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Efficacy of combined treatment with Ketoconazole 2% Cream and Adapalene 0.1% Gel vs. Ketoconazole 2% Cream monotherapy in Pityriasis Versicolor

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ABSTRACT

Objective: To compare the efficacy of combined treatment with Ketoconazole 2% Cream and Adapalene 0.1% Gel versus Ketoconazole 2% Cream monotherapy in Pityriasis Versicolor.

Study design and Setting: Randomized Controlled Trial conducted at Dermatology Department of PNS Shifa, Karachi from 19th July 2024 to 30th July 2025.

Methods: A randomized trial included 176 patients with Pityriasis Versicolor (88 per group). Group A received ketoconazole 2% cream twice daily plus Adapalene 0.1% gel nightly for 4 weeks, and Group B received ketoconazole alone. Efficacy at week 4 was defined by clinical improvement, negative Wood's lamp, and KOH microscopy. Data were analyzed in SPSS v26 using chi-square test; Means and standard deviations were calculated for continuous variables (age, BMI, disease duration), while frequencies and percentages were reported for categorical variables (gender, efficacy). The chi-square test was used to compare efficacy between groups, $p<0.05$ was considered significant.

Results: The mean age in Group A was 25.1 ± 4.0 years and in Group B was 25.8 ± 4.2 years. The majority of patients were male, and the distribution of types of pigmentation was comparable in both groups. The efficacy of combination therapy (Group A) was 89.8%, compared to 43.2% with monotherapy (Group B), demonstrating a statistically significant difference ($p < 0.001$).

Conclusions: Combination therapy with ketoconazole and adapalene was significantly more effective than ketoconazole monotherapy in the treatment of Pityriasis Versicolor

Keywords: Adapalene, Combination treatment, Efficacy, Ketoconazole

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INTRODUCTION

Pityriasis versicolor (PV) or tinea versicolor, is a common superficial fungal infection of the skin caused by Malassezia species: lipophilic yeasts which make up a part of the normal human flora.[1] Certain environmental and physiologic situations affect this commensal opportunistic pathogen by promoting its transformation from saprophytic yeast to pathogenic mycelial form leading to clinical development of PV.[2] A number of host and environmental factors affect the transition of Malassezia as a commensal yeast form to the pathogenic mycelial form. High humidity, elevated temperature, and excessive sweating as well as increased activity in sebaceous glands is also a favorable microenvironment to the growth and colonization of fungi, which has been attributed through dermoscopic studies to reasons why PV is higher and more persistent in tropical and subtropical climates.This conversion is stimulated by humidity, temperature and the presence of high serum concentration, factors that favored fungal growth and colonization.[3] Thus, a higher prevalence of the disease is mostly observed in tropical and subtropical areas with climatic conditions favorable to fungal overgrowth, where

it may reach an endemic level and at least during conventionally period such as summer.

Clinically, PV manifest as multiple round or oval macules and patches with variable pigmentation such as hypopigmented form in some places on the body of the host, hyperpigmented at others and also form erythematous to any skin toned brownish color depending upon the type of skin of the host and its immune response.4 PV diagnosis is mostly clinical and is guided by the characteristic morphology and distribution of the lesions though laboratory studies are normally conducted to confirm the diagnosis or rule out the PV pigmentary disorder and other related pigmentary disorders including vitiligo, pityriasis alba and seborrheic dermatitis. A lamp inspection of the wood is usually yellow fluorescence or yellow-green fluorescence which is characteristic of Malassezia infection. Direct microscopic observation of skin scrapings that have been impregnated with potassium hydroxide (KOH) illustrates the classical spaghetti and meat ball pattern of short hyphae and groups of spores.5

Though PV is a harmless dermatological disease, it can cause significant cosmetic anxiety and psychological distress to patients, especially to young adults who constitute the most common population to be affected. PV variants with unusual presentations have also been reported, further increasing the problem of diagnosis and anxiety in patients.6 A variety of antifungal agents have been applied in managing the superficial type of fungus, including the following PV.7 Topical and systemic azoles and allylamines are some of the most common therapeutic classes because they are able to inhibit the production of ergosterol and also destabilize the integrity of fungal cell membranes. Topical treatment is mostly used in localised disease but systemic antifungal agents are employed in extensive or recurring infections.7 of those, topical imidazoles (especially ketoconazole, clotrimazole, and miconazole) still are the first options for treatment because of well-established efficacy, cost-effectiveness, and good safety profile. 8 Ketoconazole 2% cream is especially commonly used and prescribed for localized PV. It functions by suppressing ergosterol formation in the fungal cell membrane, which causes a heightened permeability and an ultimate rupture of the membrane. Nevertheless, despite being efficient, recurrences and incomplete resolution remain common challenges. These problems often require long treatment periods, frequent applications or a use of systemic drug in recalcitrant or recurrent cases.8

With these treatment restrictions, combined protocols that improve the therapeutic index of standard antifungal therapy have drawn increasing interest. The concept of combination therapy is to attack multiple pathophysiological factors (fungicidal, epidermal turnover and post-inflammatory pigmentary changes) and thus promote a faster and more durable clinical resolution.

The recurrence and persistence of PV is greatly explained by the biological properties of Malassezia species. These pathogens have some virulence factors that promote their penetration of stratum corneum and resistance to host defenses. The infection is also likely to recur even after treatment is successful, as Malassezia is part of normal skin microflora, and the presence of increased sebum production and excessive sweating contributes to the development of new episodes of infection.[9] Ketoconazole and clotrimazole are imidazole-based antifungal agents that are considered effective, inexpensive, and safe treatment options in pityriasis versicolor due to their mechanism of action, i.e., inhibiting ergosterol synthesis causing disruption of fungal cell membranes.[1o] Long-term use and recurrence is still a frequent issue, and thus there is a need to develop better treatment modalities.

There are some clinical observations that indicate the global therapeutic response upon adapalene and ketoconazole association is quite better than single therapies. This combination is presumed to achieve a faster response of the lesions, relatively shorter duration in treatment consumed, and better patient adherence people due to its visible early effect and less adverse effects. Nonetheless, despite these promising data, evidence is scarce, in particular from South Asian populations where the endemicity of PV and its environmental influence on persistence and relapse of disease is prominent.

In these countries, which hold among the highest incidence rates of PV in the world, patients living with young adults who are also affected have a tremendous socio-economic burden and an optimal topical therapeutic regimen is warranted that is both effective and safe, affordable and satisfactory to the patient. High rates of relapse are not only cosmetically disturbing but can also induce psychosocial burden and social embarrassment, emphasizing the need for optimal therapeutic strategies that bring complete clinical as well as mycologic cure.

Hence the present study was undertaken to compare the effectiveness and safety of ketoconazole 2% cream along with adapalene 0.1% gel v/s ketoconazole 2% cream alone in pityriasis versicolor. The effect of adapalene was investigated to see whether penetration of the antifungal, clearance and risk of economic relapse could be improved compared with standard mono-therapies.

It was postulated that the association of adapalene in combination with ketoconazole would provide a significant therapeutic advantage, due to its improved complete clinical and mycological cure rates compared to ketoconazole alone, and without increasing local adverse effects. Tolerability, compliance, and adverse event profile were also evaluated.

By investigating this combination strategy, we aim to provide further evidence on the topical treatment of PV and offer an inexpensive, safe and time-efficient option for therapy

that might be particularly useful in resource-limited, high-prevalence areas including Pakistan and other parts of South Asia. The results are anticipated to help dermatologists in the personalization of treatment regimens for PV as well as in preventing recurrent infection by enhancement of topical therapeutic approaches.

METHODOLOGY

This RCT was completed from 19th July, 2024 to 30th July, 2025 in Department of Dermatology PNS Shifa Hospital Karachi. The study was started after receiving the ethical review committee approval of the institution (ERC/2024/DERM/123) and complied with Declaration of Helsinki. Trial registration the study was prospectively registered at Iranian Registry of Clinical Trials (IRCT) with free access to Trial ID: 80249 which means that it was public from the beginning and was ethically acceptable. Before enrollment, all enrollees were invited to read about the study and its goals, advantages and possible risks in a written form and written informed consents were applied by any patient. A total of 176 patients with clinico-mycological evidence of pityriasis versicolor who presented to the outpatient department were included based on non-probability consecutive sampling. They were next randomly allocated, employing athletic lottery method, into two equal parts: Group A (n=88) and Group B (n=88). Eligible candidates were both men and women 18 to 60 years of age. Exclusion criteria were as follows: subjects aged younger than 18 years, those who had a history of antifungal agent treatment within the month before entry into study, pregnant or lactating females and known allergic hypersensitivity to ketoconazole and adapalene. Those with longstanding cutaneous diseases, for example psoriasis or eczema, were not included as these may have confounded the results; nor were those with extensive systemic illness.

Diagnosis of pityriasis versicolor was based on hypopigmented or hyperpigmented scaly macules and patches, predominantly on the trunk, shoulders, and upper arms. Diagnosis was confirmed by yellowish-green fluorescence under Wood's light and direct skin scraping with 10% KOH, showing the characteristic "spaghetti and meatballs" appearance of Malassezia species.

The sample size was estimated utilizing OpenEpi version 3.01on the basis of a previous reported study in which ketoconazole with adapalene showed an efficacy of 87.5% and for ketoconazole monotherapy efficacy is found to be 47.5%. With an 80% power and a 5% level of significance, the sample size was calculated to be 176 subjects (88 in each group), providing sufficient statistical power for identifying meaningful differences between treatments.

Both groups used medication twice a day to guarantee consistency in the frequency of application of the medication and no bias was created based on the number of applications a patient in one group made. Group A was treated with ketoconazole 2% cream in the morning and adapalene 0.1% gel in the night, and Group B was treated with ketoconazole 2% cream twice in the morning and in the evening. Both groups were treated four weeks. The patients were advised to wash the affected parts using water and dry them before applying medication. Dress change and occlusive dressing were not recommended upon its application, and patients were asked to leave the medication to be absorbed naturally. Patients were advised not to spend excessive time in the sun during treatment. Patients were followed at 2nd and 4th weeks of therapy. Compliance was estimated at every visit in the follow-up by patient self-questionnaire and measuring the remaining dosage in the tubes. Patients were advised on compliance, hygiene and prevention of predisposing factors such as excessive sweating and application of oily skin products.

The main outcome measure of interest was efficacy at 4 weeks. This was defined as the presence of all three of:

- TTs normalized (no visible scaling and pigmentary changes),
- Lack of fluorescence under the Wood's lamp examination and
- Fungal elements were not identified on KOH microscopy.

The secondary endpoints were to record the incidence of side effects like flushing/burning, itching, erythema or contact dermatitis seen at each follow-up visit. All data were managed and analyzed with SPSS version 26.0 (IBM Corp., Armonk, NY, USA). Age, BMI, and duration of disease were expressed as mean ± SD; whereas gender, type of pigmentation, and efficacy were presented as frequencies and percentages. The chi-square test was applied for comparison between 2 groups of categorical outcomes including the efficacy and side effect of treatment. When appropriate, independent samples t-test was used to compare quantitative variables. P-value < 0.05 was considered as statistically significant. This approach permitted thorough comparison of both treatments with respect to efficacy and safety. To assess if the addition of adapalene to ketoconazole provides superior clinical and mycological cure rates in pityriasis versicolor-a condition well known for high rate of recurrence and incomplete clearing with a single anti-fungal agent, but responding rapidly due not only primarily to its anti-fungal but also partly keratolytic effect.

RESULTS

A total of 176 patients fulfilling the inclusion criteria were enrolled and randomly allocated into two equal groups, with 88 patients in Group A and 88 patients in Group B. All enrolled patients completed the study and were included in the final analysis. The baseline characteristics of the two groups were comparable with no statistically significant differences (**Table 1**).

The mean age of patients in Group A was 25.1 ± 4.0 years compared to 25.8 ± 4.2 years in Group B ($p = 0.32$). The mean body mass index (BMI) was 22.5 ± 3.5 kg/m² in Group

A and 22.7 ± 3.6 kg/m² in Group B (p = 0.65). The mean duration of disease was 3.7 ± 1.2 weeks in Group A and 3.6 ± 1.1 weeks in Group B (p = 0.74).

In Group A, 68 patients (77.3%) were males and 20 patients (22.7%) were females, whereas Group B included 64 males (72.7%) and 24 females (27.3%), with no statistically significant difference between groups (p = 0.48). The type of pigmentation was also similar between the groups (p = 0.94). Hypopigmented lesions were present in 46 patients (52.3%), hyperpigmented lesions in 30 patients (34.1%), and erythematous lesions in 12 patients (13.6%) in Group A, compared with 44 patients (50.0%), 32 patients (36.4%), and 12 patients (13.6%) respectively in Group B. These findings indicate that both groups were comparable at baseline.

At the end of four weeks of treatment, a statistically significant difference in efficacy was observed between the two groups (**Table 2**). Clinical and mycological cure was achieved in 79 patients (89.8%) in Group A compared to 38 patients (43.2%) in Group B (p < 0.001). Treatment failure was observed in 9 patients (10.2%) in Group A and 50 patients (56.8%) in Group B.

Both treatment regimens were well tolerated with no serious adverse events reported during the study period (**Table 3**). Adverse effects were mild and self-limiting, and no patient discontinued treatment due to side effects. Burning sensation was the most common adverse effect, occurring in 9 patients (10.2%) in Group A and 6 patients (6.8%) in Group B (p = 0.42). Erythema was observed in 12 patients (13.6%) in Group A and 5 patients (5.6%) in Group B (p = 0.09). No cases of contact dermatitis were reported in either group.

Overall, the combination therapy used in Group A demonstrated significantly higher efficacy compared to ketoconazole monotherapy, while both treatments showed good tolerability.

DISCUSSION

The present research demonstrated that this kind of combined therapy was more effective in comparison to ketoconazole monotherapy in PV treatment. Following 4 weeks of therapy, combination-treated patients (adapalene and ketoconazole) achieved a full clinical and mycological response in 89.8%

Table 1. Baseline Characteristics of Patients

Characteristic	Group A (n=88)	Group B (n=88)	P-value
Age (years, mean ± SD)	25.1 ± 4.0	25.8 ± 4.2	0.32
BMI (kg/m², mean ± SD)	22.5 ± 3.5	22.7 ± 3.6	0.65
Duration of disease (weeks, mean ± SD)	3.7 ± 1.2	3.6 ± 1.1	0.74
Gender	—	—	0.48
• Male	68 (77.3%)	64 (72.7%)	
• Female	20 (22.7%)	24 (27.3%)	
Type of pigmentation	—	—	0.94
• Hypopigmented	46 (52.3%)	44 (50.0%)	
• Hyperpigmented	30 (34.1%)	32 (36.4%)	
• Erythematous	12 (13.6%)	12 (13.6%)	

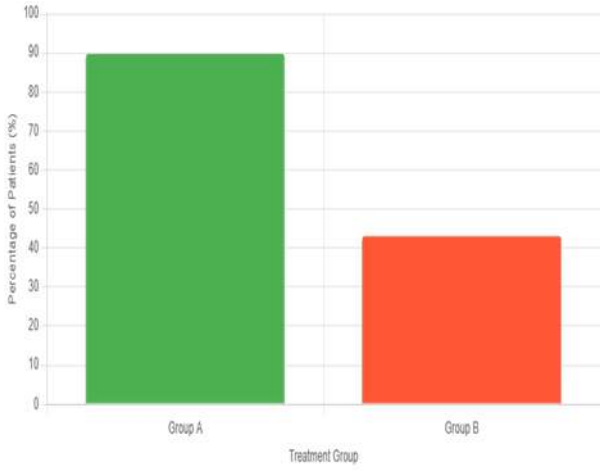
Figure 1: Efficacy: Complete Clinical and Mycological Response at Week 4.

Table 2. Comparison of Efficacy between Groups.

Efficacy	Group A (n=88)	Group B (n=88)	P-value
Yes	79 (89.8%)	38 (43.2%)	<0.001
No	9 (10.2%)	50 (56.8%)	

Table 3. Adverse events.

Side Effect	Group A (n=88)	Group B (n=88)	P-value
Burning	9 (10.2%)	6 (6.8%)	0.42
Erythema	12 (13.6%)	5 (5.6%)	0.09
Contact dermatitis	0 (0%)	0 (0%)	NA



compared to monotherapy-treated patients (43.2%) ($p < 0.001$). [11] This comparative result demonstrates the clinical and mycological effectiveness of the combination of adapalene and ketoconazole and suggests that they are highly synergistic, which increases the intensity of anti-fungal effects but does not shorten treatment duration. [12] The findings of the present study are in line with those reported previously that use of topical antifungal drugs together with keratolytic or retinoids promotes drug penetration and shortens the treatment period for fungal clearance. [13] By virtue of its comedolytic as well as an epidermal differentiation–modulating effects, Adapalene may enhance desquamation of the infected keratinocytes thereby promoting greater penetration and activity of ketoconazole into the stratum corneum. Such a combination of the above mechanisms is likely to explain the much higher clearances in these two groups.

Baseline characteristics, including age, gender, body mass index (BMI), disease duration, and type of pigmentation, were comparable between the two groups, indicating that therapeutic outcomes were independent of demographic or disease-related factors. The mean age (Group A: 25.1 ± 4.0 years; Group B: 25.8 ± 4.2 years) aligns with the known epidemiology of PV, which predominantly affects young adults. The observed male-to-female ratio also corresponds with regional reports, likely reflecting greater exposure to heat and humidity, increased sebaceous activity, and occupational factors that favor fungal proliferation.[14–15]In terms of safety and tolerability, both regimens were well tolerated and there were no grade 3/4 adverse events. Incidence and severity of mild burning in the combination group were 10.2% and that percentage in the monotherapy group was 6.8% ($p = 0.42$), respectively, and erythema was observed in 13.6% and 5.6%, respectively ($p = 0.09$). These were self-limiting responses all of which went away without any intervention. Most importantly, no contact dermatitis was found, providing the information that the combination can be used in the clinic regularly and does not influence compliance.

The multispecificity of the pharmacological characteristics of both medications may be the foundation of the effectiveness of the combined treatment. Ketoconazole (a drug belonging to the imidazole antifungal drug family) exerts its antifungal effects by inhibiting the production of ergosterol in the fungal cell membrane which leads to cellular lysis and inhibits growth. The third-generation topical retinoid Adapalene is a normalizer of follicular keratinization, a reduction of cohesion of corneocytes and epidermal turnover.[16] Collectively, these actions lead to the more rapid and efficient ablation of the infected stratum corneum, enhanced clinical resolution, and reduced recurrence.

The clinical implications of these findings are substantial, especially in tropical and subtropical areas where atmospheric PV has a high level, and relapses may be caused by a warm temperature which is resiliently supported with unremitting humidity. [17] Ketoconazole administration followed by the addition of adapalene enabled a reduction of length treatment, increase of patient compliance and satisfaction and early high visible effect. The lack of patients with significant irritation or systemic adverse reactions is also favorable to our combination as first line topical treatment of PV, in the routine dermatologic clinical practice. [18]

Regarding the public health, this combination therapy has a number of benefits such as low cost, broad availability and easy administration. These characteristics render it especially appropriate to mass usage in resource-constrained environments in which systemic antifungal therapy can be either unfeasible or unwarranted. Additionally, the better clinical and mycological treatment results in the absence of a relationship between the number of adverse events evidenced that the regimen is one of the most balanced and effective ones in terms of clinical and safety indicators today. It should however be noted that the daily application number should be uniformed among the treatment groups in order to prevent the possibility of bias in treatment outcomes.[1?–2°]

This RCT has shown that the combination regimen of ketoconazole 2% cream and adapalene 0·1% gel is superior to monotherapy with ketoconazole in the therapy of PV both clinically and statistically. The combination exhibited significantly higher rates of clinical and mycological cure, was well-tolerated among patients with no or mild side-effects. Adapalene, when combined with standard antifungal therapy, may enhance response rates and reduce the recurrence of these infections enhancing patient compliance. Additional, multicenter trials with long-term follow up are recommended to confirm these results and for assessment of the long-term relapse rate after this combination therapy.

Limitations of the study: This study had a small sample size, as well as being carried out at a single center and this may impact the generalization of its results. The relatively short follow-up might not be sensitive enough to detect long-term recurrence. Besides, the evaluation of the response to treatment was mainly clinical and not mycological by culture in such cases. Patient compliance with topical treatment and variations in skin type among the patients might also have affected the outcomes.

CONCLUSION

The present study demonstrates that the combination of ketoconazole 2% cream with adapalene 0.1% gel is more effective than ketoconazole monotherapy each twice a day in achieving faster and higher clinical improvement in pityriasis versicolor. The enhanced efficacy of the combination may be attributed to the antifungal action of ketoconazole together with the keratolytic and comedolytic effects of adapalene, which facilitate removal of infected stratum corneum and improve drug penetration. Given its favorable safety profile, the combination therapy can be

considered a promising alternative to conventional topical antifungal monotherapy. However, larger multicenter randomized controlled trials with longer follow-up are needed to confirm these findings and to evaluate relapse rates. Given its efficacy and favorable safety profile, the combination regimen may be considered a practical first-line option for patients with recurrent or extensive pityriasis versicolor.

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Authors Contribution:
Sunaina Kumari: Conception and design of study, data collection, drafting of manuscript, final approval
Atiya Rahman: Study design, supervision, methodology refinement, critical review of manuscript
Janta Choudhry: Data acquisition, literature review, initial drafting of sections
Sana Saleem: Methodology guidance, interpretation of results, critical revision, overall supervision
Jotee Rani: Data entry, statistical analysis, preparation of tables/figures
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