

Research Article

A comparative study of mycological efficacy of terbinafine and fluconazole in patients of tinea corporis

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Abstract

Objectives: This study aimed to compare the efficacy of terbinafine and fluconazole in terms of Mycological cure in the treatment of tinea corporis.

Material and methods: Total 116 tinea corporis patients who were not responding to topical antifungal therapy of 2 weeks were selected and they were randomly divided into two groups. Group-I received oral terbinafine (250 mg) daily for 4 weeks. Group-II received oral fluconazole (150 mg) once weekly for 4 weeks. Evaluation is done by mycological assessment (KOH and Culture examination) at the end of treatment.

Results: Mycological cure was noted in 36/42 (85.71%) patients in the group-I and in 37/50 (74%) patients in the group-II at the end of the treatment period. The difference between treatments at this point was not statistically significant ($P > 0.05$).

Conclusion: In view of the above findings, it is suggested that both fluconazole and terbinafine are quite effective in the treatment of tinea corporis patients in terms of Mycological cure. Terbinafine shows slightly better results than fluconazole ($P > 0.05$). The lower cost and once weekly schedule of fluconazole may favor patient compliance with lesser number of drop-outs.

Keywords: fluconazole, terbinafine, Tinea corporis, Mycological cure rate.

1. Introduction

Tinea corporis is a superficial dermatophyte infection characterized by either inflammatory or non-inflammatory lesions on the glabrous skin (i.e. skin regions except the scalp, groin, palms, and soles). It is most commonly caused by Trichophyton species, that digest keratin in the cells of the stratum corneum. *T. rubrum* is the most common infectious agent in the world and is the source of 47% of tinea corporis cases.¹

Patients typically present with an annular patch or plaque with an advancing, raised, scaling border and central clearing. The tinea corporis infection begins as flat, scaly, and often pruritic macules that subsequently develop a raised border and begin to spread radially. As the ring expands, the central portion of the lesion often clears. This pattern leads to the formation of irregular circles that gives tinea corporis its common name, ringworm.

Most patients with tinea corporis are diagnosed clinically. To avoid a misdiagnosis, identification of dermatophyte

infections requires both a fungal culture on Sabouraud's agar media, and a mycological examination, consisting of a 10% to 15% KOH preparation, from skin scrapings.

Although topical antifungals may be sufficient for treatment of tinea corporis, but systemic medications are used for patients with severe infection, for infections that do not respond to topical therapy, when the infected areas are large, macerated with a secondary infection, or in immunocompromised individuals.

Common systemic antifungal agents used are oral griseofulvin, terbinafine, fluconazole and itraconazole. Azole and Allylamine agents appear to have greater efficacy and fewer side effects than oral Griseofulvin. Terbinafine and itraconazole are equally effective in treating tinea corporis.^{2,3} An alternative is fluconazole which is given orally once a week for up to four consecutive weeks.^{4,5} Fluconazole, a synthetic triazole derivative, is an azole antifungal agent. Terbinafine is an allylamine. It is a synthetic antifungal agent. In earlier studies fluconazole has not been evaluated in direct comparison with terbinafine in the treatment of tinea corporis. Our study is a comparative study between fluconazole and terbinafine in terms of efficacy expressed as mycological cure.

2. Material and Methods

This prospective, parallel, open-label, randomized, comparative clinical trial was conducted in the department of pharmacology in collaboration with department of skin and venereal diseases from february 2010 to January 2011 at S. N. Medical College & Associated Hospital, Agra. Patients were randomly selected from the tinea cases of extensive tinea corporis attending skin OPD. Approval of Institutional Ethical Committee was taken to conduct the above study.

2.1. Inclusion criteria

Tinea corporis patients of both sexes and age between 20-45 years, patients who were not responding to topical antifungal therapy of 2 weeks, patient must be culture positive, patients from Agra or around Agra, patients do not having any other systemic disease, patients ready for therapy after knowing adverse effects.

2.2. Exclusion criteria

Evidence of hepatic or renal disease, pregnant females, nursing mother, age <20 years and >45 years, hypersensitivity or intolerance to treatment, patients who takes cisapride.

2.3. Workup before therapy

After selecting the patient, a detailed clinical record was prepared including age, sex, address, occupation, family history, duration of the disease, size and extent of lesions, history of previous treatments. Then cases were examined in detail for local and systemic examination. After that all patients were subjected to necessary investigations which include-Hb, TLC, DLC, ESR, blood sugar, weight of patient, SGPT/ SGOT, serum creatinine, urine analysis. The investigations were repeated after 2weeks and after end of treatment.

2.4. Methods

All the patients of tinea corporis attending to the out patients department were selected for the study, on the basis of inclusion and exclusion criteria. Total 116 patients were selected and they were randomly divided into two groups. Two groups which were compared and evaluated are as follows:

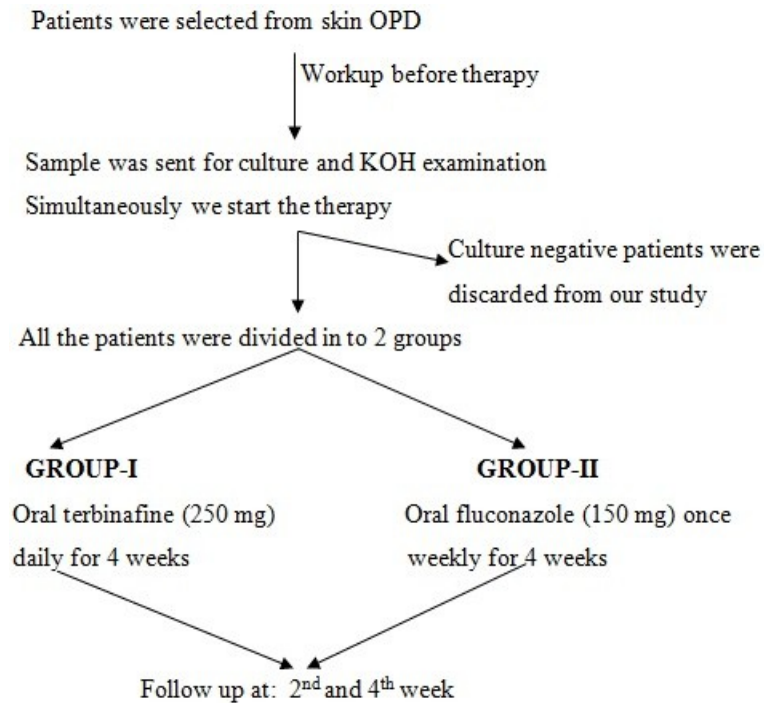
(A) GROUP I (Daily Oral terbinafine)

In this group patients were given oral terbinafine (250 mg) daily at morning time after breakfast for 4 weeks.

(B) GROUP II (Weekly Oral Fluconazole)

In this group patients were given oral fluconazole (150 mg) once weekly at morning time after breakfast for 4 weeks.

Out of 116 patients 24 patients missed during the treatment period. Therefore only 92 patients were included in the study for detail analysis(42 patients in the terbinafine group and 50 patients in the fluconazole group).

Fig-1 Showing flow diagram of material and method

2.5. Follow up and evaluation

Patients were followed at 2nd week and 4th week (after the end of treatment).

At 2nd week repeat only necessary investigations like, Hb, TLC, DLC, ESR, blood sugar, weight of patient, SGPT/SGOT, serum creatinine, urine analysis (no mycological assessment at 2nd week).

Evaluation after the completion of treatment is done by:

- KOH and
- Culture examination

Mycological cure rates: The term “Mycological Cure” is defined as both negative KOH and culture result.

2.6. Statistical analysis

The data was analyzed using online statistical calculators. Fisher Exact Probability Test was used to compare the data of both groups. $P < 0.05$ was considered as statistically significant.

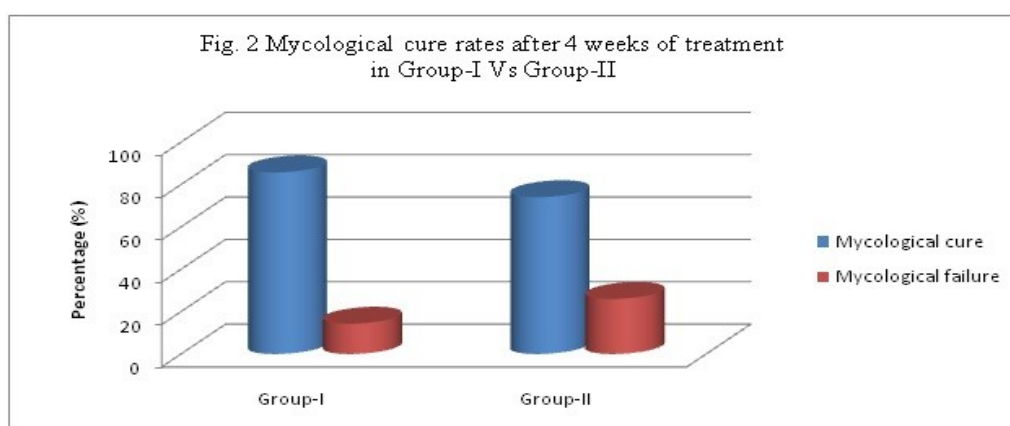
3. Results

In present study, total of 92 patients of tinea corporis of age group 20-45 yrs were analyzed. Among them 42 patients were given daily therapy of terbinafine (group I) and 50 patients were given weekly therapy of fluconazole (group II). A detailed analysis revealed that the disease was more common in males, the male to female ratio being 1.36:1 i.e. 57.61% were males and 42.39% were females (Group I- 1.47:1, Group II-1.27:1). The mean age of the sample was 30.36 ± 6.64 years (Group I- 30.40 ± 6.69 years and Group II- 30.32 ± 6.67 years). The maximum number of patients i.e. 51 (55.43%) were in age group 21-30 years. Lower extremities were the most common site of involvement i.e. 51 patients (55.43%). The most common causative organism reported was *T. rubrum* 51 cases (55.43%).

Table 1: Baseline mycological findings in group-I and group-II

Symptoms	Group-I		Group-II		Total	
	No.	%	No.	%	No.	%
Culture Positive KOH Positive	38	90.48	46	92.00	84	91.30
Culture Positive KOH Negative	4	9.52	4	8.00	8	8.70
Total	42	100.00	50	100.00	92.00	100.00

At baseline out of 92 patients all were culture positive whereas 8 patients showed negative KOH microscopy. Therefore 84 patients (91.30%) were Culture Positive and KOH Positive whereas 8 patients (8.70%) were Culture Positive and KOH Negative.



mycological cure was noted in 36/42 (85.71%) patients in the group-I and in 37/50 (74%) patients in the group-II at the end of the treatment period.

4. Discussion

Tinea corporis occurs worldwide and is relatively frequent, but its incidence is higher in tropics and subtropics. Males are infected more than females. Infection can occur from direct or indirect contact with skin and scalp lesions of infected persons or animals.

Topical therapies for treatment of tinea corporis include terbinafine, butenafine, econazole, miconazole, ketoconazole, clotrimazole, and ciclopirox. Topical formulations may eradicate smaller areas of infection, but oral therapy may be required where larger areas are involved or where infection is chronic or recurrent.⁶ Oral itraconazole, terbinafine, and fluconazole have been used successfully in the treatment of tinea corporis/ tinea cruris.

Out of 92 patients, 53 were male and 39 were female. A predominance of male patients was seen. The overall male to female ratio in the study was 1.36:1, i.e. 57.61% were males and 42.39% were females. In a study by KM Acharya et al, 1995 the male to female ratio was 1.86, i.e. 65.00% were males and 35.00 % were females.⁷

The mean age of patients was 30.36 ± 6.64 years. The youngest person was of 21 years and the eldest was of 45 years. The maximum number of patients i.e. 51 (55.43%) were in age group 21-30 years and the least number of patients i.e. 8 (8.70%) belongs to age group between 41-45 years. In a study by J. Decroix et al, 1997, the mean age of tinea corporis/ tinea cruris patients was 39.7 years.^[8]

In the present study the most common causative organism isolated after culture report was *T. rubrum*, 51 cases (55.43%) followed by *T. tonsurans*, 20 cases (21.74%), *M. canis*, 11 cases (11.96%) and *T. Mentagrophytes*, 10 cases (10.87%). In a research study conducted by G. Venkatesan et al. shows *T. rubrum* (69.6%) was the major causative species

isolated, followed by *T. mentagrophytes* (28.2%) and *M. gypseum* (2.2%) from tinea corporis patients.⁹

The mycological cure was noted in 36/42 (85.71%) patients in the group-I i.e. terbinafine group and in 37/50 (74%) patients in the group-II i.e. fluconazole group at the end of the treatment period. The difference between treatments at this point was not statistically significant ($P > 0.05$).

Fluconazole has not been evaluated in direct comparison with terbinafine in the treatment of dermatophytic skin infections. But the non-comparative or comparative studies of fluconazole or terbinafine with other drugs separately are reported so far.

Faergemann *et al* compared fluconazole 150 mg once a week with griseofulvin 500 mg once a day for 4-6 weeks in the treatment of tinea corporis and tinea cruris. In the fluconazole group, 74% (80 out of 114) were clinically cured; in the griseofulvin group, 62% (72 out of 116) were likewise without symptoms. Fluconazole once a week for 6 weeks was both clinically and mycologically effective in the treatment of tinea corporis and tinea cruris.¹⁰

In a study by Voravutinon V. the 250 mg of oral terbinafine once daily or 500 mg of griseofulvin once daily for 2 wks. The results after 6 wks follow-up, showed the mycological cure in terbinafine and griseofulvin group was 87.1 and 54.8 percent, respectively. The clinical response of the terbinafine group was also significantly higher than in the griseofulvin group.¹¹

5. Conclusion

Tinea corporis is a common problem encountered in dermatology practice. It is more common in males than females. It mainly involves Lower extremities and trunk. *T. rubrum* is the most common causative organism. Both fluconazole and terbinafine are quite effective in the treatment of tinea corporis patients in terms of mycological cure. Terbinafine shows slightly better results than fluconazole but the difference between these two is not statistically significant ($P > 0.05$).

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