#### **CLINICAL REPORT**

# Positive Effect of Modified Goeckerman Regimen on Quality of Life and Psychosocial Distress in Moderate and Severe Psoriasis

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Psoriasis is a chronic inflammatory skin disease with a profound effect on quality of life and psychosocial stress. The relationship between clinical improvement and psychosocial impact after treatment is complex. The objective of this study was to compare changes in quality of life and psychosocial distress, and overall cost-effectiveness, in patients with psoriasis receiving the modified Goeckerman regimen (UV irradiation and coal tar) with those receiving conventional treatment. Patients with moderate/severe psoriasis receiving the Goeckerman regimen were followed from admission to discharge. Clinical severity, was evaluated weekly using the Psoriasis Area and Severity Index (PASI). Psoriasis Disability Index (PDI) and Hospital Anxiety and Depression Scale (HADS) questionnaires were applied at admission and one month after discharge. Thirty-six patients with psoriasis receiving conventional treatment and 48 patients receiving the Goeckerman regimen were recruited to the study. The mean PASI score in the Goeckerman group decreased from 27.1 to 6.9 and PDI scores decreased from 25.3 to 13.8. HADS scores for anxiety and depression decreased significantly from 9.8 to 6.3 and 9.1 to 6.8, respectively. In comparison with conventional therapy, the modified Goeckerman regime showed similar clinical efficacy, with additional benefits in improving overall quality of life and psychosocial distress in patients with moderate/severe psoriasis, and more cost-effectiveness. Key words: psoriasis; quality of life; psychosocial stress; modified Goeckerman; cost-effectiveness.

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Psoriasis is a common chronic and recurrent inflammatory skin disease with a prevalence rate in Taiwan of 1.4% (1). The natural course of the disease has a profound impact on patients' quality of life, including physical, psychological, social, sexual, and occupational elements. As with many chronic skin diseases, psoriasis is a lifelong disease with no effective cure. Despite various

treatment options, long-term treatment is often required. Treatment of psoriasis ranges from topical medication for mild psoriasis to phototherapy and systemic therapy for more severe cases. In general, disease "chronicity" develops from incomplete or total treatment failure (2). The Goeckerman regimen, introduced in 1925, is a psoriasis treatment that involves combining coal-tar and ultraviolet B (UVB) light. It is one of the most effective and safest treatments for patients with severe or refractory psoriasis (3).

Stress affects patients to different degrees, with common manifestations of psychological depression, anxiety, and obsessive behaviour (4). The relationship between clinical improvement in psoriasis and its effect on psychosocial aspects is complex. The degree of impact of psoriasis on psychosocial distress depends on the patient's experiences, and may be very different in the same patient at different stages of their life. Patient's coping strategies and beliefs about their psoriasis also have a considerable effect on their quality of life and psychosocial stress.

Effective management of psoriasis requires consideration of the psychological, social, and financial impact of the disease on each individual as well as the physical symptoms. This is the first study to compare the modified Goeckerman regimen and conventional treatment with respect to improvement in quality of life and psychosocial aspects, and the cost-effectiveness of treatment methods.

#### MATERIALS AND METHODS

Study design and recruitment

This was a prospective clinical study from July 2007 to July 2009. We conducted a case-control study among patients with psoriasis in Chang Gung Memorial Hospital-Kaohsiung Medical Center, a tertiary medical centre in southern Taiwan. Patients scheduled to undergo the modified Goeckerman regimen in the dermatology department were invited to participate voluntarily in the study.

A total of 48 patients receiving the modified Goeckerman regimen were enrolled in the study. All participants were 18 years of age or older, without other significant medical conditions. Patients who were unable to stand, or attend the therapy on a regular basis, with a history of allergic reaction to Polytar®, previous skin cancer, photosensitivity, or pregnancy, were excluded from the study.

Patients with moderate-to-severe chronic plaque-type psoriasis, refractory to previous therapies were enrolled to Psoriasis Day Care Center to undergo the daily modified Goeckerman regimen for one month. Patients in the milder subgroups were either refractory to previous treatments or had subjective perception of impaired quality of life and psychosocial distress and wished to obtain additional improvements. The detailed protocol for the modified Goeckerman regimen used in the study has been described in detail by Lai et al. (3). Briefly, Polytar® (Juniper Tar 7.5%, Pine Tar 7.5%, Coal Tar solution 2.5%, Archis Oil Extract of Crude Coal Tar 7.5%; Stiefel Laboratories (Ireland) Ltd.) was diluted to different concentrations with petroleum jelly (Vaseline®) and applied to the whole body with occlusion for 5 h. Polytar® was used initially at a 2% concentration and increased to 5% after 3 days if tolerated, and then up to 10% for the rest of the treatment course. After washing off the Polytar®, phototherapy with narrow-band UVB was commenced at 400 mJ/cm<sup>2</sup>, followed by a daily increment (usually of 100 mJ, as tolerated). Only topical emollients were provided during the therapy. The patients received the treatment 5 times per week.

All clinical evaluations were performed by one investigator (EC) throughout the study. Prior to therapy, patients completed forms providing demographic information, quality of life and psychological stress (see below). Patients were re-evaluated for clinical severity on a weekly basis and were asked to complete the same questionnaires 2 months after the treatment.

Thirty-six patients with psoriasis, with a Psoriasis Area and Severity Index (PASI) score of greater than 10, receiving phototherapy concurrently with systemic and/or topical drugs from our dermatology clinics, were recruited as a control group. Questionnaires about quality of life and psychosocial issues were applied one month after completed the treatment.

#### Questionnaires and Evaluations

*Demographics*. Patient profile, including age, gender, education level, and family history, were assessed with a simple questionnaire. Other psoriasis-related questions included types of psoriasis, disease duration, initial site of lesion, and itching severity (none, mild, moderate, severe). Treatments received prior to the modified Goeckerman regimen were also documented.

Clinical severity. The PASI score is a standard method for evaluation of clinical severity and therapeutic effect in psoriasis. The score ranges from no psoriasis (score of 0) to very severe psoriasis (score of 72). Usually, a PASI score of 10 is used as a cut-off point for mild and moderate/severe psoriasis in daily clinical practice. However, the modified Goeckerman regimen at our dermatology ward is reserved for psoriasis resistant to other treatments; therefore, we have set a higher criterion of clinical severity and defined psoriasis as mild (PASI  $\leq$ 20), moderate (PASI 21–29), or severe (PASI  $\geq$ 30). Clinical improvement was recorded as the percentage reduction in the PASI score, e.g. PASI 75 implies a 75% reduction in the PASI score. Remission has been defined as clinical improvement of more than 75% of PASI score.

Quality of life. Quality of life was assessed using the Psoriasis Disability Index (PDI). The questionnaire addressed 15 aspects, relating to daily activities, work/school, personal relationships, leisure, and effects of the treatment. PDI was calculated by adding the score from each question, ranging from 0 to 45, representing least and greatest impairment in quality of life, respectively.

Psychological stress. The Hospital Anxiety and Depression Scale (HADS) was used to evaluate the psychological impact of psoriasis. The HADS is a 14-item scale, designed to evaluate patient's anxiety (HADS-A, 7 items) and depression (HADS-D, 7 items). The score of 0–7 for either subscale could be regarded as being in the normal range, a score of 11 or higher indicating

the probable presence of mood disorder, and a score of 8–10 being suggestive of the presence of the respective state (5, 6). *Translation*. Both PDI and HADS in the English version have been used in the evaluation of psoriasis. The Chinese version of HADS has been validated by several studies in China and Hong Kong (7).

#### Statistical analysis

The clinical severity, quality of life, and psychological scores among different groups before and after treatment were compared using the Wilcoxon rank-sum test or Kruskal-Wallis test, as appropriate. Psychological stress was further categorized according to HADS into no, possible, and definite anxiety/depression. A *p*-value < 0.05 was considered statistically significant. Remission times were computed with the Kaplan–Meier product limit method. All statistical analyses were conducted using the SAS software package, version 9.1 (2002, SAS Institute, Cary, NC, USA).

#### **RESULTS**

Forty-eight patients were recruited to the modified Goeckerman treatment group. Relevant epidemiological and clinical features are listed in Table I (n=48). All patients had chronic plaque psoriasis. The duration of treatment ranged from 4 to 6 weeks, with an average of 30 sessions. The mean time of remission after the treatment was 22.3 months.

The educational level of most patients (37/48) was high school or above. In terms of clinical severity, 33/48

Table I. Population characteristics in the case group and the control group

Variables	Case $(n=48)$	Control $(n=3)$	36) p-value <sup>b</sup>
Age, years, mean ± SD	39.5 ± 11.3	41.9 ± 11.2	0.356
Gender, $n$ (%)			
Male	33 (69)	33 (91.7)	0.011
Female	15 (31)	3 (8.3)	
Duration, years, mean ± SD	$13.7 \pm 7.8$	$13.3 \pm 8.3$	0.807
Education level, <i>n</i> (%)			
Primary school	7 (14.6)	5 (13.9)	0.002
Junior high school	4 (8.3)	14 (38.9)	
High school	23 (47.9)	15 (41.7)	
College or above	14 (29.2)	2 (5.6)	
Disease severity score <sup>c</sup>	$27.1 \pm 9.7$	$18.9 \pm 5.2$	
$PASI \leq 20, n$ (%)	15 (31.3)	23 (63.9)	< 0.0001
20 < PASI < 30, n (%)	10 (20.8)	12 (33.3)	
PASI ≥ 30, $n$ (%)	23 (47.9)	1 (2.8)	
Remission time, month <sup>d</sup> ,	$22.3\pm1.4$	$4.6 \pm 0.3$	< 0.0001e
mean $\pm$ SD			
PDI <sup>a</sup> , mean ± SD	$13.8 \pm 6.3$	$11.2 \pm 5.2$	0.049
HADS <sup>a</sup> , mean ± SD	$6.3 \pm 3.1$	$5.31 \pm 4.1$	0.221
Anxiety/Depression, mean $\pm$ SI	$6.8 \pm 3.3$	$5.03 \pm 2.9$	0.011

<sup>&</sup>lt;sup>a</sup>Post-treatment outcome.

PASI: Psoriasis Area and Severity Index; PDI: Psoriasis Disability Index; HADS: Hospital Anxiety and Depression Scale.

<sup>&</sup>lt;sup>b</sup>Continuous data were analysed using *t*-test, and categorical data using  $\chi^2$  test. <sup>c</sup>Disease severity in PASI score.

<sup>&</sup>lt;sup>d</sup>Remission time obtained in the control group was calculated from the time "not receiving the phototherapy" (due to clinical improvement after treatment) to the time "resuming the phototherapy" (due to the flare up of the skin disease).

<sup>&</sup>lt;sup>e</sup>By log-rank test.

Table II. Medication used in the two treatment groups and relative cost for the patients

	Case	Control
	(Goeckerman group)	(out-patients)
Systemic	Antihistamine,	Acitretin, USD 50/week
medication	USD 10/week	Methotrexate, USD 5/week
		Cyclosporine, USD 70/week,
		Antihistamine USD 10/week
Topical treatment	Vaseline,	Daivobet®, USD 30/week
	USD 10/week	Daivonex®, USD 30/week
	Polytar®,	Zorac®, USD 25/week
	USD 20/week	
Phototherapy	NB-UVB,	NB-UVB PUVA Re-PUVA,
	USD 70/week	USD 40/week
Biological agents	NA	Etanercept, USD 340/week
		Adalimumab, USD 340/week
Hospitalization <sup>a</sup>	0	NA

<sup>&</sup>lt;sup>a</sup>Cost for hospitalization is free due to establishment of the National Insurance of Health in Taiwan.

USD: United States Dollar, NB-UVB: narrow band-ultraviolet B; PUVA: psoralen plus ultraviolet A; Re-PUVA: retinoid with psoralen plus UVA; NA: not applicable.

(68.8%) had moderate-to-severe disease with a PASI score greater than 20. Of the 48 patients, 12 (25%) had a family history of psoriasis. At the end of treatment, 93.7% (45/48) showed decreased clinical severity, with a PASI score of less than 10, and more than half of the patients (56.2%) achieved PASI75.

Thirty-six patients with psoriasis not receiving the modified Goeckerman regimen but other forms of phototherapy concurrent with systemic and/or topical treatment were recruited from the clinic. Relevant demographic characteristics are documented in Table I (n=36). Notably, these patients had a different distribution in terms of severity; the majority (63.9%) of patients had mild psoriasis and only one had severe psoriasis (PASI36).

Detailed treatment options and the relative costs for the study groups are listed in Table II. The average weekly cost of the modified Goeckerman regimen was approximately 100 United State Dollars (USD 100); in contrast, the cost of conventional treatment cost was higher; being at least USD 200 per week. Post-treatment outcome (Table I) for both quality of life and psychosocial distress in both groups of patient were similar without significant difference. The proportion

Table III. Mean change in clinical severity and psychological scores before and after receiving the modified Goeckerman regimen (n = 48)

	Before Mean ± SD	After Mean ± SD	<i>p</i> -value*
PASI	$27.1 \pm 9.7$	$6.9 \pm 3.3$	< 0.0001
HADS-A	$9.8 \pm 5.0$	$6.3 \pm 3.1$	< 0.0001
HADS-D	$9.1 \pm 3.7$	$6.8 \pm 3.3$	0.001
PDI	$25.3 \pm 9.3$	$13.8 \pm 6.3$	< 0.0001

<sup>\*</sup>Wilcoxon signed-rank test for paired data.

PASI: Psoriasis Area and Severity Index; HADS-A: Hospital Anxiety and Depression Scale – Anxiety; HADS-D: Hospital Anxiety and Depression Scale – Depression; PDI: Psoriasis Disability Index.

of patients achieving PASI75 is not significantly different from those receiving the conventional therapy (data not shown).

Table III showed a mean change in the clinical severity, quality of life, and psychological stress before and after the modified Goeckerman regimen. Significant improvements were seen in terms of clinical severity, quality of life, and psychosocial distress (p < 0.0001, Wilcoxon signed-rank test). More than half of the patients with psoriasis presented with psychiatric comorbidity; the number of patients with anxiety and depression before and after treatment was significantly different (p < 0.05), as shown in Fig. 1.

The modified Goeckerman regimen resulted in a greater reduction in clinical severity than in quality of life. The results in Table III show a 75% reduction in clinical severity; by contrast, the index for quality of life (PDI) shows only a 44% reduction. To identify the areas that were most influenced by the treatment, the answers for PDI were divided into six domains. All domains showed significant improvement (Table IV, p < 0.0001); of note, the most significant improvement in quality of life was in daily activity, followed by leisure activity.

### **DISCUSSION**

Without specifically asking, dermatologists may often underestimate the degree of psychosocial distress experienced by patients with psoriasis. Apart from cosmetic disfigurement and functional impairment, psoriasis also has a profound impact on anxiety, depression, and

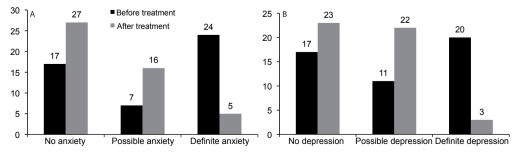


Fig. 1. Effects of the modified Goeckerman regimen on distribution of patients with or without (A) anxiety and (B) depression (n=48). The distribution of patients before and after the treatment are significantly different ((A) p=0.00001, (B) p=0002, by  $\chi^2$  test).

other psychosocial distress. In our study, some types of psychiatric impact was present in 65% of patients with psoriasis (Fig. 1).

The Goeckerman regimen is well known for its rapid clinical response and prolonged remission time. A review by Lee & Koo (8) comparing different psoriasis treatment options (Goeckerman therapy, psoralen plus ultraviolet A (PUVA), biologic agents, and conventional systemic medications) showed that the Goeckerman regimen is effective in achieving PASI75 within 3 months of treatment.

The results of our study demonstrated an improvement in clinical severity with the modified Goeckerman regimen; moreover, the treatment also had a profound effect on the patient's quality of life and psychosocial distress.

Two-thirds of patients included in the analyses were confirmed as having "moderate-to-severe" psoriasis at the start of the study; patients with mild psoriasis were admitted because of poor response to previous therapies or subjective perception of impairment in quality of life. Among the moderate-to-severe patients, over 60% had achieved PASI75 with an average treatment duration of 30 days.

Previous studies have shown a positive correlation between PASI and PDI (9). Gupta et al. (10) evaluated 100 patients who were receiving narrowband UVB and found significant improvements in symptoms and subjective quality of life. Our results are consistent with the result of previous studies showing significant improvements for all domains in patients with clearing of psoriasis (Table IV).

Depression, anxiety, body shame and guilt are common in psoriatic patients (11). Our positive results were different from previous studies and showed significant improvement in psychosocial distress after completing the modified Goeckerman regimen. Few studies (12-14) have investigated the relationship between clinical severity and patient's well-being, and found no clear association. We hypothesize that our study resulted in significant improvement in psychosocial distress and quality of life due to the rapid clinical improvement and prolonged remission with the modified Goeckerman regimen. Most of our patients had severe psoriasis that was refractory to previous topical or systemic treat-

Table IV. Changes in domains of quality of life before and after receiving the modified Goeckerman regimen (n = 48)

	Before Mean ± SD	After Mean ± SD	<i>p</i> -value*
Daily activity	$9.4 \pm 3.6$	$5.3 \pm 2.6$	< 0.0001
Work/school	$5.4 \pm 2.5$	$3.0 \pm 2.0$	< 0.0001
Relationship	$2.4 \pm 1.5$	$1.3 \pm 0.9$	< 0.0001
Leisure	$6.0 \pm 2.6$	$3.1 \pm 1.8$	< 0.0001
Treatment	$2.1 \pm 0.9$	$0.9 \pm 0.6$	< 0.0001

<sup>\*</sup>Wilcoxon signed-rank test for paired data.

ments. Since they perceived the modified Goeckerman regimen as a last resort for the potential cure of their long-term disease, they were willing to adhere to the daily treatment of the modified Goeckerman regimen for a month. Whereas missed applications and doses may occur when applying topical or oral medication at home, hospitalized treatment with the modified Goeckerman regimen avoided the problem of poor compliance. We believe that occlusion therapy with the modified Goeckerman regimen increased the skin absorption of Polytar® and decreased scaling; and that washing off the Polytar® subsequently increased the sensitivity of the skin to UVB.

Comparison of post-treatment outcomes (Table I) between conventional therapies and the modified Goeckerman regime showed similar improvements in quality of life and psychosocial distress, showing the modified Goeckerman regimen to be as effective as other therapeutic options. The approximate cost for the Goeckerman regimen is cheaper than the cost for the other treatment modalities (Table II). Biologic therapies, oral immunosuppressants and topical steroids appeared to have comparable clinical responses; however, the annual costs are higher and they cause more systemic side-effects than the modified Goeckerman regimen. The approximate annual cost for patients receiving the Goeckerman regimen is about USD 500; on the other hand, cost for conventional treatment is approximately USD 2,000. Our study also showed that patients receiving the modified Goeckerman regimen had longer remission duration (mean 22.3 months) with a 30-day treatment course. In contrast, conventional treatment required a monthly treatment of phototherapy and topical treatment with an average duration of remission of 4.6 months.

A limitation of this study is the relatively small sample size. As patients with psoriasis with a PASI score of greater than 20 comprised less than 20% of the annual patients with psoriasis selected from the daily clinic, few patients were eligible for the modified Goeckerman regimen. Review of the patient database showed that fewer than 60 patients had ever received the modified Goeckerman regimen at our hospital. Another flaw is that the study is not comparative, making the results liable to placebo influence. Psoriasis can undergo spontaneous resolution following phototherapy with adequate emollient use; however, all patients receiving the modified Goeckerman regimen had previously had multiple phototherapy sessions, and these had not conferred much benefit or demonstrated any placebo influences. Indeed, the group that had already had treatment and were seeking medical advice again may have consisted predominantly of relatively dissatisfied patients with a low degree of acceptance of their disease. Data for arthritis from the case and control group were not collected. Further study on the presence of arthritis affecting the quality of life may be conducted in future study.

There are several implications of this study. The first is that improvement in clinical severity is associated with immediate reductions in disability and psychosocial stresses in patients with moderate/severe psoriasis who are receiving the modified Goeckerman treatment. Secondly, this study emphasizes the importance of identifying those who are potentially anxious or depressed, such as those with prolonged and severe psoriasis. and implement adjunctive cognitive-behavioural stress management for patients undergoing the modified Goeckerman regimen. Lastly, in comparison with other conventional treatments, the modified Goeckerman regimen shows comparable effectiveness in terms of clinical efficacy, quality of life, and psychosocial distress. In addition, it is more cost-effective in treating patients with moderate and severe psoriasis, and leads to a longer duration of remission.

The authors declare no conflict of interest.

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