Journal of Population Therapeutics & Clinical Pharmacology

RESEARCH ARTICLE
DOI: 10.53555/hpzaaz66

COMPARISON OF EFFICACY OF ITRACONAZOLE VS TERBINAFINE IN *TINEA CORPORIS*

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ABSTRACT

Background: Infection with dermatophytes is becoming more common, particularly in tropical regions. Pathogens causing Tinea showed resistant to a number of frequently used antifungals.

Aim: To compare the efficacy of terbinafine and itraconazole in the treatment of *Tinea coporis* infection.

Materials and Methods: This randomized parallel group trial was conducted at the department of dermatology Mian Rashid Hussain Memorial Hospital Nowshera from November 2023 to March 2024. Patients were randomly distributed into two groups based on the treatment they received. Everyone was checked on every two weeks. Results were evaluated at four and six weeks. A full clinical clearance of the lesions was deemed a cure. For each patient, the KOH positive and negative as well as fungus culturing were performed. The statistical study was conducted using the Chi-square test and parametric one-way analysis of variance (F test) using SPSS 24.

Results: With 75 individuals in each group, a total of 150 patients included in the research. Compared to 81% of patients in the itraconazole group, 60 % of patients in the terbinafine group experienced a full recovery. There was a statistically significant improvement at the six-week p value < 0.05.

Conclusion: This study showed that Itracanzole effectiveness is better than terbinafine however both can be used in *Tinea corporis*. Based on this study the use Itracanazole is suggested in *Tinea* diseases. No notable side effects were shown in both of the groups.

Keywords Itraconazole, Terbinafine, *Tinea corporis*

INTRODUCTION

A superficial fungal illness known as tinea is brought on by dermatophytes, which enter and grow inside keratinized tissue (skin, hair, nails). Between 20% and 25% of people worldwide suffer with tinea [1]. In recent years, there has been an increase in the frequency of chronic and recurring cases of dermatophytosis, particularly in tropical nations [2]. The therapy recommendations provided in conventional texts and the treatment necessary in the current situation differ significantly [3,4].

Furthermore, it appears that the current situation renders the advised course of action for frequently prescribed antifungal medications invalid, leading to treatment failures and relapses when administered at standard dosages. and for the usual amount of time [5]. To address these issues, dermatophytosis therapy is becoming increasingly individualized [6, 7]. Furthermore, a number of circumstances, including the simultaneous involvement of a large body region, hair follicles, and a prior history of treatment failures, recurrences, and relapses, further impact the choice of therapy. Because of its favorable mycological and pharmacokinetic characteristics, Terbinafine is regarded as a first-line treatment for dermatophytosis [8]. It works by blocking the formation of ergosterol by inhibiting the enzyme squalene epoxidase[9]. Up until recently, the medication was consistently successful, curing over 90% of cases at dosages of 250 mg once day for two weeks [10, 11]. However, terbinafine resistance has become more common recently as a result of medication misuse, leading to a rise in clinical failures and relapses [12, 13] As a result, using a greater dose of terbinafine is advised, as demonstrated in a Murlidhar et al. publication [14] At higher dosages of 500 mg/day, terbinafine was found to be both safe and effective in the treatment of dermatophytosis in a recent research [15]. Another antifungal medication that works by preventing the formation of ergosterol is ittraconazole. When used at dosages of 100 mg once daily for two weeks and 200 mg once daily for seven days, it has demonstrated positive outcomes in the treatment of dermatophytosis [16, 17]. However, some Indian doctors have been using it for extended periods of time at dosages of 200 mg once day because of the drug's propensity for relapses at short intervals [18]. Because of its non-linear pharmacokinetic properties, a high dosage of itraconazole might not be advantageous [10].

The goal of managing dermatophytosis effectively requires the development of a successful first-line therapy that will yield the best outcomes with the fewest relapses, given the high recurrence rate when traditional dosages of antifungal drugs are used and the widespread resistance to these agents. In order to compare terbinafine and itraconazole's efficacy in treating tinea corporis, the current study was conducted.

MATERIALS AND METHODS

This randomized parallel group trial was conducted at the department of dermatology Mian Rashid Hussain Memorial Hospital Nowshera from November 2023 to March 2024. For the research, instances of *Tinea corporis* with clinical confirmation were included, and they were monitored for six weeks until their therapy was finished. The research included all willing patients between the ages of 18 and 65 who had a dermatologist's diagnosis of *Tinea corporis*, regardless of the existence or severity of dermatophytosis in other body parts. One hundred sixty five individuals in all received therapy at random and were part of the trial. We removed fifteen patients due to non-compliance with follow-up. The research excluded patients who were non-consensual, pregnant, nursing, or who had received anti-mycotic medication within two weeks of the baseline (first day) visit.

The patients were randomly allocated either to Terbinafine 250 mg twice a day (Group I) or Itraconazole 100 mg twice a day (Group II) for four weeks.

Mycological and clinical assessments: A comprehensive examination and a full medical history were taken during the screening appointment. A four-point scale ranging from 0 to 3 was used to grade various clinical signs and symptoms (0 being nonexistent, 1 being mild, 2 being moderate, and 3 being severe). Patients were checked for any lingering changes at six weeks and every two weeks after the therapy started, until the completion of the six-week course of treatment. KOH examinations were performed both at the patient's enrollment and at the conclusion of the sixth week. All KOH positive patients had fungal cultures only at the start of their treatment. A clinical assessment was done at every visit.

At six weeks, the effectiveness of the treatment was assessed. When there were no longer any visible symptoms (such as scaling, erythema, or pruritus) and a negative KOH, the patient was deemed cured. The Institutional Ethics Committee authorized the study, and prior to patient recruitment, informed permission was obtained from each participant.

Statistical analysis Repeated measure ANOVA was used to examine the trend of mean values over time for follow-up measurable data. An unpaired t test was used at those endpoints, and p values ≤0.05 were regarded as statistically significant. Statistical tool SPSS 24 was used in this study.

Effectiveness Assessment

Primary effectiveness endpoint: The percentage of patients who had a full cure at the conclusion of the treatment term from the baseline was the primary efficacy goal. At the completion of the treatment, a patient was considered to have experienced complete cure if they had experienced both clinical and mycological cure. Secondary efficaciousness endpoint: The secondary efficaciousness objectives were

1. The proportion of patients who, at the conclusion of treatment, achieve a clinical cure. The absence of all symptoms (scaling, erythema, and pruritus) at the conclusion of the treatment was considered a clinical cure.
2. The proportion of patients who, at the conclusion of treatment, have a mycological cure. At the conclusion of the therapy, a negative microscopy under potassium hydroxide (KOH) testing was considered a mycological cure.
3. Each visit's overall symptom score improved from the baseline.

RESULTS

The final study had 150 participants in all. Itraconazole was used to treat seventy five patients, whereas terbinafine was used to treat the other seventy five. The patients were randomly but equally divided into two groups, Group I and Group II, the mean age of the patients was 39.22 and 37.36 years, respectively. Group I consisted of 30 men (45%) and 45 women (55%), whereas Group II contained 35 men (50%) and 35 women (50%). 70 out of 75 patients in Group I and 68 out of 75 patients in Group II had positive baseline KOH examination results. In Group II, all KOH-positive patients had positive fungal cultures; however, in Group I, only 65 patients had positive fungal cultures [Table 1]. After six weeks, both Group I and Group II showed a statistically significant (p value < 0.05) improvement in the overall symptom score (erythema, scaling, and pruritus) as compared to the baseline [Figure 1].

Table 1: Demography and Mycological examination in both the groups.

Parameters	**Groups**	
	Group I	**Group II**
N	75	75
Male; n (%)	30 (45)	45 (55)
Female; n (%)	35 (50)	35 (50)
Age (mean ± SD)	39.22 ±10.61	37.36 ±11.33
Mycological Examination		
KOH positivity (N)	70	68
Culture positivity (N)	65	68

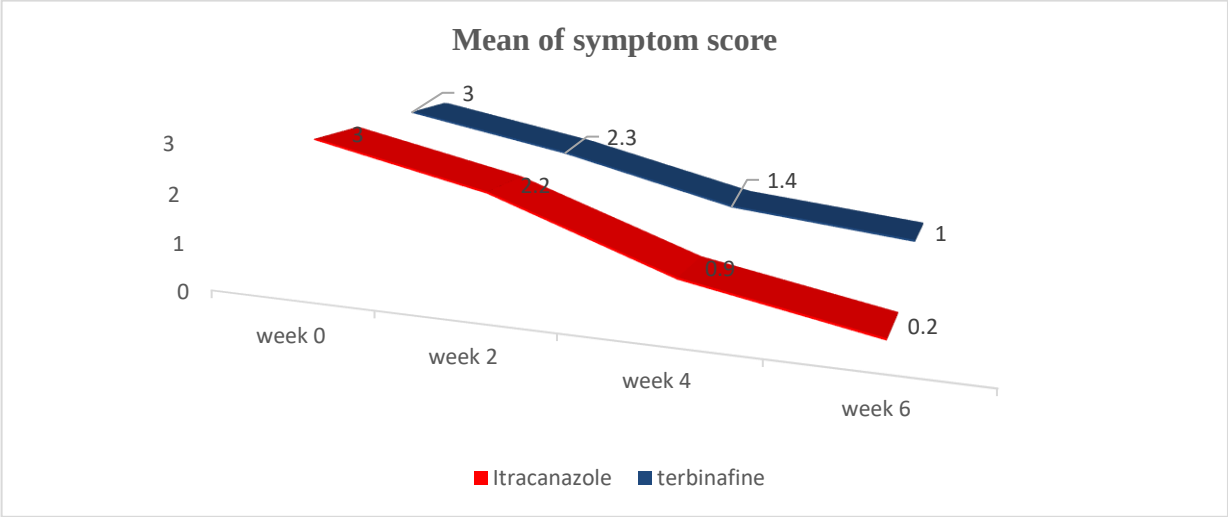

Figure 1: Weekly symptom score comparison

In all groups, the notable improvement began to appear between 0 and 2 weeks into the therapy and continued to the end of therapy. After four weeks, the overall symptom score showed a substantial improvement between the groups (p value < 0.05). At the end of six weeks, 42 patients (63%) in Group I and 55 patients (82.5%) in Group II had achieved mycological cure, while 40 patients (60%) and 54 patients (81%) in Group I and II, respectively, had reached full cure. (Figure 2).

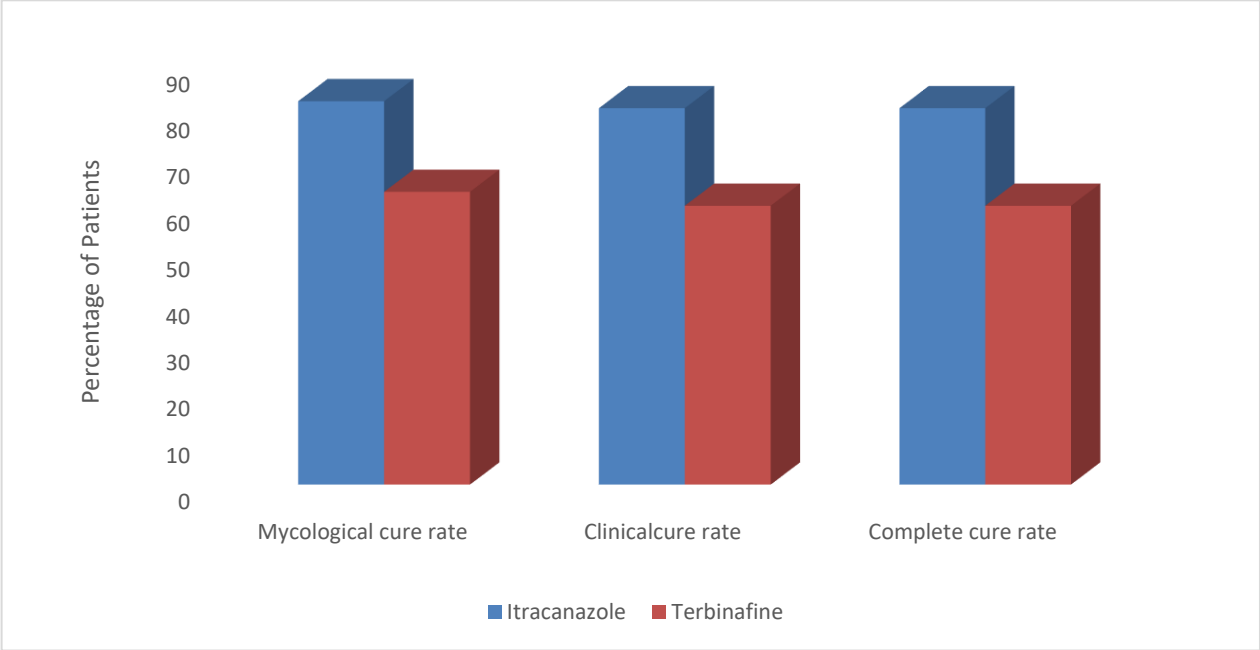

Figure 2: Cure rate of patients in percentage treated with Terbinafine and Itracanazole

At the end of four weeks, the clinical cure rate was slightly better in the Itracanazole group as compared to the terbinafine group. None of the patients showed any significant side effect in both Itraconazole and Terbinafine groups.

DISCUSSION

There has been a noticeable rise in the frequency of dermatophytosis and resistance to standard anti-fungal medication dose in recent years. The quest for an efficient first-line treatment plan that results in the quick and total clearance of dermatophytosis has become necessary due to the shift in the clinical scenario and the rising incidence of treatment failures. Topical antifungals are the first-line medications for treating dermatophytosis, according to preliminary research and guidelines.

Unfortunately, in many patients' current clinical circumstances, topical therapy alone is unable to resolve the lesions, which results in treatment failures and relapses. Systemic treatment is generally advised for such individuals.

It has been established that systemic anti-fungal medicines, including griseofulvin, terbinafine, fluconazole, and itraconazole, are effective against dermatophytes; terbinafine is the sole medication that has fungicidal properties [19, 20]. Of these, terbinafine and itraconazole are administered more frequently than griseofulvin and fluconazole, presumably because the latter need a longer course of therapy [21]. In the past, when terbinafine was taken for two weeks at a dose of 250 mg per day, it consistently shown efficacy against dermatophytosis, with over 90% of cases curing [11, 12]. But recently, there has been a rise in the prevalence of terbinafine resistance, which has led to treatment failure [14]. Despite being uncommon in clinical practice, terbinafine resistance in dermatophytosis has been documented in a small number of authors' clinical isolates. [22, 23]. Antifungal resistance has been observed as a result of poor medication concentration in skin tissues. 28 Therefore, some clinical trials have revealed that terbinafine at a greater dose of 500 mg/day is more beneficial [15, 24, 25]. As a first-line treatment for dermatophytosis, itraconazole, a triazole antifungal medication, is being utilized more frequently than in the past, but for longer durations of time [6,18]. Terbinafine and itraconazole are two frequently used systemic antifungal medications, as was previously noted. We compare the two medications' efficaciousness against tinea in our study.

At the conclusion of six weeks, there is no statistically significant difference in the full cure, despite the fact that patients in Group II reached clinical cure sooner than those in Group I (Figure 3). Only 43% of patients in a recent research by Majid *et al*. [14] were cured after two weeks of oral 250 mg terbinafine therapy for dermatophytosis. Dermatologists' daily clinical practice has seen an increase in instances that do not improve with regular oral terbinafine medication, which is a strong indication of the recent decline in clinical effectiveness. Terbinafine's mycological cure rate was reported to be 74%21 and 71% in another research [16]. In an additional research, terbinafine 250 mg/day for three weeks resulted in a 35% cure rate, which was even lower than in previous studies [22]. Terbinafine 250 mg/day was employed in each of these investigations. 50% of patients responded to a three-week course of therapy with itraconazole 200 mg/day.22 which was less than the range of cure rates (80–92%) found in other research [16, 21]. The research provides strong evidence of the inconsistent outcomes regarding the clinical effectiveness of itraconazole. In our investigation, Group I's and II's mycological cure rates were 82% and 84%, respectively. Even while the mycological cure rate is comparable to that of current research in the terbinafine and itraconazole groups.

Terbinafine and itraconazole, when administered at the recommended dosage, have been proven to be safe and well-tolerated in the treatment of dermatophytosis [6]. Although the combo therapy in this trial lasted just four weeks, all of the patients continued to receive topical medication for an additional two weeks. After four weeks, there was a moderate clinical response in the itraconazole group and a satisfactory clinical resolution in the terbinafine group of patients. In the current situation, systemic terbinafine and itraconazole monotherapy regimens at conventional dosages for a two-week period have demonstrated a significant risk of treatment failure and recurrence. While prolonging the duration of systemic antifungal medications to a maximum of four weeks may yield superior outcomes.

CONCLUSION

This study showed that Itracanzole effectiveness is better than terbinafine however both can be used in *Tinea corporis*. Based on this study the use Itracanazole is suggested in *Tinea* diseases. No notable side effects were shown in both of the groups.

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