e-ISSN: 0975-1556, p-ISSN:2820-2643

Available online on www.ijpcr.com

International Journal of Pharmaceutical and Clinical Research 2023; 15(7); 1584-1588

Original Research Article

Comparative Study of the Safety and Efficacy of Oral Terbinafine and Oral Itraconazole in Patients with Tinea Corporis and Tinea Cruris

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Received: 20-05-2023 / Revised: 21-06-2023 / Accepted: 25-07-2023
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Conflict of interest: Nil

Abstract:

Background: Recently, it was noted that the spread of superficial fungal infections with widespread resistance to different antifungal drugs used in the traditional dose, with an increase in relapse rates, caused a real medical problem because the patient's distressing clinical symptoms (itching) and skin manifestations (such as itching) were so disruptive. This study compares and contrasts the effectiveness of oral terbinafine against itraconazole in treating tinnitus corporis and tinnitus cruris.

Methods: This was a prospective, randomized comparative study. It was conducted at GMCH, Purnea, Bihar from May 2022 to April 2023. 90 patients participated in the trial. Following diagnosis confirmation, the patients were split into two groups at random. The first group consisted of 45 patients who received 500 mg of terbinafine daily for 4 weeks as oral treatment. The second group consisted of 45 patients who received itraconazole oral treatment for 4 weeks at a dose of 200 mg per day.

Results: Regarding the evaluation of recovery, there were statistically significant differences between the two research groups. We find that 86.7% of patients in the oral itraconazole treatment group had a complete recovery, compared to 72.7% in the terbinafine group.

Conclusion: When treating Tinea Corporis and Tinea Cruris, itraconazole is superior to terbinafine and should be used as the first line of defense. the continued safety of both medications, even at increased dosages and for a longer duration of time.

Keywords: Dermatophyte, Tinea Corporis, Tinea Cruris, Itraconazole, Terbinafine.

Introduction

Fungi may live anywhere and can colonize practically any habitat. Although it was formerly thought that they were related to plants, it has been known for more than 20 years that they belong to a separate kingdom and that their biochemistry differs significantly from that of bacteria and plants in certain ways, such as the pathway of lysine production.[2] While certain dermatophytes have specific regional distributions, others are found all over the world. For instance, Trichophyton concentricum is native to specific regions of the South Pacific and South America, whereas Trichophyton rubrum is the most prevalent dermatophyte and has a global range.[1-7]

The geographical distribution of dermatophytes has undergone substantial alterations as a result of human migration and travel as well as improvements in antifungal medication. Despite occurring everywhere, dermatophyte diseases are more frequent in tropical settings. Socioeconomic level, occupation, air conditioning, and shoe use are other significant epidemiologic factors.[1-10]

The most prevalent tinea-causing fungi, which number over 20 different species, are Trichophyton rubrum, Epidermophyton floccosum, Trichophyton tonsurans, and Microsporum canis.[1]

Tinea may be strongly suspected based on a clinical examination, but because it resembles other lesions clinically, a koh test that will reveal fungal hyphae is advised to confirm the diagnosis. There are various types of antifungals (such as azole compounds, allylamine compounds (terbinafine), amphotericin B, and griseofulvin) that can be used as a topical or systemic treatment. Despite the wide range of treatments, a recent rise in failure and chronicity rates has been seen.

Material and Methods

This prospective, randomized, comparative study was conducted in Department of Pharmacology with Department of Dermatology and Venereology

at Govt. Medical College and Hospital, Purnea, Bihar from May 2022 to April 2023. Patients from the dermatology and venereology outpatient department Inclusion criteria for this study included clinically confirmed tinea, direct microscopic examination using potassium hydroxide (KOH), and age greater than 18. The trial excluded patients who were pregnant, nursing, had renal, liver, or cardiac problems, had a history of drug allergies, or were on systemic immunosuppressive medications.

The final study sample included 45 patients who received terbinafine medication and 45 individuals who received itraconazole treatment.

All study participants gave written informed consent or the assent of their families to participate in the study after obtaining appropriate information, and all research participants were fully aware of the method. The data in this study were collected prospectively. The study did not encounter any significant ethical problems. After being admitted, research subjects had a clinical and laboratory evaluation before starting their treatments.

Results

44.4% of the patients in the research sample under study were between the ages of 18 and 28 years, and 20% were between the ages of 38 and 48 years (table 1).

Table 1: Distribution of the Study sample by age group

Age	No. of cases	Percentage
18-28	40	44.4%
28-38	12	13.3%
38-48	18	20%
48-58	10	11.1%
58-68	10	11.1%
Total	90	100%

As most cases in both groups -- 60% in the itraconazole group and 77.8% in the terbinafine group -- were male, we found that 68.9% of the subjects had a Sex Ratio (M:F) of 2.2:1 (table -2).

Table 2: Distribution of the Study sample bygender

Gender	No. of cases	Percentage
Male	62	68.9%
Female	28	31.1%
Total	90	100%

In the itraconazole group there are 40% females, compared to 22.2% in the terbinafine group. Regarding gender, there was no statistically significant difference between the two groups (table 3).
The mean age in the itraconazole group was 33.95± 16.1 years, whereas the mean age in the terbinafine group was 34.91±14.9 years.(table -3)

Table 3: Comparison of Basic Demographic Statistics

DemographicStatistics	Study group		P- value
	Itraconazole	Terbinafine	
Gender: Male/Female	27(60%)/18(40%)	35(77.8%)/10(22.2%)	0.06
Age(year) : Mean±SD	33.95±16.1	34.91±14.9	0.7

According to table -4, tinea cruris affected 38.9% of the research sample under study, followed by tinea corporis in 26.7% of cases and multiple tinea in 34.4% of cases (cruris and corporis). Additionally, 88.9% of the research population under study had infections lasting shorter than six months, with an average infection duration of 2.1±1.99 months. table-5.

Table 4: Comparison of Lesion Position

Lesion Position	No. of cases	Percentage
Tinea corporis	24	26.7%
Tinea cruris	35	38.9%
Multiple (cruris and corporis)	31	34.4%
Total	90	100%

Table 5: Comparison of Duration of Disease between Two Groups

Duration of Disease(month)	No. of cases	Percentage
<6	80	88.9%
≥6	10	11.1%
Total	90	100%

Table -6 shows that 15.6% of the research sample investigated had received steroid treatment in the past, whereas Table -7 shows that 10% of the sample had received antifungal creams, 6.7% had received unidentified medications, 7.8% had diabetes, and 5.6% had hypertension. We found no statistically significant variations in age, gender, disease duration, medical history, or comorbidities between the study groups.

Table 6: Comparison of Previous Treatment

Previous Treatment	No. of cases	Percentage
Steroids	14	15.6%
Antifungal creams	9	10%
Unknown treatments	6	6.7%

Table 7: Comparison of Comorbidities History between the Two Groups.

Comorbidities History	No. of cases	Percentage
Diabetes	7	7.8%
Hypertension	5	5.6%

We noticed that there were statistically significant differences with regard to the mean values of erythema in both research groups, where the percentage of decrease at the end of the fourth week was 93.95% in the itraconazole group compared to 86.69% in the terbinafine group (table -8), we found statistically significant differences with regard to the mean values of pruritus in both research groups, where the percentage of decline reached 95.71% compared to 93.51%(table -9), respectively , and we also found statistically significant differences with regard to the mean values of scales in both research groups, where the percentage of decline reached 95.42% compared to 92.99%, respectively(table -10).

Table 8: Change in erythema in both study groups

Time	Study group	
	Itraconazole	Terbinafine
First visit	2.48±0.6	2.48±0.6
After 2 weeks	1.55±0.5	1.40±0.5
After 4 weeks	0.15±0.4	0.33±0.5
P-value	0.0001	0.0001

Table 9: change in pruritus in both study groups

Time	Study group	
	Itraconazole	Terbinafine
First visit	2.57±0.6	2.62±0.5
After 2 weeks	1.46±0.5	1.40±0.6
After 4 weeks	0.11±0.3	0.17±0.4
P-value	0.0001	0.0001

Table 10: change in scales in both study groups

Time	Study group	
	Itraconazole	Terbinafine
First visit	1.75±0.7	1.57±0.7
After 2 weeks	0.62±0.5	0.51±0.5
After 4 weeks	0.08±0.2	0.11±0.3
P-value	0.0001	0.0001

In the end, the two research groups had statistically significant disparities from one another. Regarding the comparison of recovery rates between the two research groups, we find that the percentage of cases with a complete recovery (A) was 86.7% in the itraconazole treatment group administered orally, compared to 72.7% in the terbinafine group, while the percentage of cases with a significant improvement (B) was 8.9% and 15.6%, respectively, and the percentage of cases with an improvement of less than 50% (C) was 4.4% and 9.5%, respectively. Regarding the likelihood of recovery, age, gender, the length of the disease, lesions, therapeutic antecedents, and comorbidities, we found no statistically significant differences between the research groups (table 11).

Table 11: Evaluation of recovery between the two study groups

Healed evaluation	Study group		P-value
	Itraconazole	Terbinafine	
A	39(86.7%)	32(72.7%)	0.04
B	4(8.9%)	7(15.6%)	
C	2(4.4%)	5(9.5%)	
D	0(0%)	1(2.2%)	

There were 2.3% headaches, 6.5% digestive issues, and 15.2% hyperpigmentation in the itraconazole group and 2.3% digestive symptoms, 13.6%, and 15.2%, respectively, in the terbinafine group. There was no treatment termination due to adverse effects, and this was not clinically significant. No statistically significant difference existed between the two groups in terms of side effects (table 12).

Table 12: side effects between the two groups

Side effects	Study group		p-value
	Itraconazole	Terbinafine	
Hyperpigmentation	6(13.6%)	7(15.2%)	0.5
Headaches	0(0%)	1(2.3%)	
Digestive symptoms	1(2.3%)	3(6.5%)	

Discussion

This study was in line with that of Anuradha Bhatia and colleagues in India in 2019, who divided 320 patients into two groups and treated the first group with terbinafine at a dose of 500 mg for 4 weeks and the second group with itraconazole at a dose of 200 mg for 4 weeks. The cure rates were 74.3% and 91.8%, respectively, but there were differences in the proportion of patients whose lesion deteriorated, which was 12.2% and 4.1%.[3]

In the study conducted in India in 2021 by S. Brigida and his colleague, 100 patients were divided into two groups. For two weeks, the first group received treatment with terbinafine at a dose of 500 mg, and the second group received treatment with itraconazole at a dose of 200 mg. The cure rate was 70% and 88%, respectively, and 6% of patients saw an increase in liver enzymes. This did not occur in our trial, with the exception of one patient who had terbinafine therapy, and 2%, respectively.[11]

Regarding the research done by Ravindra Babu and colleagues in 2017, they separated 440 patients into three groups and solely tested the efficacy of terbinafine at a dose of 500 mg. The cure rates were 87% and 92% for the 194 patients treated for two weeks, the 211 patients treated for four weeks, and the 35 patients treated for six weeks and two weeks. 57 patients, or 80%, also had negative effects.[12]

In the 2020 trial conducted in India by Priyanka Sharma and coworkers, 60 patients were split into three groups and treated for three weeks. The cure rate was 35%, 50%, and 90%, respectively, for the first group treated with 250 mg of terbinafine, the second group treated with 200 mg of itraconazole, and the third group treated with the two therapies together.[13]

The most recent study, also carried out in India in 2019, was different from ours in that it divided the 60 patients into two groups. Terbinafine at a dose of 250 mg was administered to the first group for 4 weeks, while itraconazole at a dose of 100 mg was administered to the second group for 2 weeks. Both groups received a 2% topical sertaconazole treatment, and the results showed that neither treatment differed statistically from the other in terms of effectiveness.[14]

Conclusion

When treating tinea cruris, itraconazole is superior to terbinafine and could be used as a first line treatment. the continued safety of both medications, even at increased dosages and for a longer duration of time.

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