ASSESSMENT OF SLEEP DISORDERS BEFORE AND AFTER ITRACONAZOLE TREATMENT IN SEBORRHEIC DERMATITIS

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ABSTRACT

Objectives: To assess the prevalence of sleep disorders before and after itraconazole treatment in patients with seborrheic dermatitis. **Research object and Method:** This cross-sectional study included 45 patients diagnosed with seborrheic dermatitis who sought treatment at Can Tho Dermatology Hospital between June 2024 and November 2024. Sleep disturbances were evaluated using the Pittsburgh Sleep Quality Index (PSQI) before and after treatment. The effectiveness of itraconazole was assessed based on symptom severity (erythema, scaling, itching, and burning), scored on a 0–3 scale (none–severe) over six weeks. **Results:** Before treatment, 28.9% of patients experienced sleep disorders, with prevalence rates of 21.6% in those with moderate SD and 62.5% in those with severe SD. Following itraconazole treatment, the prevalence of sleep disorders significantly decreased to 6.7% ($p < 0.001$). Treatment outcomes improved over time, with 51.1%, 84.5%, and 95.6% of patients achieving good or excellent results at weeks 2, 4, and 6, respectively. Patients with moderate SD showed better treatment responses compared to those with severe SD. No adverse effects related to itraconazole were reported during the six-week follow-up. **Conclusion:** Sleep disturbances in seborrheic dermatitis were correlated with disease severity. After itraconazole treatment, patients experienced significant improvements in sleep quality, as indicated by lower PSQI scores. Patients with moderate SD responded more favorably to treatment than those with severe SD. These findings suggest that itraconazole is a safe and effective treatment option for managing both moderate and severe seborrheic dermatitis while also improving sleep quality.

Keywords: *seborrheic dermatitis, sleep disorders, itraconazole.*

I. INTRODUCTION

Seborrheic dermatitis (SD) is a chronic inflammatory skin disorder associated with sebaceous glands. It is prevalent worldwide, affecting both children and adults, with an estimated incidence of approximately 5% of the global population [1] . The disease is characterized by erythematous, scaly lesions primarily localized in sebaceous gland-rich areas such as the scalp, face, and upper trunk [2]. Symptoms of SD, such as itching and burning, can negatively impact patients' sleep quality. Therefore, early detection and diagnosis of sleep disorders in seborrheic dermatitis patients may help improve disease prognosis and enhance their quality of life [3]. Various scales are available for assessing

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sleep disorders, among which the Pittsburgh Sleep Quality Index (PSQI) is widely recognized for its high sensitivity and specificity. It is a cost-effective tool that can be applied in both research and clinical practice [4].

Currently, several treatment options are available for SD, administered either topically or systemically, depending on disease severity. Topical treatments are commonly used for mild cases, providing temporary symptom relief but proving less effective in severe cases. Systemic antifungal agents, including itraconazole, fluconazole, and ketoconazole, have been shown to effectively treat *Malassezia* infections and are recommended for patients with refractory, severe, or recurrent seborrheic dermatitis [5]. Itraconazole, an azole derivative with broad-spectrum antifungal activity, is widely used for the prevention and treatment of fungal infections globally. Recent studies indicate that oral itraconazole is effective in controlling symptoms and achieving favorable treatment outcomes in patients with moderate-to-severe seborrheic dermatitis [6].

In Vietnam, there are currently no studies examining the extent of sleep disturbances in SD patients or evaluating the efficacy of itraconazole in both disease management and sleep improvement. Therefore, we conducted this study to assess the prevalence of sleep disorders before and after itraconazole treatment in patients with SD.

II. RESEARCH OBJECT AND METHOD

2.1. Research object

The study subjects included all patients diagnosed with SD who visited Can Tho Dermatology Hospital between June 2024 and November 2024.

The inclusion criteria for the study were as follows: Patients had to be diagnosed with moderate-to-severe SD and prescribed oral itraconazole treatment. Eligible participants were 18 years or older and had liver enzyme levels within normal limits (AST ≤ 37 U/L, ALT ≤ 40 U/L). Additionally, only patients who agreed to participate in the study were included.

The exclusion criteria included patients who were agitated, psychotic, or uncooperative, as well as those with a history of allergy to azole antifungal medications. Pregnant or breastfeeding women were also excluded. Furthermore, patients who did not adhere to the treatment regimen were not included in the study.

2.2. Material and methods

2.2.1. Study design

This study was designed as a cross-sectional study. The sample size was estimated using the formula for population proportion estimation: $n = Z^2_{(1-\frac{\alpha}{2})} \times \frac{p\,(1-p)}{d^2}$, where α = 0.05 (level of statistical significance), $Z_{1-\frac{\alpha}{2}}$ is the corresponding Z-score, p = 0.967, based on a study by Nguyen Van Thuong (2019), which reported that 96.7% of seborrheic dermatitis cases treated with oral itraconazole achieved a good or excellent response [7], and d = 0.06 (margin of error). Using this formula, the required sample size was 35; however, 45 samples were collected in practice. The study employed a convenience sampling method for participant selection.

The treatment regimen involved administering itraconazole 100 mg, with a dosage of two capsules per day for the first two weeks. Following this initial phase, the

dosage was adjusted to two capsules per day for the first two days of each week over the subsequent four weeks. The total duration of treatment was six weeks. Patients were monitored throughout the study, with treatment outcomes assessed at 2 weeks, 4 weeks, and 6 weeks to evaluate the effectiveness of itraconazole in managing seborrheic dermatitis.

Sleep disturbances were assessed using the Pittsburgh Sleep Quality Index (PSQI). This questionnaire evaluates seven components: self-perceived sleep quality, sleep latency, sleep duration, sleep efficiency, insomnia-related symptoms (such as itching and burning), use of sleep aids, and daytime alertness. The total PSQI score is calculated by summing the scores of these components, ranging from 0 to 21 points. A PSQI score greater than 5 was used to indicate the presence of sleep disturbances.

2.2.2. Data collection

The study collected demographic data, including age, gender, place of residence, education level and occupation. Clinical characteristics related to SD were assess based on The Seborrheic Dermatitis Severity Index of Avner Shemer et al [8].

Table 1. **Seborrheic Dermatitis Severity Index**

Symptoms / Score	Erythema	Scaling	Itching	Burning
0	Absence	Absence	Absence	Absence
1	Less	Less	Less	Less
2	Medium	Medium	Medium	Medium
3	Very much	Very much	Very much	Very much

Assessment of Seborrheic Dermatitis Severity:

- Moderate severity: Total score 5 - 9 points
- Severe severity: Total score > 9 points

Evaluation of Treatment Outcomes:

- Total score: 0 points → Very good (complete recovery)
- Total score: 1-2 points → Good
- Total score: 3-4 points → Moderate
- Total score: > 5 points → Limited effectiveness

2.2.3. Statistical analysis

Statistical analysis was performed using SPSS version 27.0.0. Graphs were generated by Graphpad Prism 9.0. Qualitative variables were described using frequency and percentage, while quantitative variables were assessed for normality using the One-Sample Kolmogorov-Smirnov test. If the data followed a normal distribution, they were described using the mean and standard deviation; otherwise, the median, minimum, and maximum values were used. Data analysis involved percentage comparisons using the Chi-square test and Fisher's exact test, while paired sample comparisons were conducted using the Paired Sample T-Test and the Mann-Whitney test. Statistical parameters were presented with a 95% confidence interval (CI), and p-values < 0.05 were considered statistically significant.

III. RESULTS

3.1. Characteristics of the participants

Table 2. **Demographic data of the participants**

General characteristics (n = 45)	
Average age	38.73 ± 14.61
Gender	
Male	64.44% (29)
Female	35.56% (16)
Place of residence	
Can Tho City	40% (18)
Other Provinces	60% (27)
Education attainment	
Primary school education	4.4% (2)
Secondary school education	24.4% (11)
High school education	28.9% (13)
College/University or higher education	42.2% (19)
Occupation	
Farmers	6.7% (3)
Workers	11.1% (5)
Trader	17.8% (8)
Government employees	24.4% (11)
Students	20% (9)
Housewife	11.1% (5)
Others	8.9% (4)

The study included 45 participants with an average age of 38.73 ± 14.61 years. The majority were male (64.44%), and 60% resided in provinces outside Can Tho City. Educational backgrounds varied, with 42.2% having a college/university degree or higher, while 4.4% had only primary education. Participants had diverse occupations, including government employees (24.4%), students (20%), traders (17.8%), workers (11.1%), housewives (11.1%), and farmers (6.7%) (Table 2).

Table 3. **Distribution of the patients by disease severity**

Level of severity	**n**	**%**
Medium	37	82.2
Heavy	8	17.8
Total	45	100

The study participants predominantly exhibited moderate seborrheic dermatitis (82.2%), which was significantly higher than the proportion of those with severe seborrheic dermatitis (17.8%) (Table 3).

3.2. Sleep disorders in seborrheic dermatitis patients

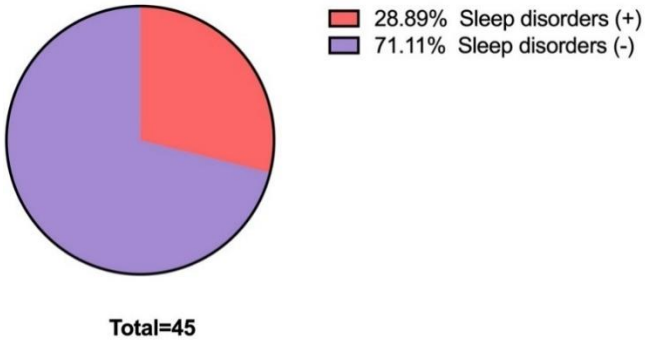

Fig 1. **Prevalence of sleep disorders on seborrheic dermatitis patients on pre-treatment**

In the study, 13 out of 45 patients (28.9%) with seborrheic dermatitis experienced sleep disorders before treatment, as assessed using the PSQI scale (Figure 1).

Table 4. **Correlations between age, gender, disease severity and sleep disorders**

Characteristics		Sleep disorders		Total	p
		Yes n (%)	No n (%)		
Age group	<50	8 (22.2)	28 (77.8)	36 (100)	0.063*
	≥50	5 (55.6)	4 (44.4)	9 (100)	
Gender	Male	9 (31)	20 (69)	29 (100)	0.743*
	Female	4 (25)	12 (75)	16 (100)	
Disease severity	Medium	8 (21.6)	29 (78.4)	37 (100)	0.034*
	Heavy	5 (62.5)	3 (37.5)	8 (100)	
Total		13 (28.9)	32 (71.1)	45 (100)	

** Fisher's Exact Test*

Sleep disorders were more common in patients aged ≥ 50 years, male patients, and those with severe seborrheic dermatitis. Sleep disturbances were significantly associated with disease severity, with a statistically significant difference (Table 4).

3.3. Changes of sleep disorders after treatment with oral itraconazole in seborrheic dermatitis patients

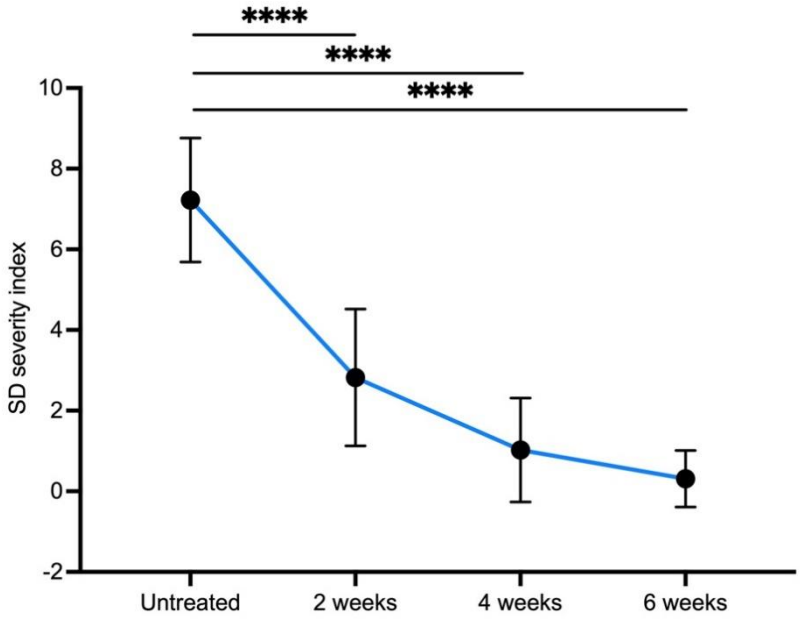

Fig 2. **Change of SD severity index during treatment with itraconazole**

Paired Sample T-test **was used to evaluated the difference between pre- and post-treatment with oral itraconazole. *******P<0.0001***

The scores gradually decreased over the follow-up period from 7.22 (before treatment) to 2.82 (after 2 weeks of treatment), 1.02 (after 4 weeks of treatment), and further declined to 0.31 (after 6 weeks of treatment). The reduction in scores at all three time points compared to before treatment was statistically significant (Figure 2).

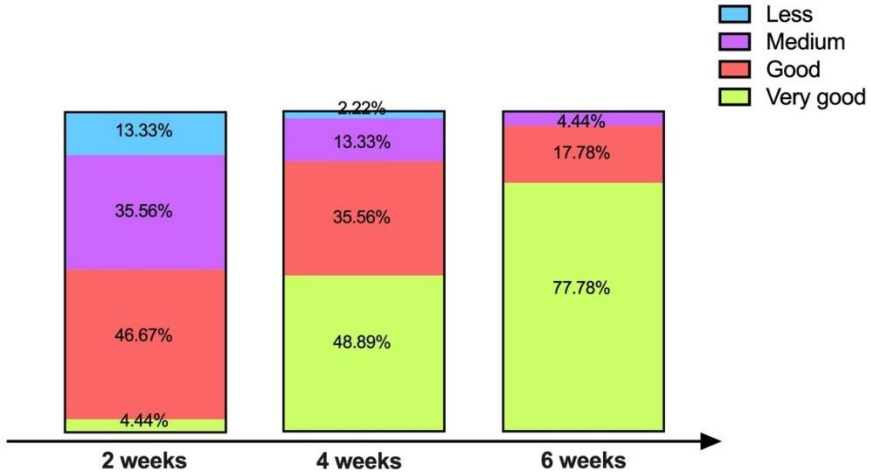

Fig 3. **Treatment response to itraconazole after 2 - 4 - 6 weeks**

After 2 weeks of treatment, 4.4% of patients had a very good response, while 46.7% had a good response to treatment. After 4 weeks, the proportion of patients with a very good response increased to 48.9%, while 35.6% had a good response. By 6 weeks, 77.8% of patients had a very good response, and 17.8% had a good response (Figure 3).

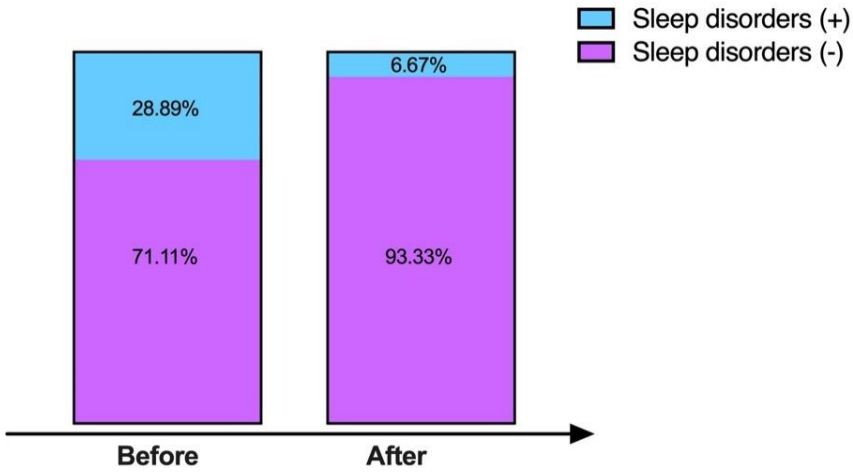

Figure 4. Change of sleep disorders pre- and post-treatment

The proportion of patients with sleep disorders after treatment (6.7%) decreased compared to before treatment (28.9%) (Figure 4).

IV. DISCUSSION

4.1. Characteristics of the participants

In our study, patients with seborrheic dermatitis had an average age of 38.73 ± 14.61 years. The condition was more prevalent in males than females, with a male-to-female ratio of 1.8. Additionally, the majority of patients had moderate seborrheic dermatitis (82.2%), which was significantly higher than those with severe cases (17.8%). These findings are consistent with the general characteristics of seborrheic dermatitis patients reported in previous studies [7,9,10]. The majority of seborrheic dermatitis (SD) patients in this study had attained a college/university education or

higher (42.2%). Additionally, government employees (24.4%) and students (20%) represented the largest occupational groups among the participants. These professions are often associated with high levels of stress, which is recognized as a significant triggering or exacerbating factor for seborrheic dermatitis. Previous studies have also suggested that psychological stress can influence disease onset and recurrence by affecting immune function and sebum production, further contributing to disease pathogenesis. These findings highlight the importance of stress management strategies as a complementary approach in the treatment and prevention of seborrheic dermatitis flare-ups [11].

4.2. Sleep disorders in seborrheic dermatitis patients

A total of 13 patients with seborrheic dermatitis were diagnosed with sleep disorders, accounting for 28.9% of the study population. This prevalence was significantly lower than that reported in a study by Bruno Halioua, which found that 71.2% of patients with dermatological conditions (such as psoriasis, seborrheic dermatitis, and contact dermatitis) experienced sleep disturbances [12]. This discrepancy may be attributed to differences in study populations, as Bruno Halioua's research included multiple dermatological conditions, whereas our study focused specifically on seborrheic dermatitis. Additionally, cultural factors, lifestyle differences across countries, and the subjective nature of the PSQI questionnaire, which relies on patient self-assessment, may have influenced the results.

The severity of seborrheic dermatitis was significantly associated with sleep disorders. Among patients with moderate seborrheic dermatitis, 21.6% experienced sleep disturbances, whereas 62.5% of those with severe seborrheic dermatitis had sleep disorders. This difference was statistically significant ($p < 0.05$). Symptoms such as burning and itching often lead to frequent scratching, making it difficult for patients to fall asleep and stay asleep, thereby significantly reducing their sleep quality. According to a study by C. Zeidler (2024), the severity of itching was positively correlated with sleep quality impairment in seborrheic dermatitis patients ($r = 0.506$, $p < 0.001$) [13]. After completing treatment, the prevalence of sleep disorders decreased from 28.9% before treatment to 6.7% after treatment.

4.3. Changes of sleep disorders after treatment with oral itraconazole in seborrheic dermatitis patients

In our study, disease severity scores gradually decreased over the follow-up period. After two weeks of treatment, 51.1% of patients with seborrheic dermatitis who received itraconazole 200 mg/day achieved good or excellent treatment outcomes. This rate was higher than that reported in studies by Avner Shemer (2008) and Nguyen Van Thuong (2019), where the proportion of patients achieving good or excellent outcomes was 34% and 30%, respectively [7,8]. This difference may be due to variations in disease severity among patients before treatment.

After four weeks of treatment, 84.5% of patients who received itraconazole 200 mg/day for the first two days of each week achieved good or excellent outcomes. This result was comparable to findings of success rate from studies by Chau Hong Hieu (88.9%) and Nguyen Van Thuong (90%), [9,10]. By the end of the six-week treatment period, 95.6% of patients in our study

achieved good or excellent outcomes, a statistically significant improvement ($p < 0.05$). This result was consistent with findings from Chau Hong Hieu (2021) and Nguyen Van Thuong (2019), who reported success rates of 90.3% and 96.7%, respectively [9,10].

Itraconazole exerts its antifungal effects by inhibiting cytochrome P450, thereby preventing the conversion of lanosterol to ergosterol, an essential lipid component for fungal cell membrane stability. Additionally, itraconazole has anti-inflammatory properties by inhibiting the 5-lipoxygenase enzyme, which reduces leukotriene B4 synthesis in the skin. This anti-inflammatory activity contributes to the reduction of seborrheic dermatitis symptoms [14]. After six weeks of follow-up, no adverse effects were reported among patients taking itraconazole and the patients who initially had moderate severity showed a higher rate of improvement compared to those with severe severity. These findings confirm that itraconazole is a safe and effective treatment for seborrheic dermatitis.

V. CONCLUSION

A considerable proportion (28.9%) of patients with seborrheic dermatitis experienced sleep disorders. Sleep disturbances were associated with disease severity, and after treatment, patients showed improvement in sleep quality, as reflected by lower PSQI scores. Itraconazole has been proven to be safe in the treatment of seborrheic dermatitis. Active treatment with oral itraconazole not only effectively improves the condition but also helps alleviate sleep disorders in patients with seborrheic dermatitis.

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