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Original Article

The Influence of Obesity on Psoriasis Treatment with Indigo Naturalis Oil Extract Ointment

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Background: The correlation between psoriasis severity and obesity has been verified; however, physicians generally do not consider obesity when they are selecting treatment methods for psoriasis or assessing treatment results. We evaluated the influence of obesity on psoriasis treatment involving indigo naturalis oil extract ointment. **Methods:** We collected the data of 116 patients from two clinical trials and divided these patients into three groups based on body mass index (BMI, kg/m²), namely healthy weight (BMI < 25), overweight (25 ≤ BMI < 30), and obesity (BMI ≥ 30) groups. We compared their treatment response data (healthy weight versus overweight group, healthy weight versus obesity group, and overweight versus obesity group). Related metabolic data were also analyzed. **Results:** For treatment response, significant differences in Psoriasis Area and Severity Index reductions (%) were observed between the healthy weight and obesity groups (61.5% vs. 26.8%, $P = 0.0093$) and overweight and obesity groups (59.3% vs. 26.8%, $P = 0.0207$) but not between the healthy weight and overweight groups. Without obesity considered, patients with hypertension or other metabolic disorders (e.g., hyperlipidemia) that were verified by blood test data tended to exhibit slightly poorer treatment responses relative to patients without these conditions. **Conclusions:** Obesity and metabolic comorbidities should be considered by physicians in psoriasis treatment decisions; patients with obesity using indigo naturalis should be encouraged to manage their obesity to achieve better psoriasis treatment responses. Future studies should investigate whether patients' comorbidities influence the effectiveness of specific treatments.

Key words: Indigo naturalis, psoriasis, obesity, metabolic diseases, traditional Chinese medicine

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Introduction

Psoriasis is a chronic, immune-mediated inflammatory skin disease, and dermatologists and patients are becoming increasingly concerned about the systemic comorbidities associated with psoriasis. Several clinical studies have reported a high correlation between obesity and psoriasis severity [1–3]. The prevalence of obesity has increased significantly worldwide during the past 30 years [4], and a body of evidence indicates that the prevalence of psoriasis has also increased over [5, 6].

Although studies have revealed a clear correlation between obesity and the severity of psoriasis, no consensus has been reached regarding the presence of a general correlation between obesity and psoriasis treatment responses and the role of medicine in this relationship. For both systemic and topical treatments, some studies of specific medicines have suggested that obesity is a negative predictor of treatment response, whereas others could not identify an association between obesity and treatment response [7–10].

Many effective treatment methods can be used to control psoriasis. However, many patients seek alternative therapies primarily due to safety concerns regarding the long-term implementation of current standard treatments (such as corticosteroid treatments). Traditional Chinese medicine (TCM) is one such alternative. Indigo naturalis is an herbal medicine that has been used in TCM for many centuries to treat various inflammatory and infectious skin diseases. Recent clinical trials have demonstrated that indigo naturalis is effective and safe for treating psoriasis topically; a study that compared the use of a crude indigo naturalis ointment and a vehicle ointment reported that 74% and 3% of the indigo naturalis and vehicle ointment groups, respectively, achieved clearance or near clearance of their psoriatic lesions [11].

However, no study has explored the link between obesity and psoriasis responses to topical herbal medicine treatments. With more patients seeking herbal treatments, the aforementioned knowledge gap should be addressed. The objective of this analysis was to assess the correlation between obesity (and related metabolic diseases) and responses to topical psoriasis treatment using indigo naturalis oil extract ointment.

Materials and methods

1. Protocols

The present study analyzed data from two clinical trials that investigated the efficacy and safety of indigo naturalis oil extract ointment in treating psoriasis (ClinicalTrials.gov Identifier: NCT01735864 and NCT02088281; Fig. 1) [12]. The protocols of both trials were approved by the Institutional Review Boards of Chang Gung Memorial Hospital and the Food and Drug Administration of Taiwan; the trials were conducted in accordance with the ethical principles established by the Declaration of Helsinki and Good Clinical Practice. Written informed consent was obtained from all participants before any trial-related procedures were performed.

2. Participants

Patients aged between 20 and 65 years were eligible to participate in the trials if they were diagnosed as having plaque psoriasis at least 1 year prior to screening, experienced psoriasis that covered <20% of their body surface area (BSA), and had a Psoriasis Area and Severity Index (PASI) score of <20. Participants were ineligible if they had a

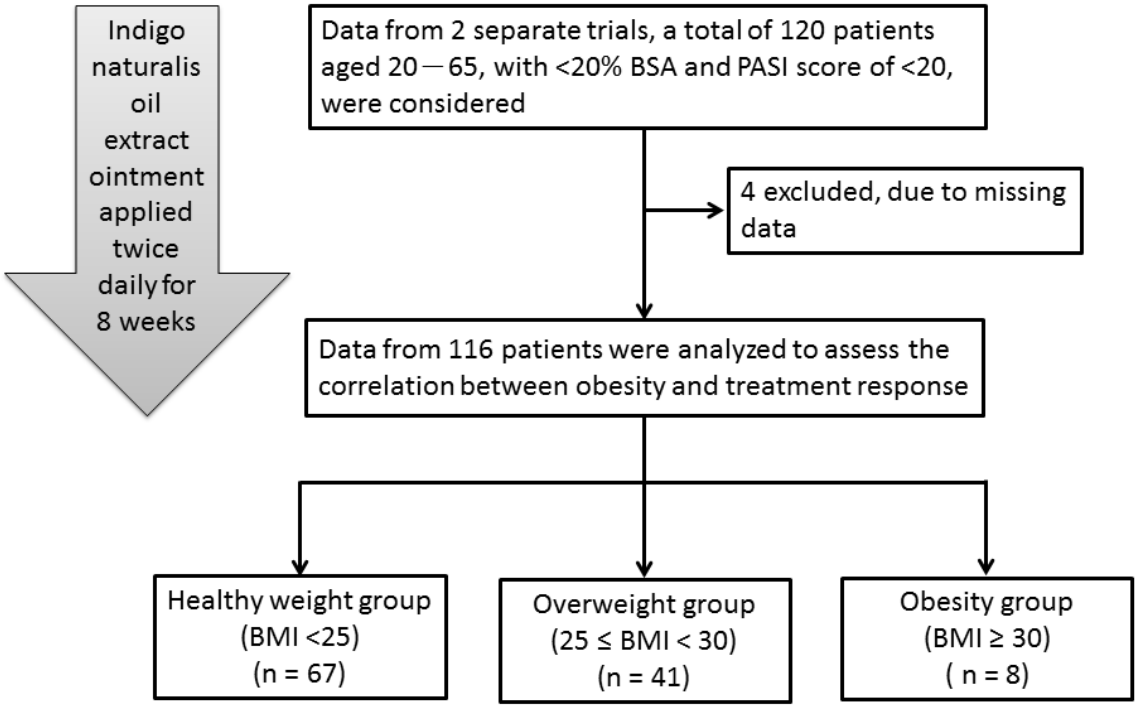

Fig 1. Study design: analysis of data from two clinical trials in which indigo naturalis ointment was shown to be effective in treating psoriasis, with subjects divided into 3 groups based on BMI to assess the correlation between BMI and treatment response.

nonplaque form of psoriasis, known malignancies (current or past), history of allergy to indigo naturalis or its excipient in the investigated ointment, aspartate aminotransferase (AST) or alanine aminotransferase (ALT) level that was more than three times the upper normal limit, creatinine level of >2.0 mg/dL, clinically significant haematological abnormalities, uncontrolled hypertension, uncontrolled metabolic disease, psychiatric disorders, or human immunodeficiency virus infection. Female patients who were pregnant or breastfeeding were also excluded. Patients were required to cease systemic antipsoriatic treatment or phototherapy for at least 4 weeks and topical treatments for at least 2 weeks before the first application of the study medication. The inclusion and exclusion criteria of the two trials were identical.

In both trials, patients with chronic plaque psoriasis were instructed to apply 0.5 g of indigo naturalis oil extract ointment per 100 cm^2 of affected skin twice daily for 8 weeks. The powdered indigo naturalis used in this study was extracted from the leaves of Baphicacanthus cusia (Nees) Bremek. The indigo naturalis oil extract ointment was prepared using an olive oil extract, and analyzed using high-pressure liquid chromatography by Chuang Song Zong pharmaceutical company in accordance with the method of Lin et al. [12]. All data were collected between November 2012 and April 2014 at the Taipei and Linkou branches of Chang Gung Memorial Hospital in Taiwan.

3. Evaluation

To determine whether obesity and obesity-

related metabolic conditions (such as hypertension, hyperuricemia, and dyslipidemia) are correlated with the response to topical psoriasis treatment of indigo naturalis, we analyzed the following data from the two trials: age, gender, duration of psoriasis, body mass index (BMI, kg/m^2), blood pressure (BP, mmHg), standard laboratory tests (haematology and biochemistry), PASI, and BSA affected by psoriasis.

For our analysis, the pool of participants from the two trials was segmented into three groups according to baseline BMI. Per the World Health Organization's BMI classification standard, healthy weight (BMI < 25), overweight (25 ≤ BMI < 30), and obesity (BMI ≥ 30) groups were established [13]. In addition to a comparison of the treatment success rates of the BMI groups (effective treatment was defined as the achievement of PASI 50, that is, a decrease of at least 50% in a patient's PASI score from baseline to week 8), baseline data from lab tests were also analyzed to determine correlations between metabolic conditions and obesity and correlations between obesity-related metabolic conditions and treatment success.

Patients were considered to have (1) hypertension if their systolic/diastolic blood pressure was over 130/85 mmHg, (2) hyperuricemia if their blood uric acid level was over 8 mg/dL, (3) dyslipidemia if their total blood cholesterol level was over 200 mg/dL and/or their blood triglyceride level was over 150 mg/dL, (4) leukocytosis if their white cell count (WBC) was over 10600/μL (for men) or 11000/μL (for women), (5) abnormal AST level if their AST level was over 34 U/L, and (6) abnormal ALT level if their ALT was over 36 U/L. Patients with indicated comorbidities maintained their own treatments as needed, they were not received TCM treatments for indicated comorbidities in this study.

4. Statistical methods

All data analyses were performed using SAS version 9.4. Data are expressed as means ± standard deviations, frequencies, and numbers (percentages). For continuous data, one-way analysis of variance (one-way ANOVA) was performed for analyses involving more than three groups, and the Kruskal-Wallis test was performed when a violation of the normal distribution assumption was observed. An independent t test was performed to compare two groups of tests, and the Mann–Whitney U test was performed if when a violation of the normal distribution assumption was observed. For categorical data, a chi-square test was performed. When the number of cells with an expected count of less than 5 exceeded 20% of the total number of cells, Fisher's exact test was performed. A P value of less than 0.05 indicated statistical significance.

Results

The demographics of the participants are presented in Table 1. The three groups comprised 116 patients, of which 67, 41, and, 8 were in the healthy weight (36 men and 31 women), overweight (32 men and 9 women), and obesity (6 men and 2 women) groups, respectively. The redistribution of the groups did not result in any statistically significant differences in baseline disease duration (number of years with psoriasis) and severity (PASI and affected BSA) between the healthy weight group and either of the other two groups.

For treatment response, significant differences in PASI reduction were observed between the healthy weight and obesity groups (61.5% vs. 26.8%, P = 0.0093) and the overweight and obesity groups (59.3% vs. 26.8%, P = 0.0207) but not between the

healthy weight and overweight groups (Fig. 2). For the percentage of patients who achieved PASI 50, a significant difference was observed between the healthy weight and obesity groups (67.2% vs. 25.0%, $P = 0.0463$). The proportions of patients who achieved PASI 50 were 45/67, 26/41, and 2/8 for the healthy weight, overweight, and obesity groups, respectively (Fig. 3).

Table 1 Demographics

	BMI < 25 N=67	25 ≤ BMI < 30 N=41	BMI ≥ 30 N=8
Gender (male/female), n*	36/31	32/9	6/2
Age (years), mean (SD)	36.6 (9.8)	37.8 (9.2)	30.7 (3.8)
Onset age (years), mean (SD)#	24.0 (9.7)	27.6 (9.8)	17.3 (9.9)
Duration of Ps (years), mean (SD)	12.6 (8.5)	10.2 (5.4)	13.5 (10.3)
PASI, mean (SD)	11.3 (3.9)	12.7 (4.1)	12.1 (4.3)
BSA affected (%), mean (SD)	10.0 (5.7)	11.7 (5.7)	8.1 (3.3)

BMI: body mass index; Ps: psoriasis; PASI: Psoriasis Area and Severity Index; SD: standard deviation; BSA: body surface area.

* $P < 0.05$ by chi-square test.

# $P < 0.05$ by one-way ANOVA.

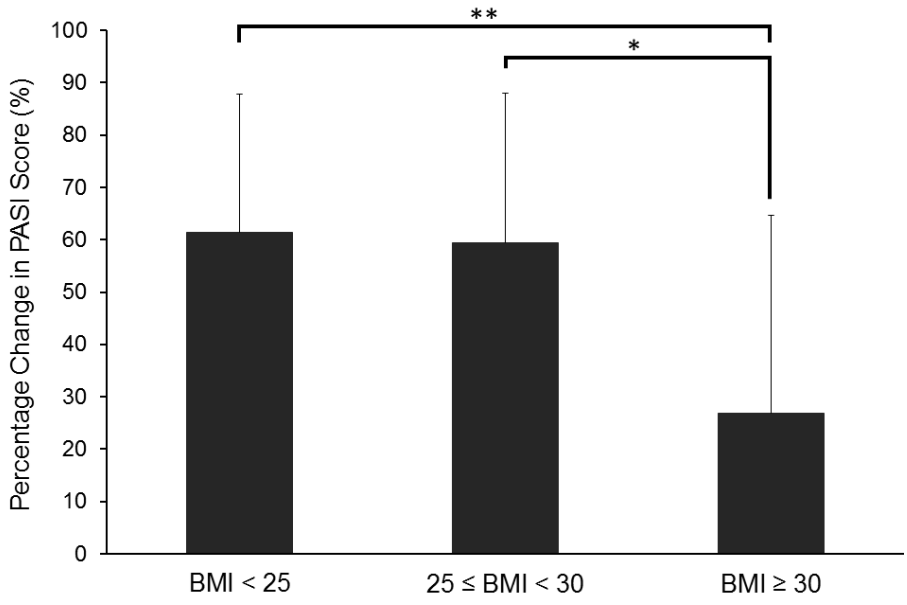

Fig 2. Percentage change in PASI score from baseline after 8 weeks of treatment with indigo naturalis oil extract ointment.

* $P < 0.05$ for comparison with 25 ≤ BMI < 30 by Mann-Whitney U test.

** $P < 0.01$ for comparison with BMI < 25 by Mann-Whitney U test.

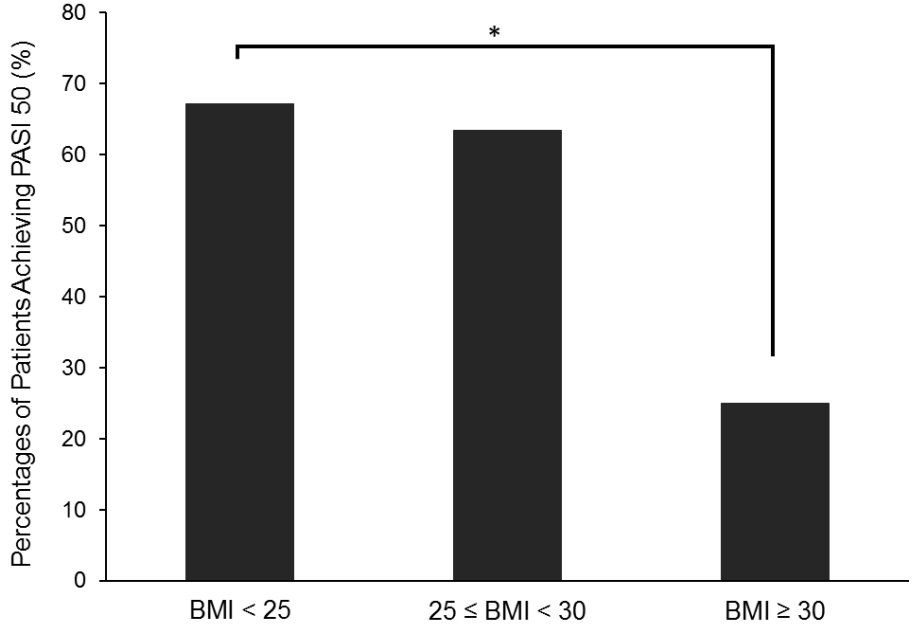

Fig 3. Percentages of patients who achieved PASI 50 after 8 weeks of treatment with indigo naturalis oil extract ointment.

* $P < 0.05$ for comparison with BMI < 25 by chi-square test.

Significant differences in hypertension were observed both between the healthy weight and overweight groups (14.9% vs. 48.8%, $P = 0.0001$) and between the healthy weight and obesity groups (14.9% vs. 50.0%, $P = 0.0356$; Table 2). For hypertriglyceridemia, a significant difference was

Table 2 Prevalence of hypertension and other metabolic disorders in each group

	BMI < 25 N=67	25 ≤ BMI < 30 N=41	BMI ≥ 30 N=8
Hypertension, n (%)	10 (14.9)	20 (48.8)*	4 (50.0)*
Hypercholesterolemia, n (%)	23 (34.3)	19 (46.3)	4 (50.0)
Hypertriglyceridemia, n (%)	9 (13.4)	15 (36.6)*	0 (0.0)
Hyperuricemia, n (%)	2 (3.0)	5 (12.2)	2 (25.0)
Abnormal AST, n (%)	2 (3.0)	5 (12.2)	1 (12.5)
Abnormal ALT, n (%)	3 (4.5)	19 (46.3)*	2 (25.0)
Leukocytosis, n (%)	3 (4.5)	1 (2.4)	3 (37.5)*†

* P < 0.05 for comparison with BMI < 25 by chi-square test or Fisher's exact test.

† P < 0.05 for comparison with 25 ≤ BMI < 30 by Fisher's exact test.

observed between the healthy weight and overweight groups (13.4% vs. 36.6%, $P = 0.0050$). For abnormal ALT level, a significant difference was observed between the healthy weight and overweight groups (4.5% vs. 46.3%, $P < 0.0001$). For leukocytosis, a significant difference was observed between the healthy weight and obesity groups (4.5% vs. 37.5%, $P = 0.0141$). No significant difference was observed for other laboratory data such as total cholesterol, uric acid, and AST levels.

When obesity was not considered, patients with hypertension or other metabolic disorders (such as hypercholesterolemia, hypertriglyceridemia, hyperuricemia, and abnormal AST and ALT levels) that were verified by blood test data tended to exhibit slightly poorer treatment responses relative to patients without these conditions (Fig. 4).

Discussion

To our knowledge, the present study is the first to focus on an herbal medicine in discussing the effects of obesity on psoriasis and psoriasis treatment. Regarding the achievement of PASI 50 and mean reduction of PASI score after 8 weeks of topical treatment with indigo naturalis oil extract ointment, our findings suggest that this topical medicine is effective but yields poorer responses in patients with obesity.

The mechanism through which obesity yields poorer responses can be explained. Obesity is a chronic and low-grade inflammatory disorder, and adipose tissue is an autoendocrine organ that secretes proinflammatory proteins (adipocytokines) including interleukin (IL)-6, IL-17, tumor necrosis factor (TNF)-α, and plasminogen activator inhibitor

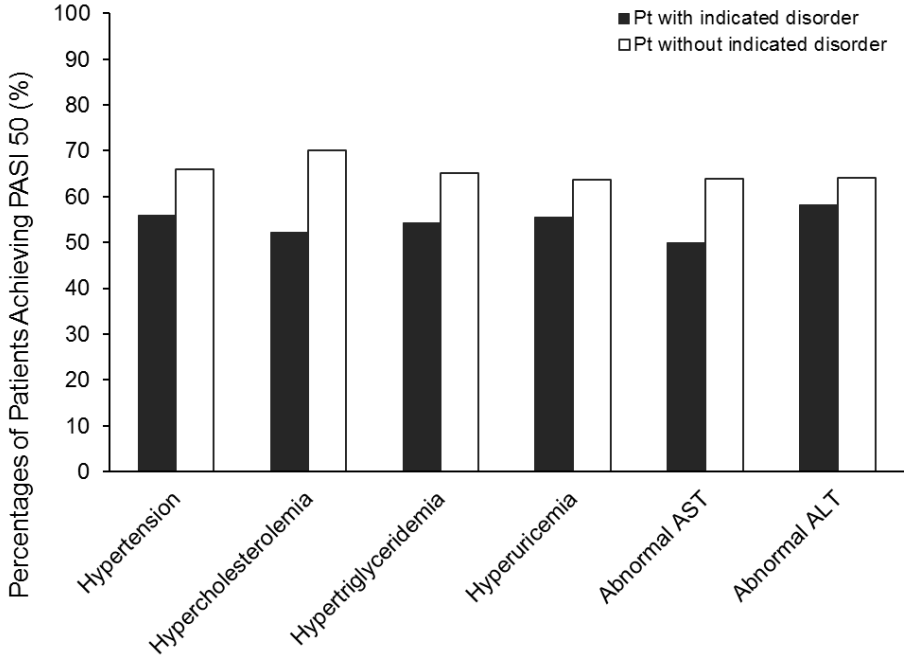

Fig 4. Percentages of patients with and without hypertension and other metabolic disorders who achieved PASI 50 after 8 weeks of treatment with indigo naturalis oil extract ointment.

The comparisons were analyzed by chi-square test or Fisher's exact test.

1. These proteins play key roles in inflammation, carbohydrate metabolism, vascular endothelial proliferation, and abnormal skin keratinocyte proliferation [14–16]. Therefore, obesity not only intensifies the psoriasis-related inflammation caused by IL-6, IL-17, and TNF-α but also leads to metabolic disorders such as abnormalities in blood sugar and lipids levels, hypertension, and cardiovascular disease [17–19]. Cytokine IL-17 plays a key role in psoriasis pathogenesis, and it is modulated by indigo naturalis [20]. Patients with psoriasis, obesity, or metabolic disorders experience increased levels of inflammatory cytokines. Therefore, patients with both psoriasis and obesity have significantly higher levels of IL-17 and other inflammatory cytokines relative to healthy weight patients with psoriasis; consequently, the rate of success for the use of indigo naturalis is lower for patients with psoriasis and obesity relative to other patients.

Recent studies of emerging treatments (such as tofacitinib) have indicated a link between higher BMI and a poorer response to treatment [21], and studies of trial data pertaining to other systemic therapies have also suggested the presence of this link [22]. For some systemic psoriasis treatments, higher incidences of systemic side effects have been observed in patients with obesity. For example, a study indicated that the hepatic and renal toxicity of methotrexate and cyclosporine, respectively, are precipitated by a patient's obesity and that the efficacy rates of these medicines are lower for patients with obesity relative to patients without the condition [23]. Research also suggests equal treatment responses in patients with obesity and healthy weight patients to some topical medicines [10]; therefore, further research should be conducted to determine whether these medicines are more suitable than other medicines for patients with obesity who are unable or unwilling to control their obesity. Currently, we remained unconvinced that the psoriasis treatment for a patient should be determined by their obesity status.

To reduce psoriasis severity and improve treatment efficacy for patients with overweight, we believe that physicians should focus on weight loss. A long-term study reported a reduction of psoriasis severity among patients following the implementation of a weight loss program [24]. In other studies, weight loss interventions have been demonstrated to improve response to biologic- and cyclosporine-based psoriasis treatments [25–27]. Considering the growing body of evidence supporting the presence of the aforementioned link, physicians should share these data with patients with psoriasis and encourage them to control their weight or undergo weight loss treatment (if they are overweight) to improve their condition.

For obesity-related metabolic conditions, the percentage of patients who achieved PASI 50 after undergoing 8 weeks of topical indigo naturalis treatment was slightly higher for the healthy weight segment relative to the segments comprising patients with metabolic disorders (hypertension, hyperlipidemia, hyperuricemia, and abnormal ALT and AST levels); however, this difference was not significant. People with obesity have a higher prevalence of hypertension, hyperlipidemia, and leukocytosis relative to the general population, and the data obtained from our pool of patients with psoriasis also reflected this trend. However, because the general population is already encouraged to undergo weight loss to improve these conditions, we remain unconvinced that these conditions must be considered separately from obesity in psoriasis treatment.

The primary limitation of the present study was

its sample size. A larger sample size may reveal more significant differences in treatment responses associated with specific metabolic disorders without obesity being considered. Furthermore, future studies should examine the extent to which weight loss improves patients' responses to topical TCM treatment.

Conclusion

Physicians should consider obesity when determining psoriasis treatments. Our findings indicate that for patients with both obesity and psoriasis, physicians should encourage weight loss to improve the efficacy of psoriasis treatments involving the use of topical indigo naturalis. More research should be conducted to determine whether the effectiveness of specific treatments are influenced by the comorbidities of a patient with psoriasis.

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原始論文

肥胖對青黛油提取物軟膏治療乾癬的影響

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背景：研究證明乾癬嚴重度與肥胖之間的相關性，但在選擇乾癬的治療方法或評估治療結果時，醫師通常不考慮肥胖因素，本研究目的在探討肥胖對青黛提取物軟膏治療乾癬效果的影響。**方法：**我們從兩項臨床試驗中收集 116 例患者的數據，並根據體重指數（BMI）將患者分為三組：正常體重組（BMI < 25），超重組（25 ≤ BMI < 30）和肥胖組（BMI ≥ 30），我們比較各組間的治療反應結果，並分析相關代謝症候群的數據。**結果：**在治療反應方面，正常體重和肥胖組之間及超重和肥胖組之間的乾癬面積和嚴重度指數（PASI）%降低均有統計學差異（61.5%對 26.8%，$P = 0.0093$）（59.3%對 26.8%，$P = 0.0207$），但在正常體重和超重組間則沒差異。另外發現病人有高血壓和其他代謝紊亂疾病共病的治療反應比沒有共病者差。**結論：**乾癬治療應考慮肥胖和代謝合併症，肥胖患者使用青黛治療乾癬時，應處理其肥胖及代謝紊亂，以取得更好的治療反應，將來應進行更多的研究以基於患者的合併症，找出更有效的治療方法及藥物。

關鍵字：青黛、乾癬、肥胖、代謝性疾病、中醫藥

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