp involved. With the IGA score, the following labels were assigned: 0, absence of disease; 1, very mild disease with only mild redness; 2, mild disease with evident redness along with mild thickness and scaling; 3, moderate disease with evident redness, thickness and scaling; 4, severe disease with inflammatory erythematous plaques along with severe thickness and scaling; and 5, very severe disease with severe inflammatory erythematous plaques.[12] The TSS was derived from the summation of the scores for the severity of redness, thickness and scaling.[12] Each parameter was graded on a scale of 0 - 4, with 0 representing no signs and 4 signifying severe signs. In cases of discordant assessments by the 2 dermatologists, an assessment by a third blinded dermatologist was requested to reach a consensus. In addition patients assessed their disease severity using the Patient Global Assessment (PGA) at weeks 0, 2, 4 and 8.[12] The PGA score is graded using the same scale as the IGA score (range, 0-4), but it differs in that the PGA score is determined by patients rather than medical staff. The efficacy of the results of the various grading systems (IGA, PGA, redness score, thickness score, and scaling score) were assessed based on the percentage of patients achieving a response of at least a 2-grade improvement from week 0.

Safety was assessed by monitoring patients' side effects, such as skin discomfort and irritation. Skin atrophy and telangiectasia were assessed by physicians. Photographs were taken at weeks 0 and 8. Patients were asked to bring their bottles of Topoxy or Topicorte cream to each follow-up visit; the amount of cream that was left at each visit was measured to assess the levels of treatment compliance.

Statistical analysis

Efficacy analysis

The patients' baseline characteristics (gender, underlying disease, family history of psoriasis, and smoking and alcohol-drinking habits) and the percentage of patients who achieved at least a 2-grade improvement in IGA, PGA, redness, thickness and scaling were presented as n (%) and were analysed using Fisher's exact test or the Chi-square test. The patients' baseline characteristics (age and duration of scalp psoriasis), TSS and area of scalp involved were presented as medians (minimum, maximum) and analysed using the Kruskal - Willis test. Differences were further analysed using the pairwise comparison method, with significance values adjusted by the Bonferroni correction for multiple tests. A *p* value of less than .05 was selected as the significance level for all statistical analyses.

Safety analysis

The safety parameter was described as the percentage of patients who experienced side effects, and it was analysed using Fisher's exact test or the Chi-square test. A *p* value of less than .05 was deemed to be statistically significant.

RESULTS

Patient disposition

In all, 105 scalp psoriasis patients were randomised equally into three groups. The first group received a placebo with coal tar shampoo (n = 35), the second group was given Topoxy with the tar shampoo (n = 35), while the third group was administered Topicorte with the tar shampoo (n = 35). Overall, 94.2% (n = 33) of the patients in the first group, 94.2% (n = 33) in the second group and 94.2% (n = 33) in the third group completed the study. Of the 99 patients who completed the study, 90 attended all four follow-up visits, while the remaining 9 patients had either two or three visits. Six patients (two from each group) were lost to follow up. Fig 1 (the study flow chart) illustrates the flow of participants through the study.

Patient demographics and baseline characteristics

The demographic data were compared across the three treatment arms (Table 1). Female was found in 66.7%, 51.5%, and 36.4% of patients in The topoxy-with-tar-shampoo treatment group, the placebo-with-tar-shampoo treatment group, and the Topicorte-with-tar-shampoo treatment group respectively. The median ages of the three groups ranged between 35 and 50 years. The durations of the scalp psoriasis ranged from 4 to 5 years. The most common underlying disease among each group was hypertension. The baseline disease characteristics (Table 2) were compared across the treatment arms. Most patients in each group had a baseline IGA score of either 3 or 4; a PGA score of either 3 or 4; a redness score of either 2 or 3; a thickness score of either 2 or 3; and a scaling score of either 2 or 3. The median TSS of each group ranged from 7 to 8 (range, 2-11). The median of the percentage of the scalp involved was 50% (range, 10%-100%) for each group. There were no statistical differences between any of the baseline disease characteristics of the 3 groups.

Efficacy (Table 3)

IGA of disease severity: The Topoxy-with-tar-shampoo treatment and the Topicorte-with-tar-shampoo treatment were significantly more effective than the placebo-with-tar-shampoo therapy in achieving at least a two-grade improvement from the baseline IGA score at week 2 (p=.002) and week 4 (p=.007), with no differences between Topoxy and Topicorte. At week 8, Topoxy was significantly more effective than the placebo in achieving at least a two-grade improvement from the baseline IGA score (p=.013).

PGA of disease severity: The Topicorte-with-tar-shampoo therapy was significantly more effective than the placebo-with-tar-shampoo treatment in achieving at least a two-grade improvement from the baseline PGA score at week 2 (p=.05). Topicorte and Topoxy were significantly more effective than the placebo in achieving at least a two-grade improvement from the baseline PGA score at week 4 (p=.004)

Redness score: The Topoxy-with-tar-shampoo treatment and the Topicorte-with-tar-shampoo therapy were significantly more effective than the placebo-with-tar-shampoo treatment in achieving at least a two-grade improvement from the baseline redness score at week 2 (p=.014), with no differences between Topoxy and Topicorte.

Thickness score: At week 2 and week 8, the Topoxy-with-tar-shampoo therapy was significantly more effective than the placebo-with-tar-shampoo therapy in achieving at least a two-grade improvement from the baseline thickness score (p=.018 for week 2, and .025 for week 8). At week 4, the Topoxy-with-tar-shampoo treatment and the Topicorte-with-tar-shampoo therapy were significantly more effective than the placebo-with-tar-shampoo treatment (p=.004), with no differences between Topoxy and Topicorte.

Scaling score: The Topoxy-with-tar-shampoo therapy was significantly more effective than the placebo-with-

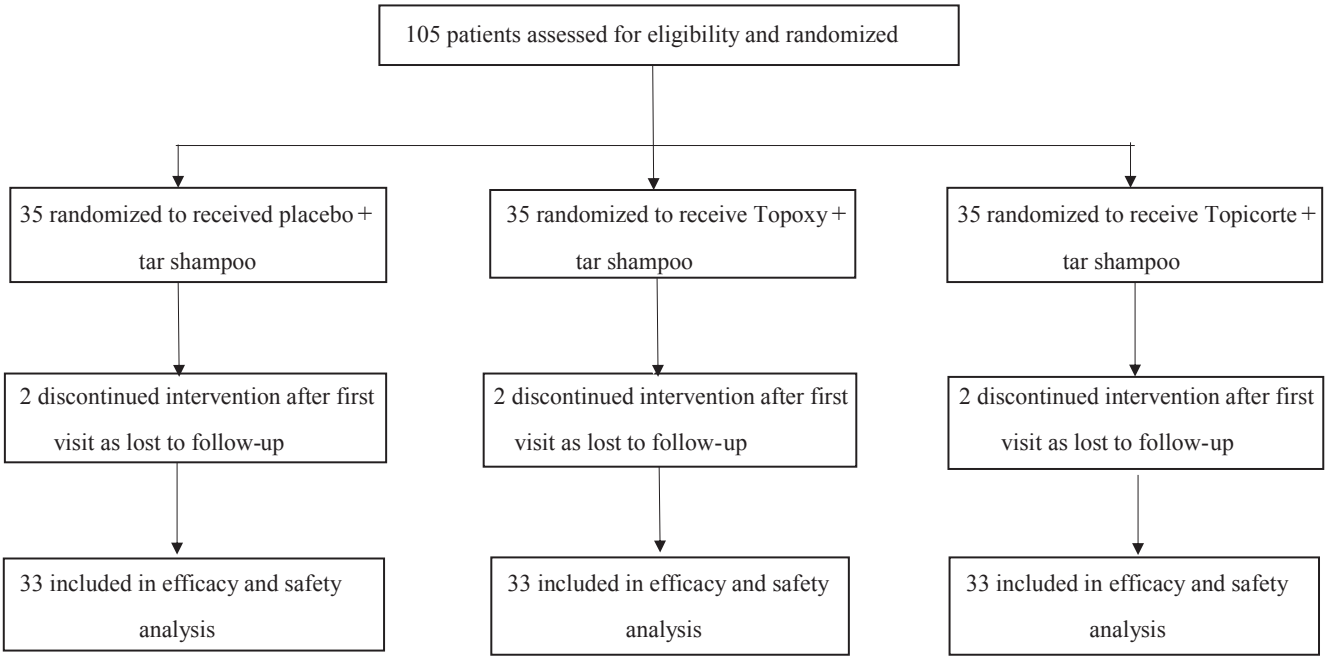

Fig 1. Flow of participants in a randomised clinical trial of 0.25% desoximetasone cream (Topoxy) compared with 0.25% desoximetasone cream (Topicorte) and a placebo.

TABLE 1. Summary of patients' baseline demographic characteristics.

Patient characteristics	Placebo (n = 33)	Topoxy (n = 33)	Topicorte (n = 33)	*P*-value
Age, years	35 (19, 66)	50 (21, 90)*	46 (20, 72)	.027
Female gender	17 (51.5%)	22 (66.7%)**	12 (36.4%)	.048
Duration of scalp psoriasis, years	5 (0.25, 21)	5 (0.08, 37)	4 (0.08, 20)	.739
Underlying disease				
Hypertension	5 (15.2%)	9 (27.3%)	6 (18.2%)	.443
Dyslipidemia	4 (12.1%)	7 (21.2%)	3 (9.1%)	.445
Diabetes mellitus	5 (15.2%)	4 (12.1%)	0 (0%)	.072
Obesity	1 (3.0%)	2 (6.1%)	4 (12.1%)	.496
Renal disease	1 (3.0%)	0 (0%)	1 (3.0%)	1.000
Malignancy	0 (0%)	0 (0%)	1 (3.0%)	1.000
Family history of psoriasis	7 (21.2%)	6 (18.2%)	6 (18.2%)	.937
Current smoker	2 (6.1%)	3 (9.1%)	3 (9.1%)	1.000
Current alcohol drinker	8 (24.2%)	4 (12.1%)	5 (15.2%)	.397

*differed significantly comparing to the placebo group; **differed significantly comparing to the Topicorte group

p value for gender, underlying disease, family history of psoriasis, current smoker, and current alcohol drinker were analyzed using Fisher's exact test or the Chi-square test. *p* value for age and duration of scalp psoriasis were analyzed using Kruskal–Willis test. Differences were further analysed using the pairwise comparison method, with significance values adjusted by the Bonferroni correction for multiple tests.

TABLE 2. Summary of patients' baseline disease characteristics.

Baseline disease characteristics	Placebo (n = 33)	Topoxy (n = 33)	Topicorte (n = 33)	*P*-value
IGA, n (%)				.220
0	0 (0%)	0 (0%)	0 (0%)	
1	0 (0%)	1 (3%)	2 (6.1%)	
2	2 (6.1%)	5 (15.2%)	9 (27.3%)	
3	16 (48.5%)	13 (39.4%)	11 (33.3%)	
4	14 (42.4%)	14 (42.4%)	11 (33.3%)	
5	1 (3%)	0 (0%)	0 (0%)	
PGA, n (%)				.437
0	0 (0%)	1 (3%)	0 (0%)	
1	0 (0%)	1 (3%)	2 (6.1%)	
2	3 (9.1%)	7 (21.2%)	4 (12.1%)	
3	13 (39.4%)	15 (45.5%)	15 (45.5%)	
4	14 (42.4%)	9 (27.3%)	10 (30.3%)	
5	3 (9.1%)	0 (0%)	2 (6.1%)	
Redness, n (%)				.797
0	0 (0%)	0 (0%)	1 (3%)	
1	8 (24.2%)	4 (12.1%)	7 (21.2%)	
2	12 (36.4%)	16 (48.5%)	13 (39.4%)	
3	12 (36.4%)	13 (39.4%)	11 (33.3%)	
4	1 (3%)	0 (0%)	1 (3%)	
Thickness, n (%)				.139
0	0 (0%)	1 (3%)	0 (0%)	
1	4 (12.1%)	6 (18.2%)	9 (27.3%)	
2	17 (51.5%)	10 (30.3%)	16 (48.5%)	
3	11 (33.3%)	16 (48.5%)	7 (21.2%)	
4	1 (3%)	0 (0%)	1 (3%)	
Scaling, n (%)				.151
0	0 (0%)	0 (0%)	0 (0%)	
1	2 (6.1%)	4 (12.1%)	5 (15.2%)	
2	11 (33.3%)	5 (15.2%)	14 (42.4%)	
3	17 (51.5%)	19 (57.6%)	10 (30.3%)	
4	3 (9.1%)	5 (15.2%)	4 (12.1%)	
Total sign score	7 (4, 11)	8 (2, 10)	7 (3, 11)	.175
Area of scalp involvement (%)	50 (10, 100)	50 (10, 100)	50 (10, 100)	.889

Abbreviations: IGA, Investigator Global Assessment; PGA, Patient Global Assessment

p value for IGA, PGA, Redness, Thickness, and scaling were analyzed using Fisher's exact test or the Chi-square test. *p* value for Total Sign Score and Area of scalp involvement were analyzed using Kruskal–Willis test. Differences were further analysed using the pairwise comparison method, with significance values adjusted by the Bonferroni correction for multiple tests.

TABLE 3. Treatment efficacy shown by number and percentage of patients achieving a response of at least a 2-grade improvement from week 0 for their IGA score, PGA score, and scalp psoriasis signs (redness, thickness and scaling), and the median of the Total Sign Score and percentage of area of scalp involvement.

	Week 2			
	Placebo (n = 32)	**Topoxy (n= 32)**	**Topicorte (n = 33)**	***P*-value**
IGA	5 (15.6%)	17 (53.1%)*	17 (51.5%)*	.002
PGA	8 (25.0%)	12 (37.5%)	18 (54.5%)*	.050
Redness	1 (3.1%)	8 (25%)*	10 (30.3%)*	.014
Thickness	4 (12.5%)	14 (43.8%)*	12 (36.4%)	.018
Scaling	5 (15.6%)	16 (50.0%)*	13 (39.4%)	.013
Total Sign Score	5 (1, 11)	3 (0, 8)*	3 (0, 8)*	<.001
Area of scalp involvement (%)	40 (5, 100)	20 (0, 90)*	15 (0, 100)*	.021
	Week 4			
	Placebo (n = 32)	**Topoxy (n= 32)**	**Topicorte (n = 33)**	***P*-value**
IGA	9 (28.1%)	20 (64.5%)*	19 (59.4%)*	.007
PGA	11 (34.4%)	22 (71.0%)*	22 (68.8%)*	.004
Redness	7 (21.9%)	15 (48.4%)	12 (37.5%)	.087
Thickness	6 (18.8%)	18 (58.1%)*	16 (50.0%)*	.004
Scaling	9 (28.1%)	18 (58.1%)*	16 (50.0%)	.047
Total Sign Score	4.5 (1, 11)	2 (0, 7)*	2 (0, 9)*	.001
Area of scalp involvement (%)	25 (1, 100)	9 (0, 90)*	10 (0, 95)*	.001
	Week 8			
	Placebo (n = 32)	**Topoxy (n= 32)**	**Topicorte (n = 33)**	***P*-value**
IGA	10 (32.3%)	21 (70.0%)*	16 (50.0%)	.013
PGA	15 (48.4%)	21 (70.0%)	23 (71.9%)	.102
Redness	6 (19.4%)	13 (43.3%)	10 (31.3%)	.130
Thickness	8 (25.8%)	18 (60.0%)*	13 (40.6%)	.025
Scaling	10 (32.3%)	19 (63.3%)	15 (46.9%)	.052
Total Sign Score	5 (1, 8)	2 (0, 9)*	2 (0, 9)	.001
Area of scalp involvement (%)	20 (1, 100)	5 (0, 100)*	5 (0, 90)*	<.001

Abbreviations: IGA, Investigator Global Assessment; PGA, Patient Global Assessment

*differed significantly comparing to the placebo group

p value for IGA, PGA, redness, thickness, and scaling were analyzed using Fisher's exact test or the Chi-square test. *p* value for Total Sign Score and Area of scalp involvement were analyzed using Kruskal–Willis test. Differences were further analysed using the pairwise comparison method, with significance values adjusted by the Bonferroni correction for multiple tests.

tar-shampoo treatment in achieving at least a two-grade improvement from the baseline scaling score at week 2 (p=.013), and at week 4 (p=.047)

Total Sign Score: At week 2 and week 4, the Topoxy-with-tar-shampoo treatment and the Topicorte-with-tar-shampoo treatment were significantly more effective than the placebo-with-tar-shampoo therapy in improving the median TSS (p<.001 for week 2 and p=.001 for week 4), with no differences between Topoxy and Topicorte. At week 8, the Topoxy-with-tar-shampoo therapy was significantly more effective than the placebo in improving the median TSS (p=.001)

Area of scalp involvement: The Topoxy-with-tar-shampoo treatment and the Topicorte-with-tar-shampoo treatment were significantly more effective than the placebo-with-tar-shampoo treatment in decreasing the area of scalp involved at week 2 (p=.021), week 4 (p=.001) and week 8 (p<.001), with no differences between Topoxy and Topicorte.

Pictures for each group of the scalp area at baseline and after eight weeks of treatment are presented in Fig 2.

Safety evaluation

Table 4 details the side effects experienced by each treatment arm. In the placebo-with-tar-shampoo treatment group, 3 (9.4%) patients at week 2 and week 4 and 2 (6.5%) patients at week 8 reported of having skin discomfort with no statistical difference from other groups. Telangiectasia was reported in 1 (3.3%) patient and 1 (3.1%) patient from the Topoxy-with-tar-shampoo treatment group and the Topicorte-with-tar-shampoo treatment group respectively with no statistical difference between two groups and to the placebo-with-tar-shampoo treatment group. No patients discontinued the treatment because of the side effects.

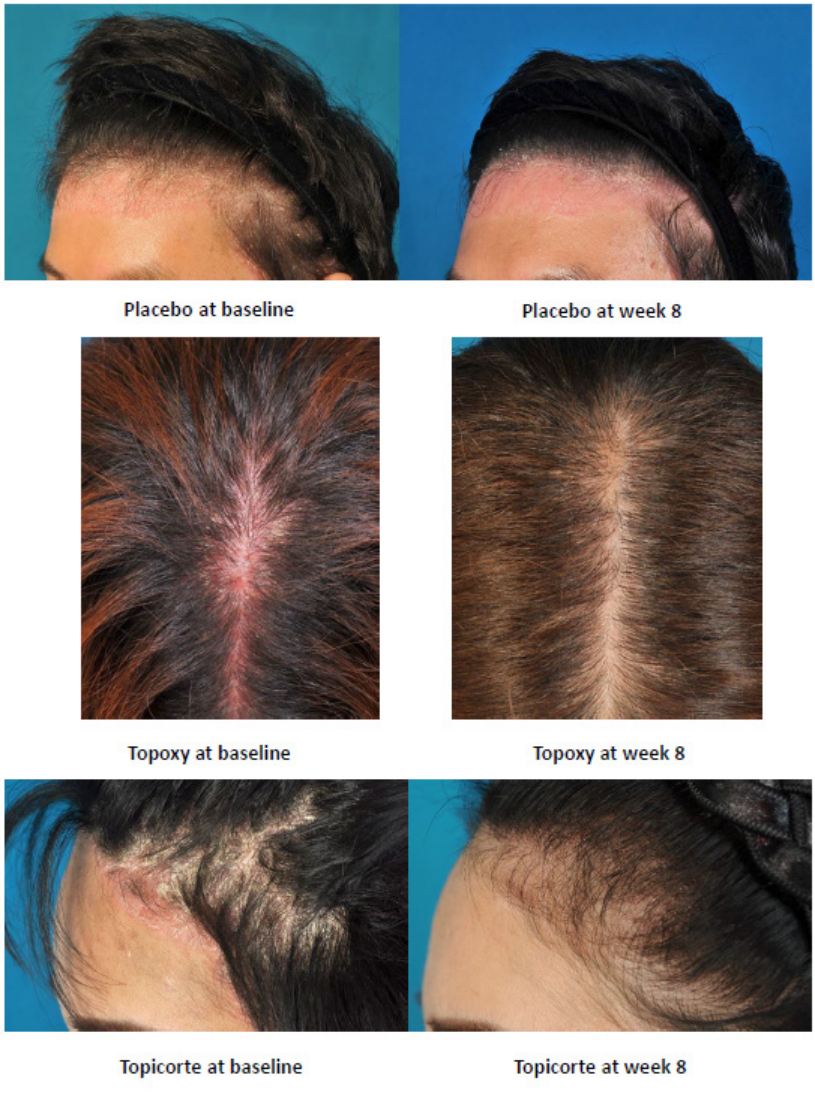

Fig 2. Pictures comparing the scalp at baseline and after eight weeks of treatment for each group. In the placebo group, minimal improvement was seen after treatment. In the case of the Topoxy and Topicorte groups, marked reductions in redness and scaling were observed.

TABLE 4. Summary of reported side effects from week 2 to week 8 of treatment.

Side effects	Placebo (n = 32)	Week 2 Topoxy (n = 32)	Topicorte (n = 33)	*P*-value
Skin discomfort, n (%)	3 (9.4%)	0 (0%)	2 (6.1%)	.281
Skin atrophy, n (%)	0 (0%)	0 (0%)	0 (0%)	–
Telangiectasia, n (%)	0 (0%)	0 (0%)	0 (0%)	–
Side effects	**Placebo (n = 32)**	**Week 4 Topoxy (n = 32)**	**Topicorte (n = 33)**	***P*-value**
Skin discomfort, n (%)	3 (9.4%)	0 (0%)	0 (0%)	.066
Skin atrophy, n (%)	0 (0%)	0 (0%)	0 (0%)	–
Telangiectasia, n (%)	0 (0%)	0 (0%)	0 (0%)	–
Side effects	**Placebo (n = 32)**	**Week 2 Topoxy (n = 32)**	**Topicorte (n = 33)**	***P*-value**
Skin discomfort, n (%)	2 (6.5%)	0 (0%)	0 (0%)	.210
Skin atrophy, n (%)	0 (0%)	0 (0%)	0 (0%)	–
Telangiectasia, n (%)	0 (0%)	1 (3.3%)	1 (3.1%)	.768

p value were analyzed using Fisher's exact test or the Chi-square test. Differences were further analysed using the pairwise comparison method, with significance values adjusted by the Bonferroni correction for multiple tests.

DISCUSSION

Topoxy was proved to be equally effective to the reference form of desoximetasone cream, Topicorte, in achieving treatment success by reducing all signs of psoriasis (redness, thickness and scaling) throughout the study. By the first two weeks, all of the parameters (IGA, PGA, redness, thickness, scaling, TSS and area of scalp involved) had improved significantly for both the Topoxy and Topicorte groups, without any significant differences between the two. After four weeks, Topoxy and Topicorte were statistically significantly superior to the placebo for all parameters except the redness score. These results proved the efficacies of Topoxy and Topicorte compared with the placebo. However, the PGA, redness score and scaling score showed no significant differences between the three groups by treatment week eight. This might be because topical steroid could lose its efficacy over time due to the down-regulation of receptor resulting in the phenomenon called tachyphylaxis.[13] Thus, the short course of corticosteroid treatment with no longer than 2-4 weeks' duration is recommended. If symptoms persist, the re-evaluation of disease is needed.[14]

Rajabi-Estarabadi et al. studied clobetasol lotion in scalp psoriasis and showed that it could lead to improvement of symptoms assessed by Psoriasis Severity Index and decreasing of transepidermal water loss.[15] However, because scalp is not the thick skin area such as palms and soles, therefore, the super potent topical steroid might not be needed.[14] Less potent topical steroid such as desoximethasone was also proved to be effective.[16] Bagel et al. studied the desoximetasone topical spray 0.25% in patients with scalp psoriasis. The results showed that it could lead to significant improvement in scalp IGA and PGA and decreasing of area of scalp involvement at 4 and 16 weeks after the product use.[16] Our results were in line with previous studies. These also showed that several formulations of desoximethasone, whether spray, or cream such as in our study worked well in scalp psoriasis.[16]

The Topoxy was found to be acceptable to, and well-tolerated by, all patients, with none experiencing skin discomfort. However, one patient in the Topoxy group experienced telangiectasia, which is a common side effect of topical steroid use. We also found telangiectasia in one patient from the Topicorte group.

It should be noted that the efficacies of Topoxy and Topicorte in our study might be higher than their efficacies in a real-life situation for 2 reasons. Firstly, tar shampoo was provided to all groups for ethical reasons. This shampoo has anti-inflammatory and antipruritic properties that are beneficial to the treatment of scalp psoriasis. These might have contributed to the relatively high efficacies of the therapies based on Topoxy and Topicorte in our study. Secondly, it is generally accepted that most patients adhere well to treatment when they are included in a research study. The limitation of this study is it was conducted in a single centre with a limited number of patients; the results may therefore not be generalisable.

CONCLUSION

The efficacies of the Topoxy and Topicorte creams were comparable, showing their treatment success through improved results for the grading systems employed (IGA, PGA, redness score, thickness score, scaling score and TSS) as well as a decrease in the area of scalp involved from treatment week 2 to week 8, compared to the placebo. Both the Topoxy and Topicorte creams were well tolerated by all patients and had a good safety profile.

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Conflicts of interest: All of the authors declare that there are no conflicts of interest.

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