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ORIGINAL ARTICLE

Comparison between therapeutic efficacy of itraconazole pulse therapy and terbinafine in treatment of tinea capitis in paediatric population.

Samia Aslam[1], Lamees Mahmood Malik[2], Fahad Iqbal[3], Zaira Aslam[4], Sajida Kousar[5], Tuyiba Ilyas[6]

ABSTRACT… Objective: To compare the therapeutic efficacy of itraconazole pulse therapy and terbinafine in the treatment of tinea capitis in children. **Study Design:** Prospective, Randomized Controlled Trial. **Setting:** Department of Dermatology, Jinnah Hospital, Lahore, Pakistan. **Period:** April 2025 to September 2025. **Methods:** A total of 118 (59 in each group) children aged 3–14 years with clinically and mycologically confirmed tinea capitis, were randomized to itraconazole pulse therapy or continuous terbinafine. Primary outcome was therapeutic efficacy noted in terms of clinical and mycological cure at 8-weeks, while secondary outcomes were recorded as time to symptom relief and adverse events. Data were anlayzed using IBM-SPSS version 26.0, taking p<0.05 as significant. **Results:** Of 118 children enrolled, 68 (57.6%) were males, with a median age of 8.1 years (IQR 5.2–9.7). A total of 113 (95.8%) completed follow-up evaluation. Therapeutic efficacy was achieved in 97 (85.8%), clinical cure in 101 (89.4%), and mycological cure in 97 (85.8%). Efficacy was noted among 91.1% with itraconazole versus 80.7% with terbinafine (p=0.114). Adverse events included gastrointestinal disturbances in 11 (9.7%) and liver enzyme elevation in 3 (2.7%) patients while no one discontinued the treatment due to adverse events. **Conclusion:** Both itraconazole pulse therapy and terbinafine were found to be effective, well-tolerated, and safe options for the treatment of pediatric tinea capitis.

Key words: Gastrointestinal Disturbance, Itraconazole, Mycological Cure, Terbinafine, Tinea Capitis.

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INTRODUCTION

Tinea capitis (TC) remains one of the most prevalent superficial fungal infections in children.[1] TC is caused predominantly by species of Trichophyton and Microsporum, with regional variation in distribution.[2] Globally, TC accounts for nearly 90% of dermatophytoses in children, reflecting both the high susceptibility of this age group and the contagious nature of the disease through direct contact, fomites, and communal settings such as schools.[3,4] In South Asia, the burden of TC is particularly high, where warm and humid climates, poor hygiene practices, and limited access to healthcare contribute to persistence and recurrence of infection.[5]

TC usually presents with scaling, pruritus, alopecia, kerion formation, and in some cases, secondary bacterial infection, leading to considerable psychosocial distress and stigmatization.[6] Untreated or recurrent cases of TC may result in permanent scarring alopecia, making early and effective antifungal therapy crucial.[7] For decades, griseofulvin was considered the first-line therapy, however, its limitations include long treatment duration, gastrointestinal intolerance, and variable efficacy against Trichophyton species.[8] Terbinafine is an allylamine antifungal which has gained widespread acceptance due to its fungicidal activity, shorter treatment course, and favorable tolerability in children.[9] Data have shown that terbinafine is effective against Trichophyton tonsurans and Trichophyton violaceum in Asian populations.[10] Itraconazole is described as triazole antifungal, and emerged as another effective systemic option against both Trichophyton and Microsporum species.[11] Pulse therapy with itraconazole involving intermittent dosing cycles enhances compliance, reduces cost, and minimize adverse effects, making it a suitable option among children.[12]

1. MBBS, FCPS, Post-graduate Resident Dermatology, Jinnah Hospital, Lahore, Pakistan.
2. MBBS, FCPS, MCPS-HPE, Professor Dermatology, Jinnah Hospital, Allama Iqbal Medical College, Lahore, Pakistan.
3. MBBS, FCPS, Consultant Pediatric Medicine, Gangaram Hospital, Lahore, Pakistan.
4. MBBS, FCPS, Consultant Dermatology, DHQ Hospital, Hafizabad, Lahore, Pakistan.
5. MBBS, FCPS, Consultant Dermatology, Jinnah Hospital, Allama Iqbal Medical College, Lahore, Pakistan.
6. MBBS, FCPS, Consultant Dermatology, Al Karim Clinic, Lahore, Pakistan.

Correspondence Address:
Dr. Samia Aslam
Department of Dermatology, Jinnah Hospital, Lahore, Pakistan.
samia_aslam30@hotmail.com

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A local study found itraconazole to be significantly more effective than terbinafine, with cure rates of 81% versus 60% with itraconazole ($p<0.05$).[13] Regional data analyzing 120 patients with onychomycosis, reported cure rates for itraconazole as82% (clinical), 90% (mycological), and terbinafine as 79% (clinical), and 87% (mycological).[14]

Not many studies have explored the comparative analysis about therapeutic outcomes of terbinafine versus itraconazole pulse therapy among children with TC. Keeping in mind the challenges of drug accessibility, cost, and adherence, evaluating these regimens in a local context among pediatric population seems essential. This study aimed to compare the therapeutic efficacy of itraconazole pulse therapy and terbinafine in the treatment of TC in children. This study may provide evidence about selecting the most effective, safe, and practical therapeutic option for pediatric patients in resource-constrained settings.

METHODS

This prospective, parallel-group, randomized controlled trial was conducted at the Dermatology Department of Jinnah Hospital, Lahore, Pakistan, during 25th April 2024 to 15th September 2025 2025, after obtaining ethical approval from the Institutional Review Board (Ref No.: ERB187/2/24-04-2025/S1 ERB, dated: 24-04-2025). Written informed consent was obtained from the parents or legal guardians. Trial registration was done as NCT07068256 (clinicaltrials.gov). Inclusion criteria were children aged between 3 and 14 years who presented with clinical features suggestive of TC, including patchy alopecia, scaly or erythematous lesions, kerion, or black dot type hair loss, with diagnosis confirmed by direct microscopic examination of scalp scrapings and plucked hairs in 10% potassium hydroxide. Patients were excluded if they had received systemic antifungal treatment in the past 4-weeks, if they had chronic systemic illnesses such as hepatic or renal impairment, if they were immunocompromised, or if they had known hypersensitivity to itraconazole or terbinafine.

The sample size was calculated using OpenEpi, considering an expected difference of 20% in efficacy between the two treatment arms, with 80% power and 95% confidence level, resulting in 118 (59 per group). Randomization was performed using a computer-generated random sequence in a 1:1 allocation ratio. Treating physicians and participants were aware of the assigned therapy due to the difference in dosing schedules; however, outcome assessors and laboratory personnel were blinded to group assignment to minimize assessment bias. Children in the itraconazole arm received itraconazole orally at a dose of 5 mg/kg/day for 1 week followed by 3 weeks off treatment, repeated for two pulses.[12] Children in the terbinafine arm received terbinafine orally at a dose of 4–5 mg/kg/day once daily for four consecutive weeks.[15] Both groups were counseled regarding adherence, avoidance of sharing personal items, and maintenance of scalp hygiene. Necessar laboratory investigations were obtained before initiation of therapy and repeated at the end of treatment. Participants were followed up at two, four, and eight weeks to assess clinical improvement, adherence, and adverse events. The primary outcome was therapeutic efficacy defined as the proportion of participants achieving both clinical cure and mycological cure at eight weeks. Clinical efficacy was defined as complete resolution of scalp lesions, scaling, alopecia, and pruritus, assessed by the dermatologist after designated duration of treatment. Mycological efficacy was determined by negative potassium hydroxide (10% KOH) microscopy at week 8. Secondary outcomes included time to symptomatic improvement and the frequency of treatment-related adverse effects through structured interviews, physical examination and post-treatment liver function tests evaluation.

Data were entered into a structured proforma and analyzed using IBM-SPSS Statistics, version 26.0. Continuous variables such as age were expressed as mean and standard deviation, or median and interquartile range (IQR) (as per Shapiro-Wilk test), while categorical variables such as gender, clinical type of TC, cure rates, and adverse events were presented as frequencies and percentages. The chi-square test or Fisher's exact test was applied for comparison of categorical variables, and an independent sample t-test or Mann-Whitney U test was used to compare continuous variables. A p value <0.05 was considered significant.

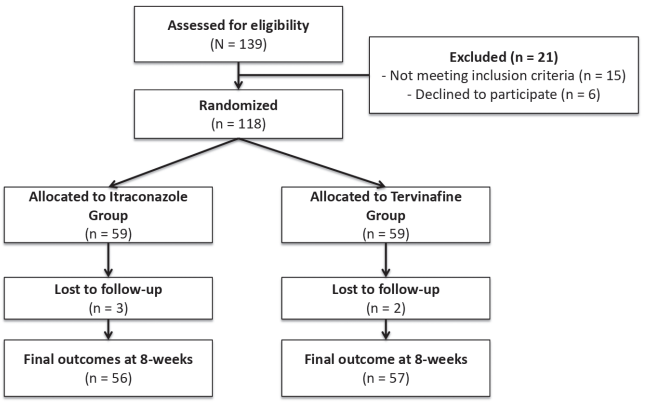
RESULTS

In a total of 118 children, 68 (57.6%) were males, and 50 (42.4%) females. The overall median age was 8.1 years (IQR 5.2–9.7). There were 70 (59.3%) children who belonged to rural areas, while 48 (40.7%) resided in urban areas. The median duration of disease at presentation was 5.0 weeks (IQR 4.0–7.0). Regarding clinical types of TC, 44 (37.3%) children presented with black dot alopecia, 52 (44.1%) with the scaling type, and 22 (18.6%) with kerion. The distribution of clinical types of TC did not exhibit any statistically significant differences across groups (p=0.594), and the details are shown in Table-I.

Of the 118 children, 113 (95.8%) completed the 8-week follow-up. Figure-1 is showing CONSORT flow diagram.

FIGURE-1

CONSORT flow diagram



The overall therapeutic efficacy was achieved in 97 (85.8%) children. Clinical cure was observed in 101 (89.4%), while mycological cure was confirmed in 97 (85.8%). The median time to symptom relief 3.0 weeks (IQR 2.0–5.0). Gastrointestinal disturbances were the most common treatment related adverse effect, reported in 11 (9.7%) children, and mild elevations of liver enzymes were detected in 3 (2.7%) children.

The primary outcome of therapeutic efficacy was achieved in 51 (91.1%) children treated with itraconazole, compared to 46 (80.7%) treated with terbinafine (p=0.114). Clinical cure alone was observed in 53 (94.6%) of itraconazole-treated children, and 47 (84.2%) of those treated with terbinafine (p=0.072). Both regimens were generally well tolerated, but gastrointestinal disturbances were reported in 6 (10.7%) of itraconazole recipients, and 5 (8.8%) of terbinafine recipients (p=0.728). Mild elevations in liver enzymes were noted in 2 (3.6%) children receiving itraconazole and 1 (1.8%) receiving terbinafine (p=0.548) (Table-II). No serious adverse events or treatment discontinuations reported.

DISCUSSION

The overall therapeutic efficacy in this study was 85.8% at eight weeks, while therapeutic efficacy was statistically similar across groups (91.1% vs. 80.7%, p=0.114). The median time to symptom relief was shorter in children receiving itraconazole, at 3.0 weeks (IQR 2.0–4.0), compared to 4.0 weeks (IQR 3.0–5.0) in those receiving terbinafine.

TABLE-I

Comparison of baseline characteristics in both study group (N=118)

Characteristics		Itraconazole (n=59)	Terbinafine (n=59)	P-Value
Gender	Male	35 (59.3%)	33 (55.9%)	0.709*
	Female	24 (40.7%)	26 (44.1%)	
Age (years), median (IQR)		8.0 (5.3-9.8)	8.2 (5.0-9.5)	0.587*
Residence	Urban	23 (39.0%)	25 (42.4%)	0.877*
	Rural	36 (61.0%)	34 (57.6%)	
Duration of disease (weeks), median (IQR)		5.0 (4.0-7.0)	5.0 (4.0-6.0)	0.771^
Tinea capitis types	Black dot alopecia	21 (35.6%)	23 (39.0%)	0.594*
	Scaling type	27 (45.8%)	25 (42.4%)	
	Kerion	11 (18.6%)	11 (18.6%)	

*Chi-square test applied; ^Mann-U Whitney test applied

TABLE-II

Treatment outcomes at the end of 8-weeks (N=113)

Efficacy and Safety Outcomes		Itraconazole (n=56)	Terbinafine (n=57)	Odds Ratio (95% CI)	P-Value
Therapeutic efficacy	Yes	51 (91.1%)	46 (80.7%)	2.58 (0.80-8.31)	0.114*
	No	5 (8.9%)	11 (19.3%)	-	
Clinical cure	Yes	53 (94.6%)	48 (84.2%)	3.38 (0.83-13.77)	0.072*
	No	3 (5.4%)	9 (15.8%)	-	
Mycological cure	Yes	51 (91.1%)	46 (80.7%)	2.58 (0.80-8.31)	0.114*
	No	5 (8.9%)	11 (19.3%)	-	
Time to symptom relief (weeks), median (IQR)		3.0 (2.0-4.0)	4.0 (3.0-5.0)	-	0.072^
Gastrointestinal disturbances	Yes	6 (10.7%)	5 (8.8%)	1.25 (0.36-4.34)	0.728*
	No	50 (89.3%)	52 (91.2%)	-	
Elevated liver enzymes	Yes	2 (3.6%)	1 (1.8%)	2.06 (0.18-23.35)	0.548*
	No	54 (96.4%)	56 (98.2%)	-	

*Chi-square test applied; ^Mann-U Whitney test applied

In a randomized trial by Zainab and colleagues conducted at Sheikh Zayed Hospital, Rahim Yar Khan, itraconazole demonstrated a significantly higher cure rate of 86.7% compared to 68.3% with terbinafine (p=0.01).[16] Time to cure was faster in itraconazole-treated children, with 58.3% cured by week 6 versus 40% in the terbinafine group (p=0.03). Side effect profiles were comparable, but tolerability was rated significantly better for itraconazole (p=0.02). The current findings echo these results, with itraconazole achieving relatively better cure rates and shorter time to symptom resolution, though statistical significance was not achieved. The lack of statistical difference in the present study may be attributed to sample size constraints, differences in species distribution, and the narrower margin in cure rates compared to Zainab et al.[16] Siddique and colleagues in Southern Punjab reported significantly higher cure rates with itraconazole (87.5%) compared to terbinafine (70%), with better tolerability and faster recovery time with itraconazole.[17] Another study analyzing 270 cases of various superficial fungal infections, identified itraconazole as the most effective systemic antifungal, followed by terbinafine and fluconazole.[18] These findings piont out the broader antifungal spectrum and clinical utility of itraconazole. Jahangir et al., found cure rates of 85.7% for itraconazole and 77.8% for terbinafine (p>0.05), without any significant variations in adverse events profile.[19] These findings suggest that while itraconazole may have an edge in certain contexts, both agents remain highly efficacious, particularly against Trichophyton species. A study from India showed that continuous itraconazole, and terbinafine had the highest mycological cure rates, at 79% and 81% respectively.[20] Itraconazole demonstrates a broad spectrum of activity against both Trichophyton and Microsporum species.[21] In contrast, terbinafine, although fungicidal and highly effective against Trichophyton, has relatively lower activity against Microsporum species, which remain prevalent in some regions.[22]

The safety profile observed in this study reinforces the favorable tolerability of both drugs. Adverse effects were mild and transient, with gastrointestinal disturbances in 9.7% and liver enzyme elevations in 2.7%, consistent with reports from previous studies. No discontinuations occurred, reflecting the safety of short-course therapy in children. These findings are congruent with global data, where discontinuation rates due to adverse events are reported at only 1%.[23-25]

Several limitations warrant consideration. Patient-level blinding was not feasible due to the inherent difference in dosing schedules between the two regimens which may have introduced some degree of performance bias. However, outcome assessment and laboratory confirmation were conducted by blinded evaluators to minimize observer bias. The

follow-up duration of eight weeks, although sufficient for initial therapeutic evaluation, was too short to assess relapse or reinfection, which are common in pediatric tinea capitis due to environmental exposure and incomplete eradication of fungal spores. While both treatment regimens were dosed according to standard pediatric recommendations, pharmacokinetic differences and variable drug adherence associated with pulse versus continuous dosing could influence drug exposure and outcomes.

CONCLUSION

Both itraconazole pulse therapy and terbinafine were found to be effective, well-tolerated, and safe options for the treatment of pediatric tinea capitis, achieving high rates of clinical and mycological cure. Adverse events were mild, infrequent, and did not require treatment discontinuation.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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AUTHORSHIP AND CONTRIBUTION DECLARATION	
1	**Samia Aslam:** Data collection, drafting.
2	**Lamees Mahmood Malik:** Concept and design.
3	**Fahad Iqbal:** Data analysis.
4	**Zaira Aslam:** Literature review.
5	**Sajida Kousar:** Proof reading.
6	**Tuyiba Ilyas:** Critical revisions.