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Original Research Article

A Comparative Assessment of Safety and Efficacy of Terbinafine and Itraconazole in Patients of Tinea corporis

Tarun Agarwal[1], Vinay Singh[2], Mohd Faisal[3]

[1]Assistant Professor, Department of General Medicine, Autonomous State Medical College, Shahjahanpur, UP

[2]Senior Resident, Hind Institute of Medical Sciences, Safedabad, Barabanki, UP

[3]Assistant Professor, Department of Pharmacology, Naraina Medical College and Research centre, Panki, Kanpur, UP

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Corresponding Author: Dr Mohd. Faisal

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Abstract:

Introduction: Tinea corporis, caused by dermatophytes, impacts the whole body. A frequent culprit is Trichophyton rubrum. Treatment with topicals is usually successful, although severe instances may need oral therapy. Climate leads to high prevalence in India. Clotrimazole and oral terbinafine are suggested for immunological variables that affect infection severity. Limited research in dermatophytosis has led to combination regimens, although their efficacy is unknown.

Aim and Objectives: This study evaluates the relative merits of Terbinafine and Itraconazole as treatments for tinea corporis by comparing their respective safety profiles and effectiveness rates.

Method: This one-year prospective study, conducted on 116 patients with Tineacorporis, aimed to assess infections and therapeutic effectiveness. Patients aged 18–60 with positive KOH tests were included, excluding those under 18, over 60, with specific medical conditions. Skin samples were collected via scraping, and microscopy identified various fungal elements. Randomized into Group 1 (terbinafine) and Group 2 (itraconazole), clinical and laboratory tests evaluated therapy effectiveness. The study provided detailed insights into Tinea corporis infections, treatment responses, and patient outcomes. Inclusion criteria covered age, diagnosis, and patient consent, while exclusions considered medical conditions, pregnancy, prior antifungal use, and other dermatological disorders.

Result: The study presents comprehensive findings on the therapeutic effects of interventions in two groups (Group 1 and Group 2) over a research period. Figure 1 illustrates variations in itching intensity, revealing that Group 1 exhibited a more favorable response, particularly in reaching a state of no itching, compared to Group 2. Figure 2 depicts changes in redness, indicating that Group 1 demonstrated a better decrease in redness than Group 2. Figure 3 shows a substantial improvement in scaling for Group 1 compared to Group 2. Additionally, Figure 4 highlights the significant reduction in itching for Group 1 throughout the research period, suggesting a more effective treatment response. Overall, the graphical representations underscore the superior outcomes in Group 1 across various parameters, indicating the potential benefits of the intervention.

Conclusion: The study has concluded that Terbinafine has shown a significant overall improvement compared to Itraconazole after one month of treatment.

Keywords: Tinea Corporis, Terbinafine, Itraconazole, Pruritis, Redness, Fungal Infection.

Introduction

A superficial fungus Tinea corporis is the term for dermatophytes-caused skin infections. Tineacorporis is an international illness. The location of these lesions, which might impact the neck, trunk, arms, or legs, clearly defines it. For dermatophyte diseases affecting various parts of the body, there are alternative names [1]. These include the scalp (tineacapitis), face (tineafaciei), groyne (tineacruris), hands (tineamanuum), and feet (tineapedis). The ability of the dermatophyte to adhere to freshly keratinized skin tissue results in dermatophytoses, and superficial fungal skin diseases [2]. The genera Trichophyton, Epidermophyton, & Microsporum contain the The dermatophytes responsible for tineacorporis. Trichophyton rubrum was considered the most common species to cause dermatophyte infections throughout the previous 70 years infections [3]. Approximately 80–90% of the strains are related to T. rubrum. Microsporum audouinii and

Trichophyton mentagrophytes are two more frequently seen isolates. Direct skin-to-skin contact with earth, animals, or other people's skin is usually how infections spread [4].

Topical or oral therapies are frequently employed to treat infections caused by dermatophytes. The majority of the time, topical medication given daily for up to three weeks is effective in treating localised tineacorporis. Nonetheless, a clinically significant improvement in the symptoms was the aim of therapy. When treating tineacorporis, nystatin topical is frequently unsuccessful [5].

One of the most common illnesses, superficial mycosis is thought to afflict about 25% of people worldwide [6]. Dermatophytes were the most prevalent causal agents of cutaneous mycoses among the many types of the disease. Often known as tinea or ringworm, this particular dermatophyte group consists of the taxa Trichophyton, Epidermophyton, and Microsporum [7]. Contact involving an infected individual or animal can transmit this disease directly, or it can spread indirectly through contaminated food [8].

India has a 36.6% to 78.4% incidence of dermatophytosis. This is because of the country's high warmth and humidity, which cause excessive perspiration, maceration, and an alkaline pH—all of which are favourable conditions for keratinophilic fungus [9]. Because certain sections of the body provide ideal growing conditions for fungus, they are thus more vulnerable to infections. certain areas are the groyne and intertriginous areas [10].

Even though tinea is a surface infection that is usually painless, by the host's immunological system, it can potentially go more into the tissues, resulting in a widespread infection. For this reason, the illness should not be disregarded [11].

The immunological state of the host has a significant impact on the manifestation and intensity of tinea. Immunity is weakened by conditions including diabetes mellitus, lymphomas, Cushing's syndrome, and ageing, which can lead to severe and systemic dermatophytosis [12]. This cutaneous fungal illness resembles ringworm, as its more popular name suggests, with a centre clearing around by an active perimeter of redness and scaling [13].

The disorder manifests as bilateral, dark red, itchy plaques in the inguinal area, with little papules or pustules at the borders and noticeable scaly edges [14].

Among the recommended topical regimens are the following:

- Clotrimazole: topically administered 1% twice a day in the form of cream, ointment, or solution.
- Ketoconazole: apply 2% cream, soap, gel, and foam once daily.
- Miconazole: Two applications to a lotion, powder, solution, ointment, or cream containing 2% each day [15].
- Naftifine: 1% gel or 1% or 2% cream, administered twice a day.
- Terbinafine: once or twice a day, 1% cream, gel, or spray solution.

When topical treatment has failed or the infection is more extensive, oral medication is required. The suggested first-line treatment is often oral terbinafine or itraconazole, which should resolve the disease in two to three weeks [16].

The following oral regimens are advised (for adults):

- Terbinafine: 250 mg every two days weeks by oral ingestion
- Itraconazole: Take one capsule with meals daily for two weeks at a dose of 100 mg or 200 mg.
- Fluconazole: 50–100 mg each day for two to four weeks, or 150–200 mg once a week.
- Griseofulvin: 500–1000 mg once a day for a period of two to four weeks [17].

Original research showing dermatophytosis as a serious threat to patients and treating physicians is few, particularly in India. As a fungicidal medication, terbinafine works by blocking the enzyme lanosterol-converting enzyme squalene epoxidase. Itraconazole has antifungistatic properties. medication by inhibiting the 14α-demethylase enzyme. To combat this issue, several dermatologists have begun to use combination regimens and greater dosages of antifungals. These routines haven't been shown effective, though [18].

Method

Research Design ““

This is a prospective study conducted on 116 patients presented with *Tinea corporis* for one year in our hospital.The purpose of this study was to examine Tineacorporis infections and assess the effectiveness of therapy using a research design. The prospective observational research focused on clinical and mycological characteristics. The sample size was based on field research to ensure proper representation. The research included patients of either sex aged 18–60 with a positive KOH test for Tineacorporis. Patients under 18 or over 60, those with hepatic or renal illness, and those on medication for diabetes, TB, and hypertension were excluded. The approach required scraping inflammatory lesion edges using a curved disposable scalpel

blade to acquire skin samples. Direct Microscopy (KOH wet mount) detected hyphae, pseudohyphae, yeast cells, spores, spherules, and sclerotic bodies in the specimens. Aseptic specimen collection was achieved using 70% alcohol. Patients were randomised into 2 separate groups (Group 1 and Group 2) by a random process, and the choices on therapy were made by treating doctors based on the particular symptoms that were present at the time of presentation. Group 1 received 250 mg of terbinafine twice daily while Group 2 received itraconazole 100 mg twice daily. Clinical and laboratory tests were prioritised to evaluate therapy effectiveness, combining direct observation of symptoms with microscopic investigation. This research design allowed for a detailed analysis of Tineacorporis infections' clinical and mycological characteristics, revealing treatment responses and patient outcomes in this group.

Inclusion and Exclusion Criteria

Inclusion

- Age must be within the range of 18 to 60 years.
- Medically verified instances of tinea corporis
- A dermatologist conducted the diagnosis.
- The patient's explicit authorization to participate in the research.
- Patients who are willing to be monitored for 8 weeks till the therapy is finished.
- There are no limitations depending on the occurrence or severity of dermatophytosis in other parts of the body.

Exclusion

- Whether it be nursing or pregnancy.
- Involuntary involvement in the research.
- Patients who received Pre-baseline anti-mycotic medication within 2 weeks.
- Any dermatological disorder except tineacorporis
- Medical conditions contraindicate antifungal drugs.

Statistical Analysis

The study used SPSS 27 software for conducting statistical analysis. MS Excel was used for creating graphs and other calculations. the continuous data were expressed as standard deviation while the discrete data were expressed as frequency and its respective percentage. Follow-up data was analyzed using repeated measure ANOVA to determine mean value trends over time. An unpaired t-test was used at those endpoints. The level of significance was considered to be $p<0.05$.

Result

Table 1 shows Group 1 and Group 2's demographic and clinical features, focusing on age, gender, and itching intensity at baseline, week 2, and week 4. Group 1 has a mean age of 27.39 ± 10.11 years, whereas Group 2 has a slightly higher mean age of 30.63 ± 10.94 years. The gender distribution is similar ($p = 0.64$), with a plurality of men. At baseline, Group 1 had more acute itching than Group 2, although the difference is not statistically significant ($p = 0.25$). At week 2, Group 1 had considerably more moderate itching than Group 2 ($p = 0.001$). Itching intensity decreases significantly in Group 1 by week 4, especially in moderate and mild categories, indicating a good treatment success.

Table 1: Distribution of gender between groups

Parameters	Group 1 (n=57)	Group 2 (n=59)	p-value
Age in years (mean ± SD)	27.39 ± 10.11	30.63 ± 10.94	0.1
Gender			
Male	50 (87.7%)	50 (84.7%)	0.64
Female	7 (12.3%)	9 (15.3%)	-
Characteristic	Group 1 (n=57)	Group 2 (n=59)	P-value
Baseline Itching			
Mild	8 (14.0%)	14 (23.7%)	0.25
Moderate	9 (15.8%)	13 (22.0%)	
Severe	39 (68.4%)	32 (54.2%)	
Nil	1 (1.8%)	0 (0.0%)	
Week 2 Itching			
Mild	26 (45.6%)	11 (18.6%)	0.001
Moderate	3 (5.3%)	1 (1.7%)	
Severe	3 (5.3%)	0 (0.0%)	
Nil	25 (43.9%)	47 (79.7%)	
Week 4 Itching			
Mild	4 (7.0%)	0 (0.0%)	0.0044
Moderate	1 (1.8%)	0 (0.0%)	
Nil	52 (91.2%)	59 (100.0%)	

Figure 1 shows itching intensity variations in Group 1 and Group 2 at baseline, week 2, and week 4. Group 1 reports 54.4% mild, 24% moderate, and 10% severe itching at baseline, whereas Group 2 reports 45.8%, 33.9%, and 16.9%. By week 2, Group 1 had less mild (10.5%) itching and more moderate (19.3%) and severe (1.8%). Group 2 finds a reduction in mild (3.4%), an increase in intermediate (18.6%), and a small change in severe (1.7%) itching. By week 4, 77.2% of Group 1 report light irritation, 3.5% moderate, and 96.5% no itching. Group 2 has 76.3% mild and 100% no irritation. Group 1 improved more than Group 2 in itching severity, notably in reaching no itching, across the trial period.

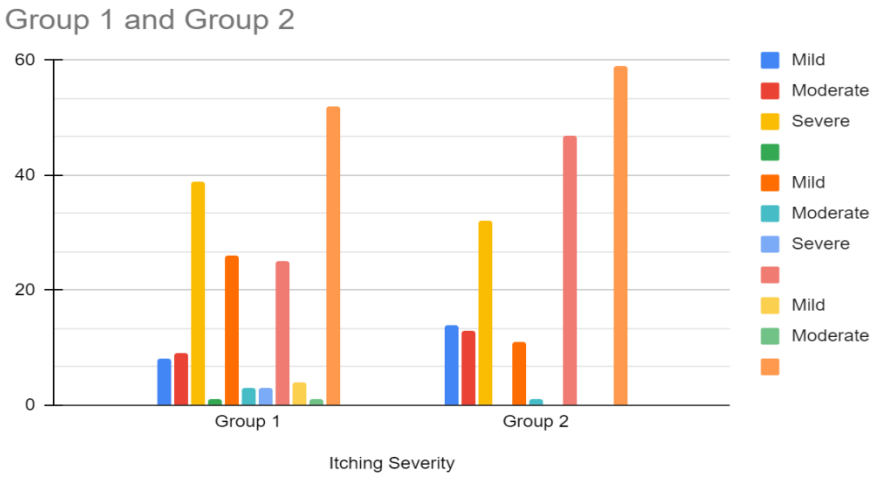

Figure 1: Comparison of change in itching between the groups across the period

Figure 2 compares Group 1 and Group 2 redness at baseline, week 2, and week 4. Group 1 reports 42% mild, 28.3% moderate, and 21.1% severe redness at baseline, whereas Group 2 reports 3.5-5.1% mild and 6.8% moderate. Group 1's light redness increases (49.2%) moderate (21.1%) and severe (11.9%) redness decreases by week 2. With 71.1% mild, 24.6% moderate, and 10.2% severe redness, Group 2 scores higher. Group 1 had a significant increase in mild (84.7%), moderate (8.8%), and severe (6.8%) redness by week 4. High rates of 98% mild, 18% moderate, and 4% severe redness in Group 2. Group 1 showed a better decrease in redness than Group 2, suggesting a better treatment response.

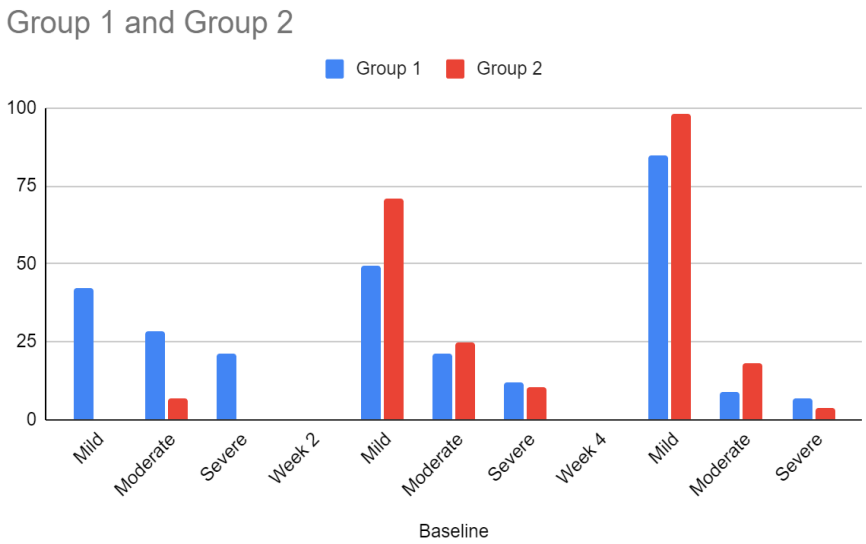

Figure 2: Comparison of change in redness between the groups across the period

Figure 3 compares Group 1 and Group 2 scaling changes at baseline, week 2, and week 4. At baseline, 78.9% of Group 1 individuals had scaling, whereas Group 2 had 89.8%, p-value 0.1. By the second week, 94.7% of Group 1 and 94.9% of Group 2 have reported scaling, and there is no statistically significant difference between the groups (p = 0.96). Group 2 shows no scaling at all

by week 4, whereas Group 1 shows a substantial drop of 1.8% (p-value not relevant). This shows that, compared to Group 2, individuals in Group 1 saw a more significant reduction in scaling during the trial, indicating a favourable treatment effect.

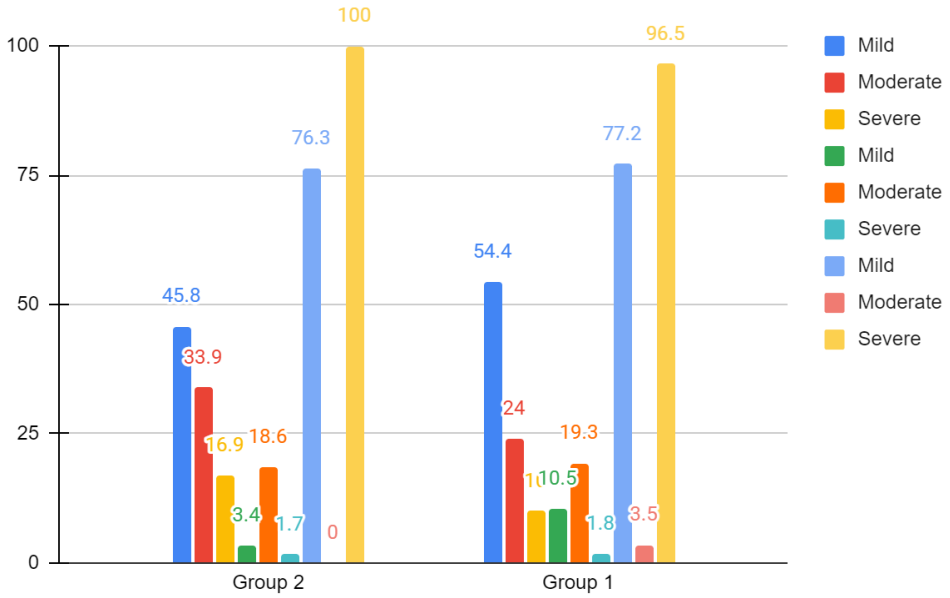

Figure 3: Comparison of change in scaling between the groups across the period

Figure 4 shows the baseline, week 2, and week 4 itching comparison between Group 1 and Group 2. At baseline, 91.2% of Group 1 people itch, whereas 8.8% do not. Itching is present in 93.2% of Group 2 and absent in 6.8%. By week 2, Group 1 had a significant reduction in itching (28.1%), suggesting a favourable response to therapy, whereas Group 2 had 15.3%. By week 4, Group 1 had reduced itching to 1.8%, suggesting consistent improvement. Group 2 itches 84.7% of the time. The graphic depiction shows that the intervention reduced itching in Group 1 more than in Group 2 across the research period.

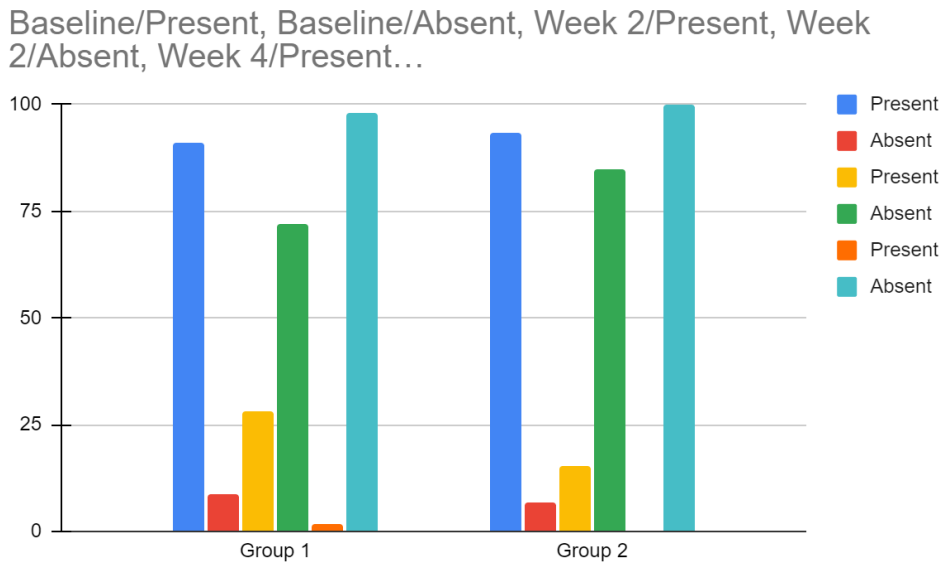

Figure 4: Comparison of change in the presence/absence of itching between the groups across the periods

Table 2 shows the comparison of Group 1 and Group 2 at baseline, week 2, and week 4 concerning the presence or lack of scaling. Although the difference was not statistically significant ($p = 0.12$), 89.5% of Group 1 individuals showed signs of scaling at baseline, whereas 96.6% of Group 2 people did. By the second week, there was no significant difference ($p = 0.9$) between the groups regarding the presence or lack of scaling. At week 4, however, the presence of scaling in Group 1 is

much lower than in Group 2 (p = 0.0001), suggesting that participants in Group 1 saw a considerable improvement in scaling throughout the research.

Table 2: Comparison of change of presence /absence of scaling balance the group

	Group I (n=57)	Group 2 (n=59)	p-value
Baseline			
Present	51 (89.5%)	57 (96.6%)	0.12
Absent	6 (10.5%)	2 (3.4%)	
Week 2			
Present	13 (22.8%)	14 (23.7%)	0.9
Absent	44 (77.2%)	45 (76.3%)	
Week 4			
Present	2 (3.5%)	0 (0.0%)	0.0001
Absent	55 (96.5%)	59 (100.0%)	

Table 3 compares Group 1 and Group 2 clinical symptoms at baseline, week 2, and week 4. At baseline, 78.9% of Group 1 individuals experienced clinical symptoms, compared to 89.8% in Group 2, p-value 0.1. By week 2, clinical symptoms are similar across groups (p = 0.96). By week 4, Group 1 had significantly improved, with just 1.8% showing symptoms compared to 100% in Group 2 (p-value not relevant). Group 1 had a significant decrease in clinical symptoms during the trial period, suggesting a better treatment success than Group 2.

Table 3: Comparison of change in overall clinical symptoms between the groups across the period

Overall	**Group 1 (n=57)**		**Group 2 (n=59)**		**p-value**
	No	%	No	%	
Baseline					
Present	45	78.9	53	89.8	0.1
Absent	12	21.1	6	10.2	
Week 2					
Present	3	5.3	3	5.1	0.96
Absent	54	94.7	56	94.9	
Week 4					
Present	1	1.8	0	0	-
Absent	56	98.2	59	100	

Figure 5 compares baseline, week 2, and week 4 side effects for Group 1 and Group 2. Group 1 reports 42% mild side effects, 28.3% moderate side effects, and 21.1% severe side effects at baseline, whereas Group 2 reports 3.5%, 6.8%, and 0%. Group 1's mild side effects (49.2%) rise while moderate (21.1%) and severe (11.9%) decrease after week 2. Group 2, with 71.1% mild, 24.6% moderate, and 10.2% severe side effects, had higher rates. By week 4, Group 1 reports a significant increase in mild (84.7%) and a reduction in moderate (8.8%) and severe (6.8%) adverse effects. Group 2 has high rates of 98% mild, 18% moderate, and 4% severe. Group 1 had fewer adverse effects, whereas Group 2 had more moderate and severe side effects throughout the trial.

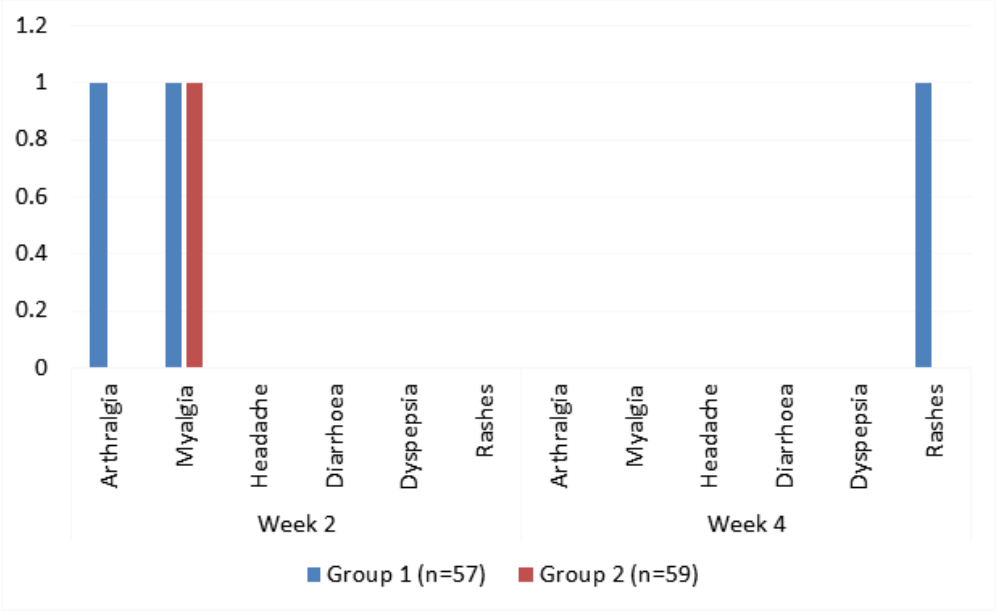

Figure 5: Comparison of side effects between the groups across the time periods

Discussion""

Common fungal diseases called dermatophytic infections are made worse by hot, muggy weather. Oral antifungal medications like terbinafine & itraconazole are frequently used for the same purpose. But when these medications are used for the prescribed length of time and at the usual doses, resistance to them is becoming more and more apparent [19]. Therefore, the goal of the research was to determine if greater dosages and longer treatment durations of terbinafine and itraconazole might be beneficial in curing tineacorporis and tineacruris. When it comes to treating Terbinafine seems to be effective against tineacorporis & tineacruris. and itraconazole is equally safe and effective [20].

Infection with dermatophytes is becoming more common, particularly in tropical regions. Antifungals are less effective than they formerly were.to ascertain which dosages and combinations of terbinafine & itraconazole work best for treating tinea infection [21]. It appears that itraconazole works better than terbinafine. When treating tinea, there is no advantage to raising the dosage or utilising a combination regimen. A lengthy course of therapy is necessary to achieve full recovery [22].

In India, dermatophytosis therapy is difficult, and larger dosages of systemic antifungals have been reported. However, there have also been several reports of higher treatment failure rates when terbinafine is used at the recommended dosage; for this reason, we carried out the current research to evaluate the efficacy and safety of terbinafine at a high dose vs itraconazole at a conventional dose. In both arms, topical ciclopiroxolamine had been given [23]. Research demonstrated that topical ciclopirox combined with a high dosage of terbinafine is a secure and efficient remedy for tineacorporis, a skin disease et cruris [24].

Common fungal diseases called dermatophytic infections are made worse by hot, muggy weather. Oral antifungal medications like terbinafine & itraconazole are frequently used for the same purpose [25]. But when these medications are used for the prescribed length of time and at the usual doses, resistance to them is becoming more and more apparent. Therefore, the goal of the research was to determine if greater dosages and longer treatment durations of terbinafine and itraconazole might be beneficial in curing tinea corporis and tineacruris. When it comes to treating Terbinafine seems to be effective against tineacorporis & tineacruris and itraconazole is equally safe and effective [26].

The tropical environment of India, characterised by high temperatures and humidity, makes superficial dermatophytosis a prevalent public health issue there. These days, the primary weapons against dermatophytes are allylamines, mostly Terbinafine, and triazoles, primarily Itraconazole. The study aims to compare the safety and effectiveness of the two drugs. The study's key finding is that tablet Itraconazole 200 mg/day for two weeks, or 14 days, may be a more effective antifungal [27].

It is usual to see an increase in dermatophyte infection cases together with a poor response to oral medications at the present dosages and treatment durations. Therefore, the study's objective was to assess the efficacy of two antifungal medications at higher doses and longer durations [28]. A study revealed that in comparison to terbinafine, itraconazole has greater rates of mycological and clinical healing. Therefore,

itraconazole is a better therapy for tineacorporis & cruris than terbinafine [29].

Conclusion

The study has concluded that Terbinafine demonstrated a notable overall improvement at week 4 compared to Itraconazole, indicating a positive treatment response. This improvement aligns with the substantial decrease in clinical symptoms and in scaling, as observed in Terbinafine group by week 4, suggesting a more favorable treatment outcome compared to Itraconazole group. The assessment of liver function, as indicated by SGPT levels, showed no significant differences between the two groups at any time point, implying comparable liver function throughout the study. This finding underscores the overall safety and similar impact on liver function between the two groups. Furthermore, the evaluation of sodium (Na) levels demonstrated that Terbinafine group experienced a more significant mean change in Na levels from baseline to both week 2 and week 4, compared to Itraconazole group. The observed differences in Na levels between the groups at week 2 and week 4 suggest a potential therapeutic advantage in terms of sodium regulation for participants in Terbinafine group. Lastly, the analysis of side effects revealed varying patterns between the groups. Terbinafine group reported fewer adverse effects overall, with a significant increase in mild side effects by week 4 and a reduction in moderate and severe side effects. In contrast, Itraconazole group experienced higher rates of moderate and severe side effects throughout the trial, indicating a less favorable tolerability profile. In summary, the findings highlight the efficacy of the intervention in Terbinafine group, particularly in improving scaling, reducing clinical symptoms, and positively influencing sodium levels, while maintaining comparable liver function. These results suggest that the treatment protocol for Terbinafine group may offer a more beneficial therapeutic outcome with fewer adverse effects compared to Itraconazole group. Further research and follow-up studies are warranted to validate and expand upon these initial findings.

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