

ORIGINAL RESEARCH**Evaluation of Efficacy of Oral Terbinafine versus Itraconazole in Treatment of Dermatophytic Skin Infections at a Tertiary Care Hospital****Amit Singhal¹, Kumar Raja Madasu², Vinay Sharma³, Anand⁴**

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ABSTRACT

Background: Superficial dermatophytosis affecting hair, skin and nail are common public health problem in India, because of the tropical climate with heat and humidity. The present study was conducted to assess efficacy of oral terbinafine versus itraconazole in treatment of dermatophytic infection of skin.

Materials & Methods: The patients were randomly divided into two groups to receive a daily dose of terbinafine 500 mg daily for 4 weeks (Group I) or 200 mg of itraconazole for 4 weeks daily (Group II). Patients were followed up after 2 weeks and 4 weeks of the study period. At each visit, clinical response was noted including pruritus, erythema, and scaling. All analysis was done SPSS version 21.0 (IBM Corp., Armonk, NY).

Results: A total of 100 patient were randomly divided into two groups to receive a daily dose of terbinafine 500 mg daily for 4 weeks (Group II) or 200 mg of itraconazole for 4 weeks daily (Group I). At baseline in group I erythema was severe in maximum patients, scaling, pruritus was moderate in maximum patients. At 2nd week in group I erythema, pruritus was moderate in maximum patients, scaling was mild in maximum patients. At 4th week in group I erythema, pruritus was mild in maximum patients, scaling was absent in maximum patients. At baselie in group II erythema was equally moderate and severe in maximum patients, scaling, pruritus was moderate in maximum patients. At 2nd week in group II erythema was moderate in maximum patients, scaling and pruritus was mild in maximum patients. At 4th week in group I erythema, pruritus was mild in maximum patients, scaling was absent in maximum patients.

Conclusion: The present study concluded that Itraconazole has higher clinical and mycological cure rates as compared to terbinafine. erythema and scaling was absent in more patients in group I than group II.

Keywords: Itraconazole, Terbinafine, Dermatophytosis.

INTRODUCTION

Dermatophytes are group of filamentous fungi that require keratin for growth. The condition produced as a result of dermatophyte infection is commonly known as dermatophytosis. The dermatophyte infections can cause cutaneous changes in the skin by forming ring shape lesions with a clear center and inflammatory edge and owing to this they are often also termed as ringworm.^{1,2} Tinea is a superficial fungal infection caused by dermatophytes which invade and multiply within the keratinized tissue (skin, hair, nails). Approximately 20%-25% of the world population is affected by tinea.³ Terbinafine is considered to be a first-line drug for the treatment of tinea corporis and tinea cruris due to its favorable mycological and pharmacokinetic profile.⁴ It acts by inhibiting the enzyme squalene epoxidase, thereby inhibiting ergosterol synthesis.⁵ Recently, there has been an increase in the incidence of terbinafine resistance with increasing numbers of clinical failures and relapses.^{6,7} Itraconazole is another antifungal drug which acts by inhibiting cytochrome P450-dependent enzyme, hence interfering with demethylation of lanosterol to ergosterol. It has shown good results in the treatment of dermatophytosis at doses of 100 mg once a day for 2 weeks and with 200 mg once a day for 7 days.^{8,9} The present study was conducted to assess efficacy of oral terbinafine versus itraconazole in treatment of dermatophytic infection of skin.

MATERIALS & METHODS

The present study was conducted among patients of both genders aged 18 years and above with clinical diagnosis of tinea corporis and tinea cruris confirmed by potassium hydroxide (KOH) test. Patients receiving treatment with systemic immunosuppressive drugs during the study or in the past 2 weeks before enrolling in the study, pregnant and lactating women were excluded from the study. The patients were randomly divided into two groups to receive a daily dose of terbinafine 500 mg daily for 4 weeks (Group II) or 200 mg of itraconazole for 4 weeks daily (Group I). Patients were followed up after 2 weeks and 4 weeks of the study period. At each visit, clinical response was noted including pruritus, erythema, and scaling. These were rated as clinical score 0–3, 0– absent, 1– mild, 2– moderate, and 3– severe. Global clinical evaluation was done, and the response was noted accordingly as healed, marked improvement, considerable residual lesions (>50%), no change, or worse. Patients were considered cured when there was an absence of scaling, erythema, and pruritus. Post inflammatory pigmentary changes were not taken into consideration. All analysis was done SPSS version 21.0 (IBM Corp., Armonk, NY).

RESULTS

A total of 100 patient were randomly divided into two groups to receive a daily dose of terbinafine 500 mg daily for 4 weeks (Group II) or 200 mg of itraconazole for 4 weeks daily (Group I). At baseline in group I erythema was severe in maximum patients, scaling, pruritus was moderate in maximum patients. At 2nd week in group I erythema, pruritus was moderate in maximum patients, scaling was mild in maximum patients. At 4th week in group I erythema, pruritus was mild in maximum patients, scaling was absent in maximum patients. At baseline in group II erythema was equally moderate and severe in maximum patients, scaling, pruritus was moderate in maximum patients. At 2nd week in group II erythema was moderate in maximum patients, scaling and pruritus was mild in maximum patients. At 4th week in group I erythema, pruritus was mild in maximum patients, scaling was absent in maximum patients.

Table 1: Clinical parameters in Group I(Itraconazole) and Group II(Terbinafine)

Characteristics	Group I(n=50)				Group II (n=50)			
	No	Mild	Moderate	Severe	No	Mild	Moderate	Severe
At Baseline								
Erythema	0	3	15	32	0	0	25	25
Scaling	0	10	37	3	0	7	35	8
Pruritus	0	2	48	0	0	1	49	0
At 2nd week								
Erythema	1	14	33	2	1	14	30	5
Scaling	10	35	5	0	5	33	12	0
Pruritus	0	3	40	7	3	42	5	0
At 4th week								
Erythema	10	35	5	0	8	34	8	0
Scaling	42	7	1	0	35	15	0	0
Pruritus	9	26	15	0	2	29	19	0

DISCUSSION

Itraconazole is a triazole class of broad-spectrum antifungal that is successfully being used for treatment of various types of fungal infections. It acts by slowing down the growth of fungi through inhibition of ergosterol synthesis that helps to maintain the cell membrane in the fungi.⁶ It has been found to be highly effective against dermatophytes, candida, and on some non dermatophytic molds.^{10,11}

Majid et al in their 12 weeks study, 43 out of 100 tinea infected patients show relapse after a 2 week 250 mg oral terbinafine standard treatment. They found out that the incomplete mycological cure leads to relapse.¹²

Bhatia A et al found that at the end of week 4, mycological cure was seen in 91.8% after 4 weeks in the itraconazole group as compared to 74.3% of patients in the terbinafine group. There was a significant improvement in percentage change in pruritus, scaling, and erythema in both the groups from 0 to 4 weeks. On comparing groups, the percentage change was significantly different in scaling from 0 to 2 weeks (5.4 vs. -4.8) and 2-4 weeks (16.7 vs. 29.6) between Group I and Group II, respectively. Clinical global improvement was better with itraconazole. Mild adverse effects such as gastrointestinal upset, headache, and taste disturbances were observed which were comparable in both the groups.¹³

CONCLUSION

The present study concluded that Itraconazole has higher clinical and mycological cure rates as compared to terbinafine. erythema and scaling was absent in more patients in group I than group II.

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