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Original Research Article

Comparative study of oral terbinafine vs. oral griseofulvin in the management of tinea capitis

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ABSTRACT

Background: Tinea capitis (TC) is a common dermatophyte infection affecting primarily prepubertal children. The present study has been designed to assess the clinico-etiological profile of the T capitis and to compare the efficacy and tolerability of terbinafine with griseofulvin.
Methods: One hundred fifty eight patients of T. capitis were divided into two groups of 79 patients each to receive either oral griseofulvin or terbinafine (according to weight). Patients in both the groups were followed up at 2, 4, 12 and 36 weeks. At every visit, clinical improvement was evaluated using clinical assessment severity score and the compliance, tolerability and side effects of the drugs were assessed along with KOH microscopy, fungal culture from the lesion and relevant blood investigations.
Results: The clinical assessment score were statistically similar in group G and group T at the start of therapy. The decline in scores in both treatment groups was statistically significant at each follow up visit. In griseofulvin group, the mean score was declined from 5.9 at baseline to 4.24 at week 2 and 2.79 at week 4, 0.82 at week 12 and 1.24 at 36 week. In the terbinafine group, the score had a mean of 6.23 at 0 week and 4.03 at week 2, 2.32 at week 4, 0.69 at week 12 and 0.83 at week 36.
Conclusions: At follow up study long lasting tissue effect of terbinafine was found but effect of griseofulvin was waned at 36 week. So terbinafine may be better option with similar side effect profile but it is better in residual clinical and mycological effect at higher cost.

Keywords: Tinea capitis, Dermatophytosis, Terbinafine, Griseofulvin, Treatment

INTRODUCTION

Tinea capitis (T. capitis) is a dermatophytic infection of the scalp, and the associated hair loss. It is the most common pediatric dermatophytic infection worldwide. T capitis is becoming a public health problem due to its increasing incidence. The exact incidence in India and other Asian countries, however, is unknown. Low socio-

economic status, large family size and crowded living conditions and contact with geophilic and zoophillic species contribute to its increasing incidence in the developing countries.[1,2] Despite changing pattern in incidence and etiological spectrum, little has changed in the treatment of T. capitis in last 40 years. Griseofulvin is still considered the gold standard in its treatment. Being fungistatic, a prolonged treatment of more than 6-12 weeks is required. Moreover, the response rate to griseofulvin therapy in patients with T. capitis has also decreased.[3] In dermatophytes, drug resistance is difficult to document as there is no accepted standardized method of antimycotic susceptibility testing and considered inter and intra-laboratory variability exists.[4] All these considerations emphasize the need to develop safe, inexpensive, effective and short course alternatives to current antifungal therapy of T. capitis.

Terbinafine is a fungicidal allylamine, which has been extensively for the treatment of onychomycosis and skin infection caused by dermatophytes. It is concentrated in hair, nail and skin leading to reservoir effect, advocating its shorter duration of treatment.[5] It has been shown to be effective and well tolerated in various trials in the treatment of T. capitis. Only few randomized, double blind, controlled trials have been done to compare the efficacy and tolerability of terbinafine with griseofulvin in other countries.[6,7] None has been performed so far in this part of country (especially North Eastern part of India).

There is a paucity of data regarding epidemiological profile of T. capitis in the Indian subcontinent. The present study has been designed to assess the clinic-etiological profile of T. capiti and to assess efficacy of terbinafine and griseofulvin in management of T. capitis. So, the present study has been designed to assess the clinico-etiological profile of the T. capitis and to compare the efficacy and tolerability of terbinafine with griseofulvin.

METHODS

One hundred fifty eight, untreated cases of tinea capitis, irrespective of sex and socioeconomic status, of age group 2 to 12 years of age, attending department of dermatology, venerology and leprology of RIMS, from September 2011 to august 2012 was included for the study. The study was taken approval by the Institutional Ethics Committee of RIMS.

Inclusion criteria

Inclusion criteria were all new cases of uncomplicated tinea capitis with age group 2 to 12 years, attending skin OPD at RIMS; who has given written consent for study and regular follow up; positive 10% KOH mount from scalp lesions including hair and skin for hyphae and spores.

Exclusion criteria

Exclusion criteria were old cases who has taken/taking antifungal for any disease in last 8 weeks; cases with history of being allergic to either terbinafine or griseofulvin; those patients who is not ready to give written consent for study; children under treatment for any other systemic illness; immunocompromised patients and patients with severe illness.

A clinical diagnosis of T. capitis was made in patients with scaly scalp lesions with or without alopecia, patients with inflammatory boggy mass studded with scales and crust, and patient with diffuse scaling on scalp, not responding to usual treatment. An informed consent was taken from the patient/or/guardian and then scraping material/hair from the lesions of scalp of patient subjected to KOH microscopic examination. The patient showing positive microscopic finding for dermaotophytes in the KOH preparation were subjected to detailed history through clinical examination and investigation as per the predesigned proforma.

Clinical assessment severity score

A clinical assessment severity score was assessed using following clinical parameters before starting treatment were erythema, pruritus, oedema, and desquamation, hair loss. This was assessed on a four point scale of 0-none, 1-mild, 2-moderate and 3-severe.

Drug distribution

One hundred fifty eight patients were prescribed to receive either oral griseofulvin or terbinafine on Alternate basis. The drugs were given on the basis of weight as follows:

Table 1: Drugs administered on the basis of weight of study participants.

Weight	Griseofulvin (once daily for 4 weeks)	Terbinafine (once daily for 4 weeks)
<20 kg	125 mg/day	62.5 mg/day
20-40 kg	250 mg/day	125 mg/day
>40 kg	500 mg/day	250 mg/day

Patient in the both group were followed up at 2, 4, 12 and 36 weeks. At every visit clinical improvement was evaluated using clinical assessment severity score. The complaint, tolerability and side effects of the drugs were assessed at each visit. Hematological and biochemical investigation were done at 0, 2 and 4 weeks. KOH microscopy was repeated at every visit and culture was put at before initiation of treatment, and after 2, 4 and 12 week completion, in each group. Hair were plucked from the affected area with a sterile forceps along with scraping of the scales and inoculated in the medium for culture. Sabouraud's Dextrose Agar medium was used to isolate the dermatophytes.

Clinical cure

It referred to all patients with clinical assessment score of ≤2.

Mycological cure

It referred to negative microscopy and culture. Baseline parameters between the two drug groups were compared using chi square test. Difference in efficacy in terms of clinical, mycological and complete cure rate was calculated. A result of chi square test with a P value of ≤0.05 was taken as significant.

RESULTS

In the study period total cases of skin, STI and leprosy, attending outdoor Department of Dermatology, Venerology and Leprosy were 34536 which includes 1233 case of dermatophytic infection containing 304 cases of T. capitis in children. One hundred fifty eight untreated cases of T. capitis were selected on the basis of inclusion and exclusion criteria and divided into two groups of seventy nine patients each. One group received griseofulvin (G) and other terbinafine (T) orally.

The age in the study population ranged from 2 to 12 years (mean 7.8 years). Majority of the patients (71%) were in the age group of 6-10 years and 95% were below 10 years. Out of the 158 patients, 38% were males and 62% were females. The female to male ratio was 1.6:1 (Table 2).

Most common symptom in the present study was scaling, reported in 94.9% of the patients followed by itching, hair loss, and papules in 78.4%, 69.6%, and 31.6% of the patients respectively (Table 3/Figure 2).

On fungal culture *T. violeceum* was the commonest isolate seen in 56/106 (52.8%) of, the culture positive cases, followed by *T. mentagrophytes* (20.7%), and *T. rubrum* 16.9% of patients. *M. canis* was isolated from 7.5% patients and *M. audouinii* was the least common and recovered in only 1.8% of patients (Table 4/Figure 1).

The clinical assessment score were statistically similar in group G and group T at the start of therapy. The decline in scores in both treatment groups was statistically significant at each follow up visit. In griseofulvin group, the mean score was declined from 5.9 at baseline to 4.24 at week 2 and 2.79 at week 4, 0.82 at week 12 and1.24 at 36 week. In the terbinafine group, the score had a mean of 6.23 at 0 week and 4.03 at week 2, 2.32 at week 4, 0.69 at week 12 and 0.83 at week 36. The reduction in clinical assessment score in terbinafine group was more is compared to griseofulvin group at each follow up visit. However, this difference was not statistically significant (Figure 3).

Table 2: Age and sex distribution of 158 patients.

Age group in year	Male		Female		Total (%) (n=158)
	G group	T group	G group	T group	
<5	06	08	14	10	38 (24)
6 to 10	20	22	34	36	112 (70.8)
>10	03	01	02	02	08 (5)
Total	29	31	50	48	158

Table 3: Clinical symptoms in patients with T. capitis.

Clinical symptoms	Group G	Group T	Total
	N (%)	N (%)	N (%)
Itching	60 (37.9)	64 (40.5)	124 (78.4)
Scaling	72 (45.5)	76 (48.1)	150 (94.9)
Hair loss	58 (36.7)	52 (32.9)	110(69.6)
Papules	22 (13.9)	28 (17.7)	50 (31.6)
Pustules	22 (13.9)	18 (11.3)	40 (25.3)

Table 4: Etiological agents in patients with T. capitis on culture.

Etiological agent	Group G	Group T	Total (n=106)
	N (%)	**N (%)**	**N (%)**
T. violeceum	28 (26.4)	28 (26.4)	56 (52.8)
T. rubrum	10 (9.43)	8 (7.54)	18 (16.9)
T. mentagrophytes	8 (7.54)	14 (13.2)	22 (20.7)
M. audouinii	2 (1.88)	0	2 (1.88)
M. canis	2 (1.88)	6 (5.66)	8 (7.54)
Total	50 (47.2)	56 (52.8)	106 (100)

Table 5: Clinical assessment score.

Follow up scores	Pre-treatment	During treatment		Follow-up	Follow up
	0 week	2 weeks	4 weeks	12 weeks	36 weeks
Group G	5.9 (79)	4.24 (70)	2.79 (64)	0.82 (60)	1.24 (27)
Group T	6.23 (79)	4.03 (74)	2.32 (68)	0.69 (64)	0.83 (30)
P value	0.85	0.91	0.60	0.32	0.015

*Number in bracket show the number of patients followed up at that week.

Table 6: Clinical cure.

Weeks of therapy	2 weeks	4 weeks	Follow up (12 weeks)	Follow up (36 weeks)
Group G	15/70 (21.4)	32/64 (50)	54/60 (90)	18/27 (66.6)
Group T	26/79 (32.5)	54/68 (79.3)	60/64 (93.7)	27/30 (90)
P value	0.16	0.013	0.40	0.016

*Figure in parentheses show the percent of patients achieving clinical cure.

Table 7: Mycological cure (KOH microscopy and culture negative).

Weeks of therapy	2 weeks	4 weeks	Follow up (12 weeks)	Follow up (36 weeks)
Group G	32/70 (46)	60/64 (93.7)	58/60 (96.6)	20/27 (74)
Group T	38/74 (51.3)	60/68 (88)	62/64 (96.8)	27/30 (90)
P value	0.68	0.76	0.98	0.024

*Figure in parentheses show the percent of patients achieving mycological cure.

Table 8: Side effects and tolerability.

Tolerability	Group G (n=79)	Group T (n=79)	Total (n=158)
	N (%)	**N (%)**	**N (%)**
No side effects	73(92)	69 (87)	142(90)
Side effects noted	06 (8)	10 (13)	16(10)

Table 9: Adverse effects.

Side effects	Group G (n=79)	Group T (n=79)	Total (n=158)
	N (%)	**N (%)**	N (%)
Pain abdomen	1 (1.2)	2 (2.5)	4
Diarrhoea	3 (3.7)	2 (2.5)	6
Dryness and somnolence	00	4 (5)	4
Lethargy	00	2 (2.5)	2
Photo eruption	02 (2.5)	00	02
Haematological and biochemical abnormality	00	00	00
Total	6 (8)	10 (13)	16

Clinical cure (clinical assessment score ≤2)

Patients in both group G and T showed a gradual reduction of clinical assessment score at various follow up intervals. The number of patients with score of ≤2 (clinical cure) at 2 weeks was 21.4% in gresiofulvin group and 32.5% in terbinafine group. The patients with clinical cure increased to 50% of griseofulvin group and 79.3% of terbinafine group at the end of therapy. This difference in clinical cure was significant.

Clinical cure at 12 week in terbinafine group was, in 93.7% of patients and it was maintained also at 36 week, in 90% of patients. But in group G, clinical cure at 12 week was, in 90% of patients but it decreased and it was only in 66.6% of patients at 36 week (Figure 4 and 5).

About 93.7% patients attend mycological cure at 4 weeks in greisofulvin group, while 88% of patients in terbinafine group. This difference was insignificant. In group T, 96.8% of patients attend mycological cure at 12 week and it was maintained in 90% of patients at 36 week. But in group G, 96.6% of patients attended mycological cure at week 12 and it decreased and was maintained only in 74% of patients at 36 week. This difference in two groups was significant (Figure 5).

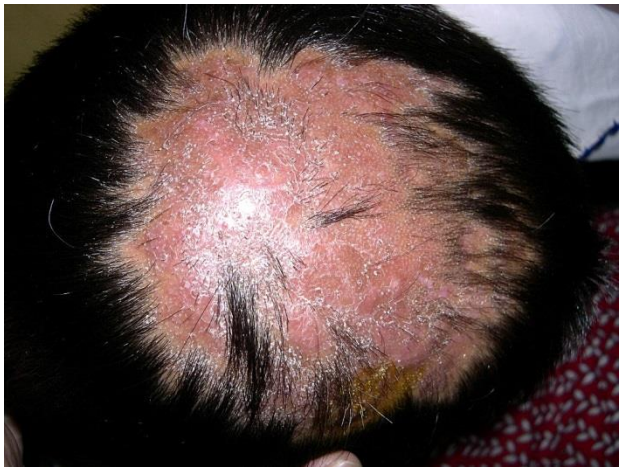

Figure 1: Kerion T. capitis.

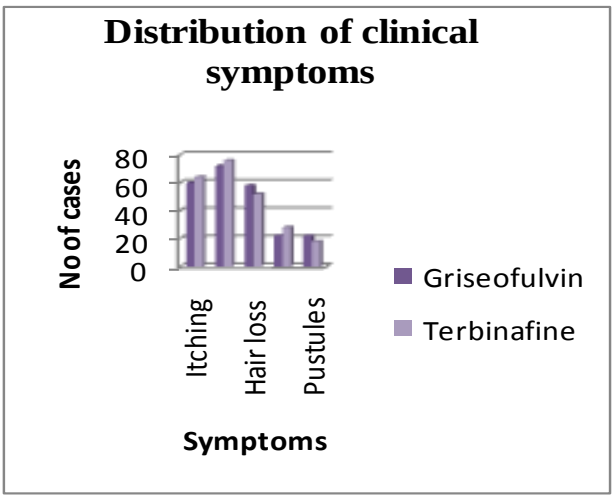

Figure 2: Distribution of clinical symptoms among study participants.

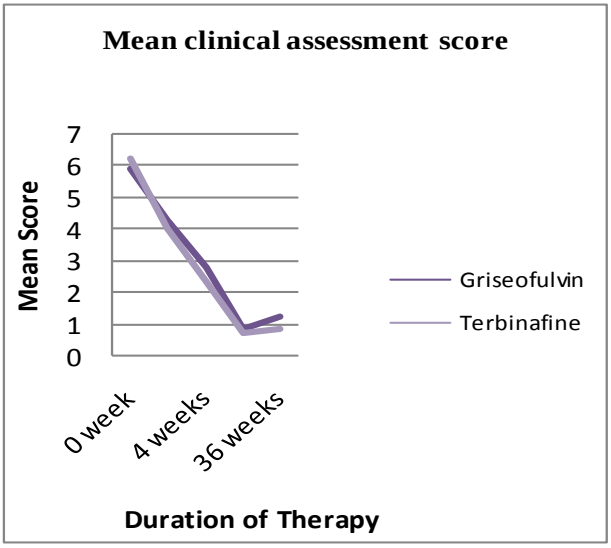

Figure 3: Mean clinical assessment score among study participants.

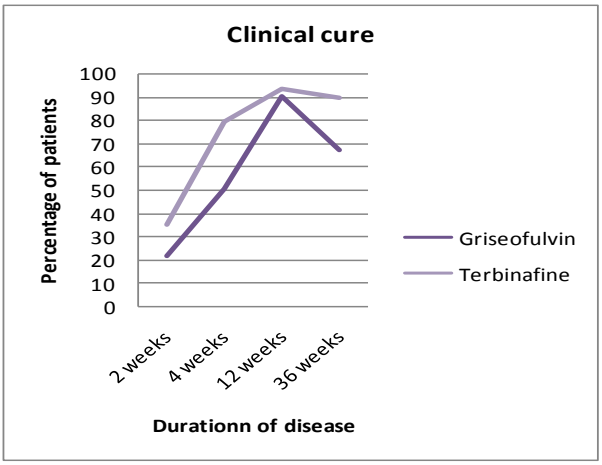

Figure 4: Status of clinical cure among study groups.

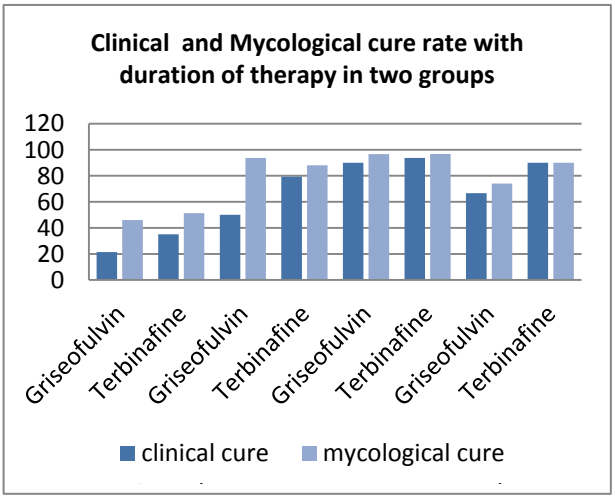

Figure 5: Clinical & mycological cure rate in relation with duration of therapy in study groups.

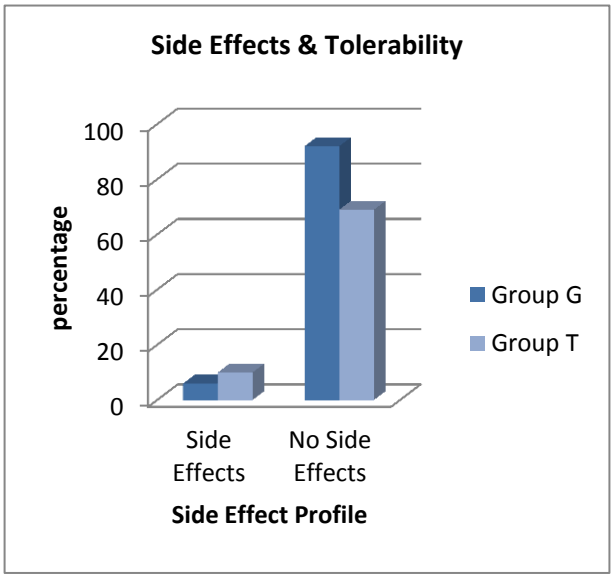

Figure 6: Safety and tolerability of study drugs on both the groups.

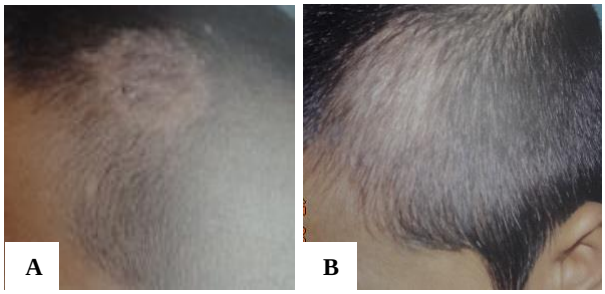

Figure 6: (A) Grey patch before treatment; (B) grey patch after 12 week of treatment.

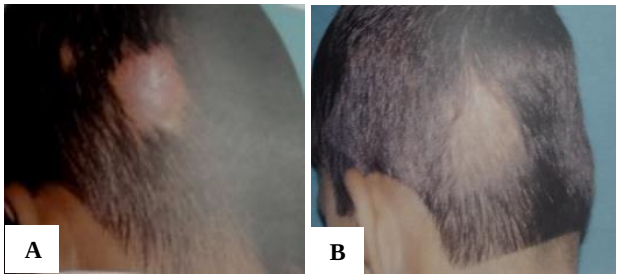

Figure 7: (A) Kerion before treatment; (B) Kerion after 12 week of treatment.

One hundred forty two patients out of 158 patients (90%) were able to tolerate the therapy without any side effects either observed by patients or observer. Side effects were seen in 10% (16/158) patients. Tolerability was assessed by observer and patients as very good/good in 88% (69/79) of the patients treated with terbinafne group and 93% (73/79) in griseofulvin treated group.

Side effects

The most common side effects noted were diarrhea in G group and dryness and somnolence in T group.

In the group G, total 8% of patients complained of some side effects during treatment period or follow up period. Out of which 3.7% of patients complained of diarrhoea, 1.2% patient's pain abdomen and 2.5% patients complained of photo eruption on face. In group T, total 13% of patients complained of some side effects. Out of this 5% of patients complained of dryness and somnolence, 2.5% patients complained of pain abdomen, diarrhoea, and lethargy separately. Haematological and biochemical investigation abnormality were not recorded in any patients in either group in study period. All these side effects noted in the study patients were mild and subsided within 1 week and did not require the discontinuation of therapy (Figure 6).

DISCUSSION

About 158 patients were included in the study. The mean age of the study population was 7.8 years. Most of the patients were under 10 years of age only eight patients were above 10 years of age. 70.8% of total patients were between 6-10 years of age. Similar to my study, a study carried out in by Kumar et al also reported the maximum incidence in same age group of 6-10 years. About 95% of the study population was under 10 years of age.[8] In the present study, out of 158 patients, 98 (62%) were females and 60 (38%) were males with female male ratio of 1.6:1. There was an overall preponderance of girls in our study. This was also observed by Reddy et al and Dastghaib et al.[9,10]

Most common symptoms of the patients presenting with T. capitis in our study was scaling seen in 94.9% of the patients followed by itching, hair loss, and papules in 78.4%, 69.6%, and 31.6% of the patients respectively. Our findings are similar to the results reported by Figueroa et al in Ethopia.[11] Non inflammatory variants (73%) were more common than the inflammatory variants. This is in accordance with majority of the previous studies from India and West. Sahgal et al reported a much higher incidence of 84% of non-inflammatory variants in their study.[12] Kerion was observed in 26% of all our cases. The incidence of kerion has greatly varied in other studies. Sahgal et al reported kerion in 18%, while Kumar et al and Singal et al observed an incidence of 10% and 6.5% respectively in their studies.[8,12,13]

Clinical assessment scores

The efficacy of griseofulvin and terbinafine has not been compared in north eastern part of India. There was a significant reduction in clinical assessment score in both groups at each follow up from baseline. The reduction in mean score was more in terbinafine group as compared to griseofulvin group at the end of therapy but the difference was not statistically significant. Similar reduction in score was also noted by Cáceres-Ríos et al.[6] However, they noted a worsening of clinical scores in griseofulvin treated group between 8th and 12th visit week. Contrary to our findings, they also observed that the score reduction in terbinafine group was significantly more than griseofulvin group at the end of 12 week.

Clinical cure

This parameter has not been evaluated in any of the previous studies comparing the efficacy of griseofulvin and terbinafine. In the present study clinical cure rate at each follow up period was better in terbinafine group than griseofulvin It can be inferred that patients on terbinafine achieved more cure (at 4 weeks) when compared to griseofulvin. More ever the response was also maintained at follow up interval at 12 week and 36 week in terbinafine group which shows its reservoir action after completion of therapy.

Mycological cure

Mycological cure with griseofulvin and terbinafine has not been compared from North Eastern part of India. In

the present study, mycological cure rate achieved after 2, and 4 weeks of griseofulvin therapy was higher than of terbinafine therapy. Fuller et al and Gupta et al also did not notice any statistically significant difference in mycological cure.[14,15] Mycological cure rates achieved in our study may appear to be higher as compared to western countries because of overall lower isolation rates on fungal culture. Mycological cure achieved in group T, was maintained at 36 week, while it was decreased from 94% to 74% in griseofulvin group. This may be due to long lasting tissue action of terbinafine which is not present in griseofulvin. In contrast, Caceres et al in their analysis of 50 patients found that mycological cure rate in terbinafine group at 12 week was significantly higher than griseofulvin group.

Side effects and tolerability

Tolerability as assessed by investigator in our study was 87% in terbinafine group and 92% in griseofulvin group. Griseofulvin was well tolerated in a larger number of patients as compared to terbinafine group. Similar results were seen in study by Fuller et al, which showed the tolerance assessed by investigator in griseofulvin group was 88% as against 83% in terbinafne group.[14] Side effects were noted in 10% of the total population in our study. The incidence of side effects was less as compared to study by Fuller et al which have shown side effects in 42% and 31% of the patient's respectively.[14]

The most common side effects noted in our study was GIT side effects like abdominal pain and diarrhoea, seen in 9 patients (6%) of the study population. Fuller et al noticed GI side effects in 12% of griseofulvin treated group and 7% of the terbinafine treated group.[14] GIT side effects were seen in only 4% of the study population by Caceres et al.[6] Dermatological side effects were the most common side effect seen by Fuller et al, while Lipozencic et al reported fever and pharyngitis as most common side effect in their study.[14,16] Such side effects were not encountered in the present study. Complaints of dryness and somnolence were noted in 6% of patients of terbinafine group by Lipozencic et al.[16] Lipozencic et al reported neutropenia in 1 patient treated with terbinafine.[16] All side effects noted in our study were mild and did not require the discontinuation of the therapy. Similarly, no serious side effects were noted by other comparative studies of terbinafine and griseofulvin group.

CONCLUSION

One hundred fifty eight, untreated cases of clinically diagnosed T. capitis and confirmed by KOH microscopic examination, subjected to detailed history and clinical examination. A clinical assessment severity score was assessed using following clinical parameters of erythema, pruritus, oedema, desquamation and hair loss. Baseline hematological and biochemical investigations were done. One hundred fifty eight patients of T. capitis were divided into two groups of 79 patients each to receive either oral griseofulvin or terbinafine (according to weight). Patients in both the groups were followed up at 2, 4, 12 and 36 weeks. At every visit, clinical improvement was evaluated using clinical assessment severity score and the compliance, tolerability and side effects of the drugs were assessed along with KOH microscopy, fungal culture from the lesion and relevant blood investigations.

The efficacy of the drugs was assessed as clinical and mycological cure observed at end of therapy and follow up period. Fungal culture was positive in 106/160 (66.6%) of the total patients. Approximately 50% of the G group patients and 79% of T group patients attained clinical cure at end of the therapy. Clinical cure was higher in terbinafine group. It was also higher at 36 week follow up.

About 93.7% of G group patients and 88% of T group patients had shown a mycological cure at end of the therapy at 4 week. It was decreased at 36 week of follow up and was present in only 74% of cases in G group, but it was maintained above 90% in T group. Tolerability assessed was 87% in terbinafine group and 92% in griseofulvin group; griseofulvin was better tolerated from terbinafine. The most common side effect noted in griseofulvin group was GIT side effects including abdominal pain and diarrhoea and in terbinafine group was dryness and somnolence. No serious side effects were noted in either terbinafine or griseofulvin group.

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Ethical approval: The study was approved by the institutional ethics committee

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