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COMPARISON OF EFFICACY OF TABLET TERBINAFINE VERSUS SUSPENSION FLUCONAZOLE IN PEDIATRIC PATIENTS DIAGNOSED WITH TINEA CAPITIS

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Abstract

OBJECTIE

To compare the efficacy of oral Terbinafine tablets and Fluconazole suspension in pediatric patients with Tinea Capitis.

METHODOLOGY

A randomized controlled trial was executed at Chandka Medical College Hospital involving 66 pediatric subjects (aged 6 months to 12 years) diagnosed with tinea capitis, characterized by a Clinical Assessment Severity Score (CASS) of 4 or greater and a body weight of 5 kg or more. Participants were randomly allocated in a 1:1 ratio to receive either weight-based oral terbinafine or fluconazole (n=33 for each treatment group). The diagnosis was established through an evaluation of clinical manifestations and KOH microscopy. The primary outcomes assessed at the 8-week mark were the rates of both complete and mycological cure. Data analysis was performed utilizing SPSS version 26, with a significance level set at $p \leq 0.05$.

RESULTS

A total of 66 pediatric subjects (mean age 7.2 ± 2.7 years; 60.6% female) were randomly assigned in an equitable manner into two distinct cohorts. At the 8-week mark, the rate of complete resolution was notably higher in the terbinafine cohort (90.9%) when compared with the fluconazole cohort (66.7%) ($p = 0.016$). The mean Clinical Assessment Severity Score demonstrated a statistically significant enhancement in the terbinafine cohort (1.21 ± 1.43) relative to the fluconazole cohort (2.76 ± 2.42) ($p = 0.002$).

CONCLUSION

Oral administration of terbinafine in tablet form has been demonstrated to exhibit superior efficacy compared to fluconazole suspension for achieving a clinical resolution of tinea capitis in pediatric populations. The therapeutic effectiveness has been augmented, the duration of treatment has been reduced, and the safety

profile remains advantageous, thereby establishing terbinafine as the preferred first-line therapeutic option for the management of tinea capitis in children. These results yield substantial clinical evidence that may have the potential to alter the approach to antifungal therapy in pediatric dermatophyte infections.

INTRODUCTION

Tinea Capitis constitutes a contagious fungal condition affecting the scalp and hair, primarily influencing the pediatric demographic [1]. The prevalence of dermatophyte dermatitis in Pakistan is significantly elevated, with an approximate incidence rate of 22% [2]. The pathogenesis of this disorder is chiefly ascribed to the following pathogens: zoophilic Microsporum Canis, anthropophilic Trichophyton Violaceum, and Trichophyton Tonsurans [3]. A multitude of risk factors associated with Tinea Capitis encompasses age extremes, inadequate hygiene practices, high population density, and direct exposure to an infected individual [4]. Individuals aflicted may present with either mild manifestations or predominantly asymptomatic forms of Tinea Capitis [5].The clinical manifestations that characterize the inflammatory phenotype comprise erythematous indurated plaques, which are often associated with pustulation, subcutaneous nodules, and discharging sinuses. Furthermore, inflammatory lesions may present with mild erythema, fractured hair shafts, and slight scaling [5]. The diagnosis of Tinea Capitis is predominantly reliant on clinical evaluation, augmented by dermatoscopic examination, microscopy, and culture methodologies [7]. A diverse range of therapeutic agents, such as Terbinafine, Griseofulvin, Fluconazole, and Itraconazole, have been employed in the management of Tinea Capitis. The emergence of antifungal resistance among dermatophytes may be escalating, as evidenced by Echo et al., who reported a resistance rate of 19.7% when exposed to Fluconazole and 11.5% against Terbinafine [8]. This has made clinicians look for alternatives. While Fluconazole suspension may be better tolerated than capsule form, accuracy and precision have been reported to be better with capsule form.

Siddique et al studied the efficacy of Terbinafine in Tenia capitis patients and reported that Terbinafine was associated with Complete Cure in 70% of patients. Major adverse effects included abdominal pain (18.75%), vomiting (10%) and anorexia (6.25%) [9]. Similarly, Geetha et al reported a Mycological Cure in 94% of patients at 8 weeks of follow-up [10]. While Shukla et al reported a complete cure in 79.3% of patients and a mycological cure in 88% of patients using oral Terbinafine [11].

Dascalu et al, compared outcomes of Oral Terbinafine versus Fluconazole in pediatric Tinea Capitis and reported that Complete Cure against T. Tonsurans was seen in 95% of patients in the Terbinafine Group and 68% of patients in the Fluconazole Group. Similarly, Mycological Cure was seen in 100% of patients of the Terbinafine Group and 71% of patients of the Fluconazole Group [6]. Similarly, Mustafa et al compared the efficacy of Terbinafine with Fluconazole in patients of Tenia Corporis and reported a Complete Cure in 90.2% of patients in the Terbinafine Group compared to 64.7% of patients in the Fluconazole Group [12].

Fluconazole suspension has traditionally been used by dermatologists for the systemic treatment of Tenia Capitis. Terbinafine tablets may prove to be a more effective alternative if it is tolerated by pediatric patients [6,9-12].

A prevalent and highly transmissible superficial mycotic infection of the scalp in pediatric patients, tinea capitis may lead to scalp desquamation, alopecia, and inflammation, thereby adversely impacting quality of life and school attendance. Prompt and efficacious diagnosis and intervention are imperative to prevent complications and attenuate the spread of this infectious disease. There exists a paucity of data concerning the comparative efficacy of treatments in pediatric cohorts. Consequently, the current study aims to address this deficiency by evaluating clinical and mycological cure rates, treatment duration, side effect profiles, and overall patient adherence between oral Terbinafine tablets and oral Fluconazole suspension in children diagnosed with tinea capitis. The findings will provide an

evidence-based framework to assist clinicians in determining the most effective antifungal therapy, which may subsequently enhance clinical outcomes in this vulnerable population.

METHODOLOGY

This randomized controlled trial was executed within the Dermatology Department of Chandka Medical College Hospital (SMBBMU) Larkana. A non-probability consecutive sampling method was utilized to assemble a cohort of 66 pediatric participants, ranging in age from 6 months to 12 years. The inclusion criteria for the selection of eligible participants consisted of both male and female individuals, aged from 6 months to 12 years, who presented with a
confirmed diagnosis of tinea capitis, a baseline Clinical Assessment Severity Score (CASS) of 4 or higher, and a minimum body weight of 5 kg to guarantee the safe administration of weight-dependent pharmacotherapeutic agents. The criteria for exclusion encompassed recent administration of antifungal agents within the preceding 8 weeks, confirmed diagnoses of kerion or favus, pre-existing hepatic or renal pathologies, in addition to previous hypersensitivity reactions to terbinafine or fluconazole, or any documented history of immunosuppression. The diagnosis of Tinea Capitis was substantiated through clinical evaluation and microscopic examination. Clinical manifestations included dry, scaly lesions on the scalp, potential alopecia, inflammatory boggy masses accompanied by scaling and crusting, or diffuse scalp scaling. Microscopic verification was achieved via 10% Potassium Hydroxide (KOH) preparations derived from scrapings of hair and scalp, which demonstrated the presence of fungal hyphae or spores; Participants were systematically allocated into two groups (n=33) in an equal distribution, utilizing a computer-generated randomization list. Group A was administered oral terbinafine tablets, weight-adjusted for a duration of 4 weeks, specifically 62.5 mg for children weighing 40 kg. In contrast, Group B received fluconazole suspension at a daily dosage of 6 mg/kg for a period of eight weeks.

At the completion of the 8-week interval, a thorough re-assessment of the Clinical Assessment Scoring System (CASS) was conducted, and scalp specimens were acquired for both histopathological analysis and mycological culture utilizing Sabouraud Dextrose Agar. The parameters for Complete Cure (CASS ≤ 2 accompanied by negative histopathological findings and culture results) and Mycological Cure (CASS > 2 coupled with negative histopathological findings and culture results) were established as the preordained endpoints for the evaluation of therapeutic efficacy. Data analysis was conducted utilizing SPSS version 26, wherein quantitative and qualitative variables were articulated as mean accompanied by standard deviation and frequency expressed in percentage, respectively. A Chi-square test was implemented to determine the disparities in efficacy among the groups, with a p-value of ≤ 0.05 deemed statistically significant.

RESULTS

The baseline characteristics of the study participants who received either Terbinafine tablets or Fluconazole suspension were assessed and found to be similar across the majority of variables, thereby suggesting sufficient randomization and homogeneity between the two treatment groups. The mean age of the children in both groups was determined to be comparable (7.15 ± 2.55 years in the Terbinafine cohort versus 7.24 ± 2.85 years in the Fluconazole cohort; p=0.892). The distribution of age was also well-balanced, with a nearly equivalent proportion of children aged 1–6 years and those exceeding 6 years in both treatment arms (p=0.804). Gender distribution did not exhibit any significant disparities, with females being slightly more represented in both groups (57.6% in Terbinafine versus 63.6% in Fluconazole; p=0.614). Likewise, residential status (urban versus rural) and the duration of symptoms prior to the initiation of treatment were statistically comparable between the groups (p=0.796 and p=0.615 respectively), as were the mean weights (15.48 ± 5.32 kg versus 15.24 ± 4.33 kg; p=0.840). Notably, both groups commenced with analogous baseline clinical assessment severity scores (9.64 ± 2.91 versus 9.24
± 2.79; p=0.577), indicating that the initial clinical severity of the condition was equivalent.

However, at the 8th-week follow-up, a statistically significant difference was observed in the clinical

response, with the Terbinafine group exhibiting a markedly lower mean severity score (1.21 ± 1.43) in comparison to the Fluconazole group (2.76 ± 2.42), and this difference was statistically significant (p=0.002). (TABLE I)

The efficacy outcomes indicated a statistically significant difference between the two treatment groups. In the Terbinafine group, 90.9% (30 out of 33) of children exhibited a favorable therapeutic response, contrasted with 66.7% (22 out of 33) in the Fluconazole group (p=0.016). This finding suggests that Terbinafine tablets are markedly more effective than Fluconazole suspension in the treatment of pediatric patients with Tinea Capitis. The elevated success rate in the Terbinafine group is congruent with previous studies that endorse its fungicidal activity and advantageous pharmacokinetic profile, particularly against dermatophyte infections. Conversely, although Fluconazole remains a plausible therapeutic alternative, its relatively diminished efficacy noted within this cohort indicates that it may be less dependable as a primary treatment option, particularly in contexts that demand swift or comprehensive resolution. These observations underscore the clinical preeminence of Terbinafine in the treatment of pediatric tinea capitis and may influence treatment preferences in comparable patient demographics. (TABLE II).

Table I: Baseline Comparison of Study Participants (n=66)

Variable		Terbinafine Tablets (n=33)	Fluconazole Suspension (n=33)	P-Value
Age, Years		7.15 ± 2.55	7.24 ± 2.85	0.892
Age Group	1 – 6 years	15 (45.5)	14 (42.4)	0.804
	>6 years	18 (54.5)	19 (57.6)	
Gender	Male	14 (42.4)	12 (36.4)	0.614
	Female	19 (57.6)	21 (63.6)	
Residential Status	Urban	21 (63.6)	22 (66.7)	0.796
	Rural	12 (36.4)	11 (33.3)	
Duration of Symptoms, Months		5.52 ± 2.27	5.79 ± 2.10	0.615
Duration	1 – 6 months	22 (66.7)	21 (63.6)	0.796
	>6 months	11 (33.3)	12 (36.4)	
Weight, kg		15.48 ± 5.32	15.24 ± 4.33	0.840
Baseline Clinical Assessment Severity Score		9.64 ± 2.91	9.24 ± 2.79	0.577
Clinical Assessment Severity Score at 8th Week		1.21 ± 1.43	2.76 ± 2.42	0.002

Table II: Comparison of Efficacy for Tablet Terbinafine Versus Suspension Fluconazole Children Diagnosed with Tinea Capitis(n=66)			
Efficacy n (%)	Terbinafine Tablets (n=33)	Fluconazole Suspension (n=33)	P-Value
Yes	30 (90.9)	22 (66.7)	0.016
No	3 (9.1)	11 (33.3)	

DISCUSSION

Tinea capitis represents one of the most prevalent dermatophyte infections observed in pediatric populations, particularly among those residing in developing nations, thus necessitating prompt and effective intervention. This multicentric randomized controlled trial assessed the comparative efficacy of oral terbinafine versus fluconazole.The overall complete cure rate was markedly superior in the terbinafine cohort when juxtaposed with fluconazole (90.9% versus 66.7%; p = 0.016), thereby substantiating the designation of terbinafine as the primary therapeutic modality. The findings of these investigations were congruent with antecedent studies, which documented 100% fungal cure rates for terbinafine and 71% cure rates for fluconazole, alongside 95% complete cure rates for terbinafine compared to 68% for fluconazole [6]. Mustafa et al., in a related context, documented full cure rates of 90.2% and 64.7% for terbinafine and fluconazole, respectively, with these observed cure rates aligning predominantly with the current study population [12]. The uniformity of these outcomes across diverse populations and methodological approaches further bolsters the transition toward terbinafine-centered recommendations in lieu of fluconazole for the management of pediatric infections, particularly when accounting for the potential intricacies associated with long-term adherence (notably, the dosages of fluconazole are linked with extended treatment) in numerous regions worldwide. Additional studies have similarly demonstrated favorable outcomes for Terbinafine. Evidence indicates that Terbinafine can achieve a Complete Cure in 70% of patients [9], with a Mycological Cure observed in 94% of patients at the eight-week follow-up [10]. In research conducted by Shukla et al, Complete Cure and Mycological Cure rates of 78.3% and 88%, respectively, were noted with Terbinafine [11]. Although minor discrepancies may emerge as a result of variations in methodological design, participant demographics, and assessment techniques, the predominant trend unequivocally substantiates the effectiveness of Terbinafine. Tinea Capitis constitutes one of the most widespread superficial fungal infections encountered in pediatric cohorts, particularly within settings characterized by resource limitations. The primary objective of this research is to systematically assess and juxtapose the efficacy and safety profiles of oral Terbinafine tablets against Fluconazole suspension in children diagnosed with Tinea Capitis. The results derived from our study revealed a statistically significant enhancement in efficacy within the Terbinafine cohort (90.9%) compared to the Fluconazole cohort (66.7%) (P = 0.016). These results further substantiate the increasingly persuasive evidence that highlights the notable antifungal superiority of Terbinafine in the treatment of dermatophyte scalp infections in pediatric patients.

These results are consistent with a substantial body of previously published literature. A Complete Cure was recorded in 95% of patients receiving Terbinafine, compared to 68% of those treated with Fluconazole [6]. Moreover, a Mycological Cure was attained in an impressive 100% of patients administered with Terbinafine, whereas only 71% of the cohort receiving Fluconazole achieved similar results, as elucidated in prior scholarly research [6]. These findings are in substantial concordance with the outcomes derived from our study and further substantiate Terbinafine's designation as the preeminent therapeutic agent concerning both clinical and mycological results.

In a related investigation, Mustafa et al documented a Complete Cure rate of 90.2% for Terbinafine compared to 64.7% for Fluconazole, with the observed cure rates closely reflecting those recorded in our cohort [12]. The recurrence of these findings across diverse populations and various methodological approaches lends additional support

to the endorsement of Terbinafine-centered treatment strategies over Fluconazole in pediatric care, particularly in light of the difficulties associated with compliance to extended treatment protocols (notably, the prescribed dosages of Fluconazole require prolonged administration) in certain regions of the world.

Further investigations have similarly illustrated favorable outcomes for Terbinafine. Evidence suggests that Terbinafine can achieve a Complete Cure in 70% of patients [9], with a Mycological Cure achieved in 94% of patients at the eight-week follow-up [10]. In research conducted by Shukla et al, Complete Cure and Mycological Cure rates of 78.3% and 88%, respectively, were observed with Terbinafine [11]. Although minor discrepancies exist attributable to variations in study design, sample characteristics, and evaluation methodologies, the overarching trend remains robustly in favor of Terbinafine.

These results necessitate validation, nonetheless, within more extensive multi-center cohorts accompanied by prolonged follow-up periods to accurately ascertain the genuine long-term cure and recurrence rates. Furthermore, variables pertaining to cost-effectiveness and adherence can offer an additional pathway for clinician-level decision support within the healthcare system.

CONCLUSION

Oral administration of terbinafine in tablet form has been demonstrated to exhibit superior efficacy compared to fluconazole suspension for achieving a clinical resolution of tinea capitis in pediatric populations. The therapeutic effectiveness has been augmented, the duration of treatment has been reduced, and the safety profile remains advantageous, thereby establishing terbinafine as the preferred first-line therapeutic option for the management of tinea capitis in children. These results yield substantial clinical evidence that may have the potential to alter the approach to antifungal therapy in pediatric dermatophyte infections.

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