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Efficacy of oral fluconazole versus oral terbinafine in the treatment of tinea capitis

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Abstract--Objective: To compare the effectiveness of oral Fluconazole vs oral Terbinafine in the treatment of tinea capitis. Place and Duration: This Randomized control trial was conducted from 6th December, 2019 to 6th June, 2020 in the Department of Dermatology, Hayatabad Medical Complex, Peshawar. Subject and Method: The study was carried out at Department of Dermatology, Hayatabad Medical Complex Peshawar. Through consecutive sampling technique, all patients meeting the diagnostic requirements for inclusion were selected from the OPD. The parents or guardians of the patients provided written informed consent and were advised that the information would be kept confidential because it was all done only for the purpose of the study. To confirm Tinea Capitis in all patients, a thorough history, physical examination, and microscopy were performed. Through the use of a lottery, patients were randomly split into Group A and Group B. For four weeks, patients in Group A received Fluconazole 6–8 mg/kg once weekly. Terbinafine 3-5 mg/kg was given once daily to patients in Group B. Patients were evaluated using the Total Sign and Symptom Score (TSSS) and microscopic inspection at the time of study enrolment, as well as at 4- and 8-week intervals after those times. Three clinical signs and symptoms—erythema, scaling, and pruritis—were used to assess patients using the TSSS and were scored on a four-point scale (0-absent, 1-mild, 2-moderate, 3-severe). By using TSSS and mycological cure, oral Terbinafine and Fluconazole were evaluated for efficacy. Patients who were lost to follow-up were not included in the study. Name, age, and

sex were all recorded together with the other information given above in a pre-made proforma. To prevent any bias in the study's findings, the exclusion criteria were strictly followed. Results: A total of 62 patients were selected for the study; 31 patients in each group. Efficacy was observed in 14 (45.2%) patients in Group A receiving Fluconazole compared with 22 (73.3%) patients in Group B treated with Terbinafine. Conclusion: Oral Terbinafine is more effective than oral Fluconazole in the clinical & mycological cure of tinea capitis.

Keywords--diflucan, fluconazole, lamisil, terbinafine, tinea capitis.

Introduction

Tinea capitis is the scalp fungal infection including both hair and skin of scalp. It is mainly caused by *Microsporum* and *Trichophyton* species¹⁻². It is a communicable disease spreading either by direct contact with infected person or indirectly by sharing personal items like towel or comb. Clinically it can be classified into two subtypes: inflammatory and non-inflammatory³⁻⁴. Non-inflammatory type can present as scaling or loss of hair, while the inflammatory subtype can manifest as tender plaques covered with broken hair or pustules. Inflammatory subtype may also present with cervical lymphadenopathy. Tinea capitis most commonly affects children of 3 to 9 years of age. Systemic antifungal therapy is necessary to cure tinea capitis, as topical agents alone cannot treat infection involving hair shaft and hair follicles⁵⁻⁶. Previously Griseofulvin was considered the treatment of choice but is not preferred nowadays due to its side effects and longer duration of treatment. Newer antifungal agents, such as Terbinafine, Itraconazole, and Fluconazole are effective substitute for tinea capitis⁷.

In 2018, a study conducted in Egypt for antimicrobial susceptibility of tinea capitis, found that dermatophyte species were more sensitive to Terbinafine (76.1%) as compared to Fluconazole (40.2%). In 2012, a study compared effectiveness of Griseofulvin, Terbinafine and Fluconazole for tinea capitis at Delhi, India by Grover et al⁸⁻⁹. A study conducted in Punjab, Pakistan, compared effectiveness of Itraconazole vs Terbinafine in the tinea capitis treatment. Cure was seen in significantly higher percentage of patients with Itraconazole (86.67%) compared to Terbinafine (68.33%)¹⁰. The purpose of this study was to determine the efficacy of oral Fluconazole vs oral Terbinafine in the treatment of tinea capitis, as no study had been conducted on this topic before in our locality. This study was conducted with the intension that if it gives first hand evidence of the therapeutic effect of these medicines, it would be shared in the shape of guidelines and protocols for the knowledge of local health researchers for better management of this disease in our local population of Khyber Pakhtunkhwa.

Methods

This Randomized control trial was conducted from 6th December, 2019 to 6th June, 2020 in the Department of Dermatology, Hayatabad Medical Complex, Peshawar. Total sample size was 62 patients selected by Consecutive non-

probability sampling technique, thirty-one (31) in each group, using efficacy of Terbinafine against dermatophyte species as 76.1% and efficacy of Fluconazole against dermatophyte species as 40.2.10 With 95% confidence level and 90% power of the test under WHO sample size formula.

Inclusion criteria

1. Children of both genders, 2 to 10 years of age.
2. Children presenting with patchy hair loss with or without erythema, scaling, itching, papules and pustule for one month.
3. Skin scraping from the lesion show presence of fungal hyphae on KOH microscopy.

Exclusion Criteria

1. Patients who had used any topical or oral antifungal treatment in the past six weeks before the start of study which may result in bias.
2. Patients having hypersensitivity to Fluconazole or Terbinafine.
3. Patients with congenital or acquired prolong QT interval because Fluconazole is arrhythmogenic.
4. Patients with deranged liver functions as Terbinafine is hepatotoxic.
5. Patients having diabetes or immunocompromised status leading to low immunity and delayed treatment response resulting in bias.

Formal permission from hospital ethical committee was obtained to conduct this study at Department of Dermatology, Hayatabad Medical Complex, Peshawar. Through consecutive sampling technique, all patients meeting the diagnostic requirements for inclusion were selected from the OPD. Written informed consents were attained from the parents or guardians of the patients by informing them that confidentiality would be maintained as this is all for the purpose of study only (attached as Annex-II). Complete history and examination of all patients with great care and Tinea Capitis was confirmed through microscopy.

Patients were randomly divided into two groups through lottery method; Group A and Group B. Patients in Group A were given Fluconazole 6-8 mg/kg once weekly for 4 weeks duration. Patients in Group B were administered with Terbinafine 3-5 mg/kg once daily. All patients were assessed during enrollment into the study and after 4 weeks and 8 weeks, using Total Sign and Symptom Score (TSSS) and microscopic examination. Patients were evaluated using TSSS on the basis of three clinical signs and symptoms i.e Erythema, Scaling, Papules and Pruritis. Efficacy of oral Terbinafine and oral Fluconazole were assessed by TSSS and mycological cure. Any patient lost to follow up was excluded from the study. Name, age, and sex were all recorded together with the other information given above in a pre-designed proforma. To prevent any bias in the study's findings, the exclusion criteria were strictly followed.

SPSS version 20 was used to enter and evaluate all of the data that was collected. For qualitative variables including gender, efficacy, and post-treatment clinical signs and symptoms like erythema, scaling, and itching, frequencies and percentages were estimated using the TSSS. For quantitative variables including

age, disease duration, and treatment duration, mean and standard deviation were determined. To assess effectiveness between groups, the Chi-square test was used. Age, gender, treatment length, and disease duration were used to stratify efficacy in order to look for effect modifiers. A chi square test was used after stratification, with a p value of 0.05 being considered significant. Tables, graphs, and charts are used to present the results.

Results

A total of 62 patients were included in the study by dividing them through lottery method into two equal groups; 31 patients in group A (fluconazole) and 31 patients in group B (terbinafine). One patient in group B was lost to follow up after 4 weeks treatment therefore she was excluded from the study. Results showed a slightly increased occurrence of tinea capitis in girls, with p value of 0.8 which was statistically not significant (Table 1).

Table I
Shows the patients distribution with reference to gender

Gender	Total number n=62		P value
	Frequency	Percentage	
Male	29	46.7%	0.8
Female	32	51.6%	
Missing	1	1.6%	

Mean age of patients suffering from tinea capitis was 5.7 with SD \pm 2.548. (Table 2).

Table II
Shows the patients distribution with reference to Age-groups

Age Group	Total Number 61		Mean \pm SD	P value
	Frequency	%age		
2-4	24	39.3%	5.7 \pm 2.548	0.743
5-7	20	32.8%		
8-10	17	27.9%		

At the time of enrolment, erythema was observed almost equal in both groups. After eight weeks treatment, higher percentage of patients in group B were having absent erythema compared to group A. The difference was statistically significant (p value 0.001) (Table 3).

Table III
Shows the Erythema and scaling in both groups at Enrolment and After 8 weeks Treatment

Erythema	Group A (Fluconazole) n=31		Group B (Terbinafine) n=30		P value
	At Enrolment	After 8 weeks	At Enrolment	After 8 weeks	
Absent	0(0%)	4(12.9%)	0(0%)	12(40%)	0.001
Mild	0(0%)	10(32.3%)	0(0%)	12(40%)	0.4
Moderate	3(9.7%)	14(45.2%)	3(10%)	6(20%)	0.05
Severe	28(90.3%)	3(9.7%)	27(90%)	0(0%)	0.0002
Scaling	Group A (Fluconazole) n=31		Group B (Terbinafine) n=30		P-value
	At Enrolment	After 8 weeks	At Enrolment	After 8 weeks	
Absent	0(0%)	0(0%)	0(0%)	12(40%)	0.00004
Mild	0(0%)	6(19.4%)	0(0%)	15(50%)	0.0021
Moderate	4(12.9%)	22(71%)	4(13.3%)	3(10%)	0.007
Severe	27(87.1%)	3(9.7%)	26(86.7%)	0(0%)	0.002
Absent	0(0%)	0(0%)	0(0%)	12(40%)	0.00004

Complete clearance of scaling was seen in 12 (40%) patients in group B compared to 0 patients in group A, p value was significant (0.00004). Both groups had equal number of patients complaining of itching at enrolment. After 8 weeks treatment, 6 (20%) patients were having complete resolution of itching in group B. Itching could not be completely eliminated in group A, p value was statistically significant (0.0002) (Table 4).

Table IV
Shows the itching in both groups at Enrolment and After 8 weeks Treatment and efficacy of Fluconazole and Terbinafine

Itching	Group A (Fluconazole) n=31		Group B (Terbinafine) n=30		P value
	At Enrolment	After 8 weeks	At Enrolment	After 8 weeks	
Absent	0(0%)	0(0%)	0(0%)	6(20%)	0.0002
Mild	0(0%)	8(25.8%)	0(0%)	12(40%)	0.25
Moderate	2(6.5%)	20(64.5%)	2(6.7%)	11(36.7%)	0.003
Severe	29(93.5%)	3(9.7%)	28(93.3%)	1(3.3%)	0.0005
Duration of Treatment	Efficacy	Group A (Fluconazole) n=31	Group B (Terbinafine) n=30	P value	
In 4 weeks	Effective	14 (45.2%)	22 (73.3%)	0.003	

	Not Effective	17 (54.8%)	8 (26.7%)		
In 8 weeks	Effective	23 (74.2%)	29 (96.7%)	<0.001	
	Not Effective	8 (25.8%)	1 (3.3%)		

Fluconazole was efficacious in about half of the enrolled patients after four weeks treatment, which improved to 23 (74.2%) after eight weeks treatment. Clinical improvement was seen in 22 (73.3%) patients after 4 weeks of terbinafine treatment, which increased to 29 (96.7%) after 8 weeks treatment. The p value at 4 and 8 weeks of treatment with terbinafine vs fluconazole was 0.003 and <0.001 respectively which was statistically significant. Efficacy of fluconazole and terbinafine was stratified with age showing equal efficacy in all the three age groups, p value was not significant (0.53) (Table 5).

Table V
Shows the Efficacy in various Age Group in Both Groups

Age Group	Group A (Fluconazole) n=31		Group B (Terbinafine) n=30	
	Effective	Not Effective	Effective	Not Effective
2-4	11 (35.5%)	2 (6.5%)	11 (36.7%)	0 (0%)
5-7	6 (19.4%)	3 (9.7%)	11 (36.7%)	0 (0%)
8-10	6 (19.4%)	3 (9.7%)	7 (23.3%)	1 (3.3%)
Total	23 (74.2%)	8 (25.8%)	29 (96.7%)	1 (3.3%)
P Value	0.530		0.241	

Efficacy of fluconazole and terbinafine was stratified with gender showing more improvement in females of both groups. But p value was statistically not significant (0.75) (Table 6).

Table VI
Shows the Efficacy in relation to gender

Gender	Group A (Fluconazole) n=31				Group B (Terbinafine) n=30			
	Effective	%age	Not Effective	%age	Effective	%age	Not Effective	%age
Male	10	32.3%	4	12.9%	14	46.7%	1	3.3%
Female	13	41.9%	4	12.9%	15	50.0%	0	0.0%
Total	23	74.2%	8	25.8%	29	96.7%	1	3.3%
P Value	0.750				0.309			

Group A (Fluconazole)



Before treatment



After 8 weeks of treatment

Group B (Terbinafine)



Before treatment



After 8 weeks of treatment

Discussion

Tinea capitis is a common and serious fungal illness that is frequently seen in children and adolescents, but it is extremely uncommon in adults¹⁰⁻¹¹. From non-inflammatory lesions to severe inflammatory variations, the clinical appearance is highly varied. Grey patch and black dot are examples of non-inflammatory forms, whereas kerion and favus are examples of inflammatory lesions that, if left untreated, might lead to cicatricial alopecia¹²⁻¹³. In this study tinea capitis was observed to be slightly more common in girls than boys, p value was 0.8 which was statistically not significant. Similar occurrence of gender distribution was seen in study by Sharma K et al in which 61% females were affected with tinea capitis¹⁴⁻¹⁵. This may be due to the trend of tightly braided hair styles among girls & repeated trauma due to combing which favour fungal growth¹⁶. In addition, more sharing habits in girls in our community beside poverty, less education of health care, substandard shampoo products, unhygienic environment, common joint family system where household items are used commonly by all family members. In contrast, studies by Bhat YJ et al and Wani MM et al showed higher number of affected males i-e 69.3% and 61% respectively¹⁷⁻¹⁸. The reason for this difference can be due to the fact that both these studies were carried out in rural areas where females are rarely brought to health care facility. Hence less females are reported although the actual number might be high¹⁹.

In our study, maximum number of patients belonged to 2-7 years age group while the mean age of enrolled patients was 5.70 ± 2.548 . Other studies also showed younger children to be affected more commonly. Grover et al reported 53.7% of patients in their study were having 2-8 years age.⁶⁷ This nature of disease favouring younger children can be attributed to no awareness of hygiene in young children and close contact with one another²⁰⁻²¹. In this study clinical cure was evaluated by total signs and symptom score (TSSS) which included erythema, scaling and itching. Treatment with terbinafine showed complete clearance of erythema in majority of patients compared to very few patients having absent erythema in group A, p value was significant (0.001). This is in accordance with study conducted by Zainab A et al in which 60 patients were treated with

terbinafine and 33.3% had complete resolution of erythema²²⁻²³. This similarity was seen because terbinafine was having superior efficacy in killing the causative organism, thereby leading to decrease in inflammation over time and decrease in erythema. Scaling was a common feature at the time of enrollment. Scaling was completely cleared in about half of the group B patients but complete clearance of scaling could not be achieved in group A, p value was 0.00004 was statistically significant. Krafchik B et al reported absent scaling in 31% patients after 8 weeks of treatment with terbinafine.⁵⁶ This similarity was seen because majority of tinea capitis cases presenting with scaling were due to trichophyton species which was more susceptible to terbinafine²⁴⁻²⁵.

Clinical cure was also assessed by improvement in itching. Majority of patients in both groups were affected by itching at the time of enrollment. This is in contrast to study by Reddy S et al who observed only 31% patients suffering from itching. This difference can be explained by the fact that majority of patients in reference study were below 3 years age and hence underreporting of itching cannot be ignored. With treatment the percentage of patients in group B having unnoticeable itching was 20% after 8 weeks treatment²⁶. Improvement in itching with treatment has not been focused in the studies we have reviewed.

Efficacy of terbinafine was better than fluconazole at the end of 8 weeks treatment. This difference was statistically significant (p value < 0.001). This is in accordance with study conducted by Krafchik B et al which showed 86% patients were having clinical cure with 6 weeks terbinafine use²⁷. Friedlander SF et al showed 72% of enrolled patients were disease free with 4 weeks treatment of terbinafine. A study conducted in Pakistan by Zainab A et al treated 60 patients with terbinafine and showed a cure rate of 68.3%. Grover C et al got a response rate of 84% and 88% with fluconazole and terbinafine respectively²⁸. Elewski BE et al was having clinical cure rate of 63% after 4 weeks of terbinafine treatment. The similarity in results can be contributed to similar age group being enrolled and same strength of treatment being used²⁹.

Stratification of efficacy with respect to age showed no difference in efficacy based on age of patient. It was not statistically significant (p value 0.530). This is in accordance with study conducted by Elewski BE et al showing no difference in treatment efficacy against age or gender.⁵⁸ This similarity shows that efficacy of terbinafine is not related to age of patient but type of organism and dosage regimen. Both treatment modalities were more effective in female patients. But this was statistically not significant (p value 0.309). Study conducted by Grover C et al showed response rate with terbinafine was 88%, of which 48% were females. This can be explained by the fact that action of terbinafine is mainly on the fungal wall to render it dead and host factors i-e gender doesn't increase or decrease its efficacy³⁰.

Conclusion

This study has revealed that oral terbinafine (in a dose of 3-5mg/kg once daily for 4-8 weeks) is more effective than oral fluconazole (in a dose of 6-8mg/kg once weekly) in the treatment of tinea capitis.

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