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Comparative Study Of Efficacy Of Topical Luliconazole Versus Topical Ketoconazole In The Treatment Of Pitrayiasis Versicolor

Ameen Mohammed Atiyah[1], Saad H. Salman[2], Aliaa Sameer Al-Nashme[3] and Noor Swadi[4]

[1]Iraqi Ministry of Health, Baghdad Health Directorate \ Al-Karkh, Al-Furat General Hospital, Baghdad, Iraq.
[2,3,4]Department of Medicine, College of Medicine, Ibn Sina University of Medical and Pharmaceutical Sciences, Baghdad Iraq.

Abstract: **Background:** Comparative study of efficacy of topically applied luliconazole cream against topically applied ketoconazole cream in pitryiasis versicolor treatment. **Method :** a research on 48 participants diagnosed by clinical examination and mycological test using KOH to verify the presence of Malassezia in pitryiasis versicolor and the follow-up of the patients after 2 weeks and 4 weeks of the topical therapy of luliconazole cream and ketoconazole cream. **Result:** there are 48 participants enrolled in the current study, with a mean age of 29±3.38, a predominance of male patients (73%), and a mean duration of symptoms of 32.2±2.244. Luliconazole cream shows higher efficacy against pityriasis versicolor after 2 weeks of application (53.85%), while ketoconazole cream shows lower efficacy (40.91%). After 4 weeks of topical application, luliconazole shows higher efficacy (88.46%) than ketoconazole (81.82%). **Conclusion:** The present study clarify that topical luliconazole exhibits a greater efficacy than ketoconazole in treatment of pitryiasis versicolor.

Keywords: Luliconazole, Pitryriasis Versicolor, Topical, Ketoconazole.

INTRODUCTION

Pityriasis versicolor (PV) is a common dermatological fungal infection affecting superficial layers of the skin characterized by scaly, dyspigmented macules that arise due to the proliferation of *Malassezia* species on the stratum corneum.(Brandi, N. *et al*., 2019; Choi, F. D. *et al*., 2019; Diongue, K. *et al*., 2018) These yeasts, which are primarily lipophilic, transform from a commensal yeast phase into a pathogenic mycelial form under specific environmental or host-related triggers. (Faergemann, J. 1999; Hald, M. *et al*., 2015) The clinical manifestation of this condition typically involves well-demarcated hypo- or hyperpigmented patches predominantly affecting the neck, upper trunk and shoulders. (Łabędź, N. *et al*., 2023; Saunte, D. M. *et al*., 2020) Although these lesions most frequently occur in these regions, atypical presentations involving the face, axilla, or even the scalp, which are often associated with *Malassezia* species such as *M. globosa*, *M. sympodialis*, and *M. furfur*, have been increasingly documented. (Saunte, D. M. *et al*., 2020; Leung, A. K. *et al*., 2022) The pathogenesis is largely driven by a combination of high ambient humidity and increased sebum production, which facilitates the conversion of these dimorphic fungi into their filamentous form. (Jasiuk, A. *et al*., 2025; Angel, M. A. *et al*., 2019) Epidemiological trends indicate a significantly higher prevalence in tropical climates, where hot and humid conditions may affect up to 50% of the population. (Zhou, Y. B. *et al*., 2024) Clinical diagnosis is often confirmed by mycological means, though physical examination remains the primary approach for identifying the characteristic scaling macules. In addition, particular origins of pigment variations remain unidentified, several theory exist. The hypopigmented type of PV, in which the skin color does not darken in response to sun exposure, are generally most noticeable in the summer. Malassezia which produce Azelaic acid, a dicarboxylic acid may contribute to the hypopigmentation state through its inhibitory or harmful effects on melanocytes. (Galadari, I. *et al*., 1992; Nazzaro-Porro, M., & Passi, S. 1978)

Erythematous and hyperpigmented lesions may occur due to inflammatory response to the yeast. (Galadari, I. *et al*., 1992)
Essential diagnosis through techniques such as potassium hydroxide preparation which reveals characteristic hyphae and spores and Wood's lamp examination, which can elicit diagnostic yellow-green fluorescence. (Faergemann, J. 1999; Jasiuk, A. *et al*., 2025).

Various treatment modalities are prescribe for PV, including systemic and topical azoles, selenium sulfide and allylamines. A recent evidence-based assessment determined that most treatment approaches for PV have comparable effectiveness; nevertheless, randomized controlled studies are necessary to evaluate their relative efficacies. (Hu, S. W., & Bigby, M. 2010).

***Corresponding Author:** Ameen Mohammed Atiyah

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Ketoconazole is a synthetic antimycotic imidazole derivative with hydrophilic character. It has a activity against dermatophytes and yeasts with wide spectrum . (Odds, F. C. *et al*., 1980; Thienpont, D. *et al*., 1979).

A new optically active imidazole antifungal is called luliconazole. (Niwano, Y. *et al*., 1998) The chemical structure of luliconazole has a unique character. It has an action against filamentous fungi by a high-potency inhibitory effect, including dermatophytes.Initial research indicated that luliconazole may also be efficacious against Malassezia species. (Uchida, K. *et al*., 2003).

The aim of this study was to evaluate the clinical efficacy of topically applied luliconazole versus topically applied ketoconazole in patients with PV.

METHOD

A comparative study conducted in AL Yarmouk Teaching Hospital, dermatology department during the period from December 2024 to October 2025. All participants signed informed consent approved by the institutional ethics committee of Baghdad Medical College, Baghdad, Iraq.

A study enrolled approximately 48 patients aged 14 to 46 years which diagnosed clinically and microscopically using KOH 10% confirmed *Malassezia* infections.

Participants were randomly assigned to two parallel treatment groups to receive either daily topical application of 1% luliconazole or 2% ketoconazole for 28 days.

Participants with PV who have already received systemic or topical antifungal therapy or pregnant women in the last 1 month are excluded.

Assessment of treatment response involved primary endpoints focused on the objective reduction of dyspigmented lesions and the complete eradication of fungal elements, confirmed by direct microscopy at each biweekly follow-up visit. Furthermore, clinical improvement was quantified using a standardized. Statistical analysis was performed using chi-square tests for categorical variables, with p-values < 0.05 considered indicative of clinical significance.

Compliance with these regimens was monitored via self-reported daily logs to ensure consistent adherence, a critical factor in limiting the high recurrence rates associated with dermatophytosis.

The findings derived from this evaluation are anticipated to provide clinicians with an evidence-based framework for selecting more potent topical regimens in the routine therapy of recurrent *Malassezia* infections. Given the necessity of accurate clinical response metrics, outcomes were categorized by complete mycological clearance, defined as the absence of fungal elements, confirmed by negative potassium hydroxide mounts.

RESULT

The study population demonstrated a high level of adherence to the assigned therapeutic protocols, with participants reporting minimal disruption to their daily routines. The mean age of the patients in the present study is 29±3.38 with predominance of male participants, and a mean duration of symptoms is 32.2± 2.24. Table 1.

Table 1: Demographic characteristics of both group participants regarding age & duration of disease.

Demographics	Group-A / Mean±SD	Group-B/ Mean±SD
	(n=26)	(n=22)
Age (years)	28.2±7.78	29.4±8.48
Duration (month)	32.2± 2.24	31.2± 2.44
Frequency and percentage of participants as per sex in both groups. (n=48)		
Sex	Group A	Group B
Male	20 (76.9%)	15 (68.8%)
Female	6 (23.1)	5 (31.2 %)
Total	26(100%)	22(100%)

The results after 2 weeks of application of luliconazole creams and ketoconazole creams, and after 4 weeks of application, are shown in Table 2.3, based on the subjective dermatological examination and mycological testing with KOH.

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Table 2: Comparison of therapeutic efficacy in both groups after 2 and 4 weeks. (n=48) Table-(2)

	After 2 weeks		After 4 weeks		P-value
Efficacy	Group-A (26)	Group-B (22)	Group- A (26)	Group-B (22)	0.024
Yes	14(53.85)	9 (40.91)	23 (88.46)	18 (81.82)	
No	12(46.15)	13(58.9)	3(11.54)	4 (18.18)	
Total	26 (100%)	22(100%)	26 (100%)	22(100%)	

DISCUSSION

Pityriasis versicolor (PV) are a commonly skin superficial fungal infections characterized by scaly, dyspigmented macules that arise due to the proliferation of *Malassezia* species on the stratum corneum. (Borelli, D. *et al*., 1991; Gupta, A. K. *et al*., 2002).

Imidazole group e.g (clotrimazole, micoconazole, ecoconazole, ketoconazole) topical antifungal, that are now well established effective therapy in superficial ring worm infections with a low incidence of side effect. (Gupta, A. K. *et al*., 1994)

In the present study, male patients are affected more often (72.9%) than female patients (27.1%). Pityriasis versicolor was most commonly found in teenagers aged (10-30) years. Almost 91% of patients were asymptomatic. Only 9% of patients expressed worry over the cosmetic or aesthetic alterations associated with hypo- or hyperpigmentation.

These results show similarity to Jha S ' findings, in participants' age of 31.1 (SD =9. 22). Likewise, participants' age distribution, especially in the younger age group of (18-30) years, confirms both this study's findings and that of Jha S. (Jha, S. 2021)

The first therapeutic line of topical antifungal agents can effectively treat PV. In cases that are severe, intense, resistant, or persistent, oral medication is regarded as a second-line therapy. The antifungal drug comprise Ketoconazole and Fluconazole. (Gupta, A. K., & Foley, K. A. 2015).

The mycological analysis data indicated that the luliconazole cream achieved a significantly higher rate of negative potassium hydroxide results.

After 2 weeks of topical therapy with luliconazole cream, 54% were negative in the treated group A, and around 41% were negative in the treated group B while after 4th week with treatment of luliconazole 89% of the patients were negative in group A, while 82% of the patients treated with ketoconazole were negative in group B.

This differential remained statistically significant, suggesting that the heightened structural affinity of luliconazole provides superior sustained antifungal activity against *Malassezia* colonies. Moreover, clinical efficacy data revealed that patients treated with luliconazole experienced a more rapid reduction in symptom, correlating with its potent in vitro activity against *Malassezia* spp. and favorable pharmacokinetic characteristics in the stratum corneum. (Khanna, D., & Bharti, S. 2014)

These results corroborate previous findings that topical azoles for Malassezia-related dermatoses demonstrate efficacy rates typically ranging between 70% and 90%. (Leung, A. K. *et al*., 2022)

Future investigations should focus on the quantitative assessment of fungal burden, potentially utilizing real-time polymerase chain reaction to monitor the decline of *Malassezia* DNA within the skin. Furthermore, the 1% luliconazole cream represents a viable alternative for recalcitrant cases, particularly as clinicians seek to address the challenges posed by emerging resistant fungal strains and the effect of topical luliconazole that decreases the recurrence of attacks of the pitryiasis versicolor that need long-term follow-up of the patients.

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