

# Comparative assessment of therapeutic efficacy of topical luliconazole versus topical ketoconazole in the treatment of pityriasis versicolor

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## Abstract

**Background:** Pityriasis versicolor is a mild, persistent, typically asymptomatic fungal stratum corneum infection caused by *Malassezia* yeasts. Pityriasis versicolor is a common benign, superficial skin fungal infection, also known as tinea versicolor. It is a disease linked with *Malassezia* yeasts. Clinical features of Pityriasis versicolor show both hypo and hyper pigmented scaly macules. **Objective:** To compare the efficacy of topical luliconazole vs topical in ketoconazole in treatment of Pityriasis versicolor **Design:** Hospital based observational prospective analysis **Duration:** One year from January 2018 to December 2018 **Setting:** Dermatology outpatient department **Participants:** 100 patients **Methods:** A total of 100 patients with skin lesions of Pityriasis versicolor attending the Dermatology Outpatient Department. The patients were randomly divided into two groups Group A and Group B with each group containing 50 patients each. The first group i.e. Group A were treated with topical luliconazole 1% and the other group were treated with topical ketoconazole 2%. Both groups were advised to apply twice daily for 4 weeks i.e. 28 days. Both clinical and mycological assessment was done to all the patients in both the groups initially and on two follow-ups one being in the 2<sup>nd</sup> week i.e. 14 days and the other follow up in the 4<sup>th</sup> week i.e. 28 days. **Results:** 1<sup>st</sup> follow up after 2 weeks i.e. 14<sup>th</sup> day 81% were negative in the treated luliconazole group and around 70% were negative in the treated ketoconazole group. On the 2<sup>nd</sup> follow up after completion of 4<sup>th</sup> week i.e. 28<sup>th</sup> day 95% of the patients were negative in the treated luliconazole group while 74% of the patients treated with ketoconazole group were tested negative. **Conclusion:** Both topical luliconazole and topical ketoconazole were effective in treating pityriasis versicolor, But topical luliconazole has been found to be more effective than topical ketoconazole over a span of 4 weeks.

**Key Word:** Pityriasis versicolor, Luliconazole, Ketoconazole, Potassium Hydroxide -KOH

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## INTRODUCTION

Pityriasis versicolor is a superficial chronically recurring, stratum corneal fungal infection characterized by scaly irregular dyspigmented macules most often found on the trunk and limbs.<sup>1,2,3</sup> It is one of the world's most prevalent pigmentary skin disorders. It often occurs in teenagers and young adults, but is also seen in other age groups. It is similarly impacting men and women and there has not been a particular ethnic predominance.<sup>4,5</sup> Pityriasis versicolor is usually diagnosed on the basis of its clinically presented hypo or hyper pigmented, scaled patches or plaques.<sup>6,7,8</sup> It does not result in either permanent scarring or pigmentation disorders. Nonetheless, following effective treatment, recurrence of disease can occur in many

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cases.<sup>9,10,11</sup> A skin scrapping with 10% KOH will detect the organism and it reveals small dense hyphae's with a large number of different sized spores ranging from spaghetti to meat-ball shapes. In treating pityriasis versicolor with an overall positive result there are many systematic and topic anti-fungal products of different form being used. Luliconazole, a member of the azole class, has good fungicidal activity, close to that of terbinafin against *Trichophyton* spp. Luliconazole is an antifungal medication that is new, optical effective and novel.<sup>12</sup> A ketene dithioacetate formulation has been incorporated into the imidazole campaign to improve the specific chemical structure of luliconazole, and it has a strong inhibitory activity against filament fungi such as Dermatophytes and *Malassezia* organisms. Ketoconazole is a water soluble synthetic imidazole group of antifungal medicinal products with a wide range of anti-mycotic activity with a broad spectrum of activity against dermatophytes and yeast. Ketoconazole is used to combat serious fungal skin infections.<sup>13,14,15,16</sup> The goal of the present study is to evaluate this therapeutically more effective drug in the treatment of Pityriasis versicolor with topical luliconazole (1%) cream compared with topical ketoconazole (2%).

## MATERIALS AND METHODS

**Place of Study:** Outpatient Department of dermatology

**Type of Study:** This was a hospital based observational study.

**Sample Collection:** Sample size : 100 patients.

**Sampling Methods:** Consecutive sampling

**Inclusion Criteria:** Patients with confirmed diagnosis of pityriasis versicolor with 10% KOH mount

**Exclusion Criteria:** Patients with Pityriasis versicolor skin lesions who already received topical or systemic antifungal treatment and pregnant women

## OBSERVATIONS AND RESULTS

Out of 100 patients, 86 patients were selected for this study. 60 Patients were male constituting 69.7 % and the rest 26 were females constituting 30.3%. The male to female ratio was 2.3: 1 which shows male predominance.

**Statistical Analysis:** Data were presented in the form of statistical Tables and charts. SPSS software version 20 was used for statistical analysis.

**Ethical Approval:** Approval was taken from the Institutional Ethics Committee prior to commencement of the study.

A total of 100 patients with skin lesions of Pityriasis versicolor attending the Dermatology Outpatient Department were taken. The patients were randomly divided into two groups Group A and Group B with each group containing 50 patients each. The first group i.e. Group A were treated with topical luliconazole 1% and the other group were treated with topical ketoconazole 2% . Both groups were advised to apply twice daily for 4 weeks i.e. 28 days.

The diagnosis of Pityriasis versicolor is usually made based on clinical examination findings but both clinical and mycological assessment was done to all the patients in both the groups initially and on two follow-ups one being in the 2<sup>nd</sup> week i.e. 14 days and the other follow up in the 4<sup>th</sup> week i.e. 28 days. The mycological assessment was done by scraping of the skin from the edge of the lesion and scrapings were collected directly on to the slide. Potassium hydroxide 10% was added to the collected material and observed under the microscope. Upon 10% potassium hydroxide (KOH) mount examination it revealed, hyphae's which were growing into strands within clumps of keratinocytes. Thick-walled spores were spotted in grape like clumps. Individual spores and short stubby hyphae's were floating in the clear areas between clumps of keratinocytes. Many of the short hyphae's were dystrophic. It had resemblance of spaghetti and meatball. The KOH mount was observed and result classified as positive or negative for *Malassezia* fungi.

**Table 1:** Number of Patients with Negative Potassium hydroxide - KOH Mount in both the groups at the onset, on 1<sup>st</sup> follow up in the 2<sup>nd</sup> week i.e. 14th Day and on the 2<sup>nd</sup> follow up in the 4<sup>th</sup> week i.e. 28th Day of this Study

Time Period	Luliconazole Group (A) (Number of Patients with Negative KOH Mount)	Ketoconazole Group (B) (Number of Patients with Negative KOH Mount)	P value*
At the beginning	4	7	>0.05
1 <sup>st</sup> follow up (on 14th day)	35	30	>0.05
2 <sup>nd</sup> follow up (on 28th day)	41	32	<0.05*

Total of 14 patients didn't turn up for the follow up visits. At the first follow up 5 patients didn't attend and in the 2<sup>nd</sup> follow up 9 patients didn't follow up and we excluded them from our study.

1<sup>st</sup> follow up after 2 weeks i.e. 14<sup>th</sup> day 81% were negative in the treated luliconazole group and around 70% were negative in the treated ketoconazole group. On the 2<sup>nd</sup> follow up after completion of 4<sup>th</sup> week i.e. 28<sup>th</sup> day 95% of the patients were negative in the treated luliconazole group while 74% of the patients treated with ketoconazole group were tested negative.

## DISCUSSION

Pityriasis versicolor is a fungal disease from the category of superficial fungus. This fungus causes chronic and recurrence infection of the layer of the skin that is created by lipophilic yeast from *Malassezia*. Human to-human transmission is possible through direct contact. In our study male patients are affected more (69.7%) than the female (30.3%). The most common age group affected with pityriasis versicolor were the teenagers belonging to the age group of 10 – 30 years. Almost 90% of patients were asymptomatic. Only 10% of the patients were concerned about the cosmetic or aesthetic changes seen with the occurrence of hypo or hyper pigmentation. Topical agents can effectively treat pityriasis versicolor. The first line of treatment for the pityriasis versicolor is topical medicines, In the event of serious, extreme, recalcitrant or chronic cases, oral therapy is seen as a second line of treatment. These antifungal agents include Ketoconazole and Luliconazole. In the beginning of our study by using KOH mount we found that around 9% of the patients belonging to luliconazole group were found to be negative and in the ketoconazole group 16% of the patients were negative. On the 1<sup>st</sup> follow up after 2 weeks i.e. 14<sup>th</sup> day 81% were negative in the treated luliconazole group and around 70% were negative in the treated ketoconazole group. On the 2<sup>nd</sup> follow up after completion of 4<sup>th</sup> week i.e. 28<sup>th</sup> day 95% of the patients were negative in the treated luliconazole group while 74% of the patients treated with ketoconazole group were tested negative. During the follow-up tests of this research, mycological changes in versicolor lesions of Pityriasis were statistically significant among both treated groups. Previous studies by Savin RC *et al.*<sup>17</sup>, Balwada RP *et al.*<sup>18</sup>, Chopra V *et al.*<sup>19</sup> and Nagpal VB<sup>20</sup> showed 80 – 90% cure rate with ketoconazole treatment for pityriasis versicolor.

## CONCLUSIONS

The treatment of pityriasis versicolor was effectively performed with both topical luliconazole as well as with topical ketoconazole, however topical luliconazole over period of 4 weeks was found to be more effective than

topical ketoconazole. The two were nearly identical in contrast with the 2 weeks of topical treatment with both luliconazole and ketoconazole.

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