International Journal of Medical Research Professionals
P-ISSN: 2454-6356; E-ISSN: 2454-6364
DOI: 10.21276/ijmrp

IJMRP

Original Research Article.

Evaluation of Efficacy of Oral Terbinafine Versus Itraconazole in Treatment of Dermatophytic Infections: An Institutional Based Study

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ABSTRACT

Background: The present study was conducted for evaluating the efficacy of oral terbinafine versus itraconazole in treatment of dermatophytic infection of skin.

Materials & Methods: A total of 80 patients were enrolled in the present study. Inclusion criteria for the present study included patients with clinical diagnosis of tinea corporis and tinea cruris confirmed by potassium hydroxide (KOH) test. All the patients were divided broadly into two study groups as follows: Group A: Patients receiving terbinafine for one month, and Group B: Patients receiving itraconazole for one month. Both clinical and mycological evaluation of patients was done at 15 days follow-up and 30 days follow-up. At every follow-up visit, recording of the response was done which included assessment of pruritus, erythema, and scaling. Scoring was done as absent (Score 0), mild (Score 1), moderate (Score 2) and severe (Score 3).

Results: Mean scaling score, Pruritis score and erythema score at baseline among patients of group A was 1.35, 2.52 and 1.63 respectively. Mean scaling score, Pruritis score and erythema score at baseline among patients of group B was 1.12, 2.29 and 1.48 respectively. Significant better results were obtained among patients of group B in comparison to patients of group A.

Conclusion: Better results were seen among patients managed with Itraconazole.

Key words: Dermatophytic, Terbinafine, Itraconazole.

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Article History:

Received: 14-08-2019, **Revised:** 05-09-2019, **Accepted:** 23-09-2019

Access this article online	
Website: www.ijmrp.com	Quick Response code
DOI: 10.21276/ijmrp.2019.5.5.075	

INTRODUCTION

Dermatophytes are fungi that invade and multiply within keratinized tissues (skin, hair, and nails) causing infection. Based upon their genera, dermatophytes can be classified into three groups: Trichophyton (which causes infections on skin, hair, and nails), epidermophyton (which causes infections on skin and nails), and Microsporum (which causes infections on skin and hair). Based upon mode of transmission, these have been classified as anthropophillic, zoophilic, and geophilic. Finally, based upon the affected site, these have been classified clinically into tinea capitis (head), tinea faciei (face), tinea barbae (beard), tinea corporis (body), tinea manus (hand), tinea cruris (groin), tinea pedis (foot), and tinea unguium (nail). Other clinical variants include tinea imbricata, tinea pseudoimbricata, and Majocchi granuloma.[1-3]

Clinical manifestations vary depending on the causal agent and on the host immune response; they may last months or years, and may be asymptomatic or manifest only as pruritus. In the majority of cases, however, infection manifests itself as blistering, fissures, scales, or spots.[4,5]

Terbinafine is the orally available allylamine antifungal. With a favorable mycological and pharmacokinetic profile, terbinafine is considered to be a first-line drug for the treatment of tinea corporis and cruris. Terbinafine acts by inhibiting the enzyme squalene epoxidase thus inhibits the synthesis of ergosterol, an important component of fungal cell membrane leading to fungal cell wall disintegration.[6,7] Itraconazole is a highly keratinophilic and lipophilic triazole. Secretion in sebum is a major route by which the drug reaches the stratum corneum.[8] Hence; the present study was conducted for evaluating the efficacy of oral terbinafine versus itraconazole in treatment of dermatophytic infection of skin.

MATERIALS & METHODS

The present study was conducted for evaluating the efficacy of oral terbinafine versus itraconazole in treatment of dermatophytic

infection of skin. A total of 80 patients were enrolled in the present study. Inclusion criteria for the present study included patients with clinical diagnosis of tinea corporis and tinea cruris confirmed by potassium hydroxide (KOH) test.

All the patients were divided into broadly into two study groups as follows:

Group A: Patients receiving terbinafine for one month

Group B: Patients receiving itraconazole for one month

Both clinical and mycological evaluation of patients was done at 15 days follow-up and 30 days follow-up. At every follow-up visit, recording of the response was done which included assessment of pruritus, erythema, and scaling. Scoring was done as absent (Score 0), mild (Score 1), moderate (Score 2) and severe (Score 3). KOH examination was done at the time of enrolling the patient and at the end of the one month. All the results were recorded in Microsoft excel sheet and were subjected to statistical analysis using SPSS software. Student t test was used for evaluation of level of significance.

Table 1: Demographic data

Variable	Group A	Group B
Mean age (years)	38.4	41.9
Males (%)	60	40
Females (%)	70	30
Rural residence (%)	80	20
Urban residence (%)	70	30

Table 2: Comparison at baseline

Variable	Group A	Group B	p-value
Scaling	1.35	1.12	0.23
Pruritis	2.52	2.29	0.84
Erythema	1.63	1.48	0.64

Table 3: Comparison at 15 days

Variable	Group A	Group B	p-value
Scaling	1.01	0.95	0.88
Pruritis	1.68	1.56	0.37
Erythema	1.16	0.77	0.00 (Significant)

Table 4: Comparison at 30 days

Variable	Group A	Group B	p-value
Scaling	0.63	0.31	0.00 (Significant)
Pruritis	0.98	0.39	0.00 (Significant)
Erythema	0.43	0.17	0.00 (Significant)

RESULTS

Mean age of the patients of group A and group B was 38.4 years and 41.9 years respectively. 60 percent of the patients of group A and 70 percent of the patients of group B were males. The majority of the patients were of rural residence. Mean scaling score, Pruritis score and erythema score at baseline among patients of group A was 1.35, 2.52 and 1.63 respectively. Mean scaling score, Pruritis score and erythema score at baseline among patients of group B was 1.12, 2.29 and 1.48 respectively. Significant better results were obtained among patients of group B in comparison to patients of group A.

DISCUSSION

Dermatophytes are the most common agents of superficial fungal infections worldwide and widespread in the developing countries, especially in the tropical and subtropical countries like India, where the environmental temperature and relative humidity are high. Treatment of dermatophytosis consists of oral or topical antifungal drugs or a combination of both, depending on the extent and severity, site of infection, and causative organism. Topical antifungals are generally considered the first-line therapy for uncomplicated, superficial dermatomycoses owing to their high efficacy and low potential for systemic adverse effects. These drugs are compounded into various types of vehicles, i.e., creams, lotions, gels, or sprays to facilitate penetration and efficacy depending on the site of involvement. They readily penetrate the stratum corneum when applied to the skin surface, which leads to killing of the fungi or inhibition of their growth, achieving clinical and mycologic eradication. Itraconazole is anti-inflammatory primarily because of its inhibitory effect on the synthesis of 5-hypoxygenase metabolites, which are involved in several inflammatory diseases such as SD. Terbinafine, an orally and topically active antimycotic agent, inhibits the biosynthesis of the principal sterol in fungi, ergosterol, at the level of squalene epoxidase. Squalene epoxidase inhibition results in ergosterol-depleted fungal cell membranes (fungistatic effect) and the toxic accumulation of intracellular squalene (fungicidal effect). Terbinafine has demonstrated excellent fungicidal activity against the dermatophytes and variable activity against yeasts and non-dermatophyte molds in vitro.[9-11] Hence; the present study was conducted for evaluating the efficacy of oral terbinafine versus itraconazole in treatment of dermatophytic infection of skin.

Mean age of the patients of group A and group B was 38.4 years and 41.9 years respectively. 60 percent of the patients of group A and 70 percent of the patients of group B were males. The majority of the patients were of rural residence. Mean scaling score, Pruritis score and erythema score at baseline among patients of group A was 1.35, 2.52 and 1.63 respectively. Mean scaling score, Pruritis score and erythema score at baseline among patients of group B was 1.12, 2.29 and 1.48 respectively. Significant better results were obtained among patients of group B in comparison to patients of group A. In a previous study conducted by Sigurgeirsson B et al, authors evaluated long-term effectiveness of treatment with terbinafine vs itraconazole in onychomycosis. At the end of the study, mycological cure without second intervention treatment was found in 34 (46%) of the 74 terbinafine-treated subjects and 10 (13%) of the 77 itraconazole-treated subjects (P<.001). Mycological and clinical relapse rates were significantly higher in itraconazole vs terbinafine-treated patients (53% vs 23% and 48% vs 21%, respectively). Of the 72 patients who received subsequent terbinafine treatment, 63 (88%) achieved mycological cure and 55 (76%) achieved clinical cure. In the treatment of onychomycosis, continuous terbinafine provided superior long-term mycological and clinical efficacy and lower rates of mycological and clinical relapse compared with intermittent itraconazole.[12]

Mishra M et al, in a previous study, compared the clinical efficacy of oral itraconazole pulse therapy and oral terbinafine pulse therapy in onychomycosis. Sixty patients were randomly assigned to receive oral itraconazole 100 mg, two capsules twice daily for seven days a month and the other group of sixty patients received oral terbinafine 250 mg, one tablet twice daily for seven days every month. Four such monthly pulses were administered for each drug. The patients were evaluated at 4-weekly intervals till sixteen weeks and then at 24, 36 and 48 weeks. They observed a clinical cure rate of 82% and mycological cure rate of 90% in the group of patients treated with itraconazole while the group with terbinafine showed clinical and mycological cure rates of 79% and 87% respectively. This difference was not statistically significant. Both oral itraconazole and terbinafine are effective in the treatment of onychomycosis when administered in the pulse dosage form.[13]

Leyden J et al described the pharmacodynamics, pharmacokinetics, and pharmacology of terbinafine and itraconazole and the features that form a framework for comparing their efficacy. Minimal inhibitory concentrations (MICs) of terbinafine for dermatophytes are essentially equal to minimal fungicidal concentrations (MFCs). Both itraconazole and terbinafine penetrate keratinizing tissue; levels reached in nail plate exceed those in plasma. Therapeutic levels of the itraconazole persist in nails for up to 6 months after discontinuation of 3 months of therapy (200 mg/day) and during various pulsed cycles. After discontinuation of 1 month of therapy, terbinafine persists at therapeutic levels in the nail. Itraconazole has an affinity for mammalian cytochrome P-450 enzymes as well as for fungal P-450–dependent enzyme, and thus has the potential for clinically important interactions. Terbinafine is not metabolized through this system and has little potential for drug-drug interactions. The low MFCs exhibited by terbinafine for dermatophytes may be important in its clinical efficacy and low relapse rates.[14]

CONCLUSION

Better results were seen among patients managed with Itraconazole. However, further studies are recommended for better exploration of results.

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Source of Support: Nil. **Conflict of Interest:** None Declared.

Cite this article as: Sachin B Khond, S. Bhoopathy. Evaluation of Efficacy of Oral Terbinafine Versus Itraconazole in Treatment of Dermatophytic Infections: An Institutional Based Study. Int J Med Res Prof. 2019 Sept; 5(5): 321-23. DOI:10.21276/ijmrp.2019.5.5.075