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Research Article

Comparative Evaluation of Efficacy & Safety of Oral Terbinafine versus Fluconazole in Patients with Tinea Corporis

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ABSTRACT
Background: Tinea corporis is among the most common dermatophyte infections in India and often requires systemic therapy when topical treatment fails. Terbinafine and fluconazole are widely used systemic antifungals with differing pharmacological profiles.
Objectives: To compare the efficacy and safety of oral terbinafine 250 mg once daily for 2 weeks versus oral fluconazole 150 mg once weekly for 4 weeks in adults with tinea corporis.
Methods: In this observational comparative study conducted at a tertiary care center (November 2020–October 2021), 30 KOH-positive adults with Tinea corporis ≥10% body-surface area involvement, recurrent disease and non-response to topical therapy were randomized to receive either terbinafine or fluconazole. Patients were followed at weeks 0, 1, 2, 3, 4, 5 and 8 for clinical signs & symptoms (erythema, scaling, itching), adverse events and laboratory safety parameters. Compliance was assessed by pill counts. Primary endpoint was clinical cure at end of therapy; secondary endpoints included change in individual signs and relapse during follow-up.
Results: Of 30 participants (93% male; mean age 31.6±10.6 vs 34.5±14.1 years in terbinafine and fluconazole groups), clinical cure rates were 100% with terbinafine versus 79% with fluconazole. Itching resolved completely with terbinafine and improved with fluconazole (post-treatment mean 0.21±0.43). Erythema and scaling resolved in both groups. One patient in the fluconazole arm developed a maculopapular rash after the first dose and was withdrawn. Relapse occurred in 5/14 (36%) evaluated patients in the fluconazole arm within four months; none relapsed in the terbinafine arm. No clinically significant laboratory abnormalities were observed.
Conclusions: Short-course oral terbinafine (250 mg daily for 2 weeks) achieved higher clinical cure with zero relapse compared with fluconazole (150 mg weekly for 4 weeks) in adults with extensive tinea corporis, with good overall tolerability. However, larger blinded trials with mycologic endpoints are warranted.

Keywords: Tinea Corporis; Terbinafine; Fluconazole; Dermatophytosis; Antifungal Therapy; Comparative Study.

INTRODUCTION

Dermatophytes invade keratinized tissues (skin, hair, nails) causing superficial infections[1]. They are classically grouped into Trichophyton, Epidermophyton and Microsporum genera[2,3]. Clinically, disease is categorized by anatomic site (e.g., tinea capitis, corporis, cruris, pedis)[4]. India's tropical climate, characterized by high temperature and humidity, overcrowding, poor hygiene, and widespread irrational use of topical corticosteroid–antifungal combinations has

contributed to an alarming increase in chronic, recurrent, and extensive dermatophytosis. Topical antifungal agents remain the first-line therapy for localized disease. However, systemic antifungal therapy is indicated in cases of: Extensive involvement (≥10% body surface area), Recurrent or chronic dermatophytosis, Failure of topical therapy, and Immunocompromised status[5]. Terbinafine is an allylamine with fungicidal activity via squalene epoxidase inhibition, while fluconazole is a triazole with fungistatic activity via 14-α-demethylase inhibition[6,7]. Few head-to-head comparing data of these two drugs exist for tinea corporis in Indian settings[8].

MATERIALS AND METHODS

Study Design and Setting: An Observational comparative study was conducted in the Department of Pharmacology, Andhra Medical College in collaboration with the Department of Dermatology & Venereology, King George Hospital, Visakhapatnam for 12 months. Ethics approval was obtained from the Institutional Ethics Committee.

Participants:

Inclusion Criteria: Adults (18–60 years) with clinical tinea corporis involving ≥10% body surface area, recurrent disease, KOH-positive microscopy, and non-response to topical therapy were included.

Exclusion Criteria: patients with renal/hepatic/cardiac/hematologic disorders, and those who were pregnant or lactating were excluded. Written informed consent was obtained.

Randomization and Interventions: Thirty patients were randomized to two groups of 15 patients in each group:

- Terbinafine 250 mg orally once daily for 2 weeks (Group A)
- Fluconazole 150 mg orally once weekly for 4 weeks (Group B)

Assessments and Endpoints: Follow-up visits were scheduled at weeks 0, 1, 2, 3, 4, 5, and 8. Clinical signs and symptoms including erythema, scaling, and itching, were scored. Safety laboratory parameters (random blood sugars, complete blood picture, liver function tests, renal function tests) and electrocardiogram were recorded at baseline and at week 5. Compliance was assessed via pill counts, with ≥80% considered good. The primary endpoint was clinical cure at the end of therapy, while secondary endpoints included changes in clinical signs and relapses within four months.

Statistics: Data are presented as mean ± SD. Within- and between-group comparisons were performed using paired/unpaired Student's *t*-tests, with significance set at $p < 0.05$. Categorical variables such as clinical cure rate were expressed as frequency and percentage, and comparison between the two groups was performed using the Chi-square test.

RESULTS

Cohort: Thirty patients were enrolled (28 males, 2 females). The mean age was 31.6 ± 10.6 years in the terbinafine group and 34.5 ± 14.1 years in the fluconazole group. Vital signs and baseline laboratory parameters were within normal limits.

Primary Endpoint: Clinical cure at the end of therapy was achieved in 100% of patients receiving terbinafine versus 79% in the fluconazole group.

Secondary Endpoints: Itching improved significantly in both groups ($p < 0.001$), with complete resolution in the terbinafine group; the post-treatment itching score in the fluconazole group was 0.21 ± 0.43. Erythema and scaling resolved in both groups ($p < 0.001$ within groups; no significant between-group difference). One fluconazole-treated patient developed a maculopapular rash after the first dose and was withdrawn from the study. Relapse occurred in 5 of 14 (36%) evaluable fluconazole-treated patients within four months, whereas no relapses were observed with terbinafine.

Safety: No clinically meaningful changes were observed in lab parameters CBP, LFT, RFT, or ECG in either group.

Tables

Table 1. Demographics and baseline characteristics

Variable	Terbinafine 250 mg OD (2 wks)	Fluconazole 150 mg weekly (4 wks)
Age (years)	31.6 ± 10.6	34.5 ± 14.1

Height (cm)	166.0 ± 3.6	167.4 ± 5.5
Weight (kg)	62.5 ± 8.9	64.9 ± 8.5
Temperature (°F)	98.52 ± 0.10	98.49 ± 0.10
Pulse rate (/min)	78.66 ± 0.97	78.53 ± 0.92
Respiratory rate (/min)	18.4 ± 0.82	18.4 ± 0.83
Systolic BP (mmHg)	118.6 ± 3.5	118.0 ± 4.14
Diastolic BP (mmHg)	72.66 ± 4.5	72.0 ± 4.14

Table 2. Clinical Signs and Symptoms (Mean ± Sd) Before and After Treatment

Parameter	Terbinafine (Before)	Terbinafine (After)	Fluconazole (Before)	Fluconazole (After)
Erythema	2.4 ± 0.51	0	2.14 ± 0.36	0
Scaling	2.13 ± 0.35	0	2.21 ± 0.43	0
Itching	3.0 ± 0.0	0	2.93 ± 0.27	0.21 ± 0.43

Table 3. Treatment Exposure and Clinical Cure

	Terbinafine	Fluconazole
Dose	250 mg daily	150 mg once weekly
Duration	2 weeks	4 weeks
n	15	15
Clinical cure after therapy (%)	100	79

Figures

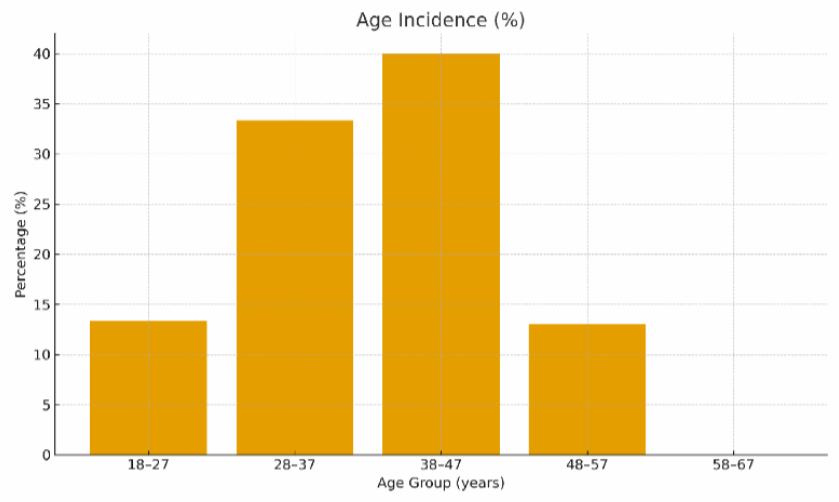

Figure 1. Age incidence (%) in study cohort

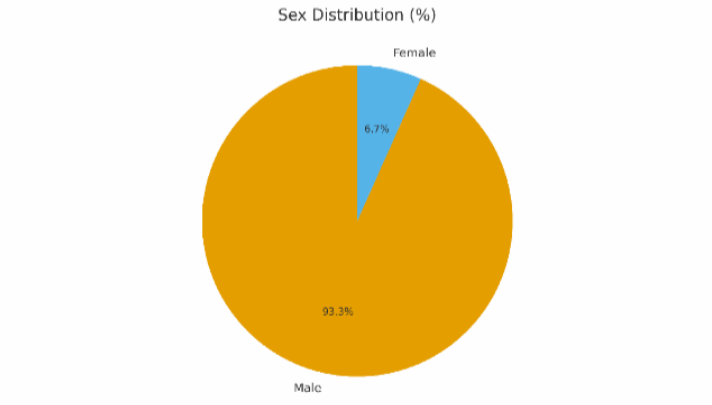

Figure 2. Sex distribution (%)

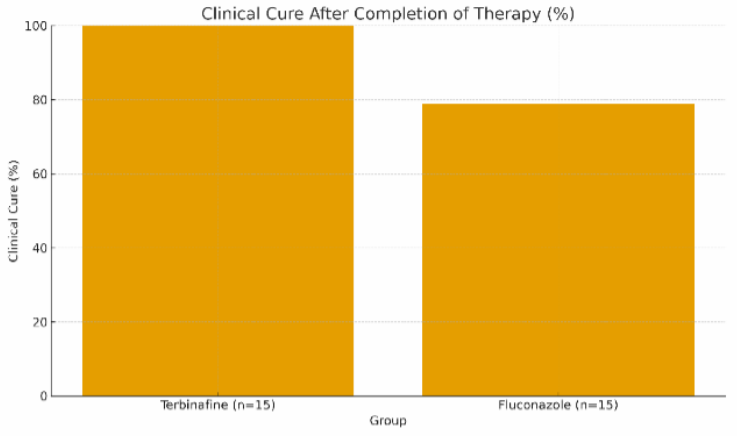

Figure 3. Clinical cure after completion of therapy (%)

DISCUSSION

The present prospective comparative study evaluated the efficacy and safety of oral terbinafine (250 mg once daily for 2 weeks) versus oral fluconazole (150 mg once weekly for 4 weeks) in adult patients with extensive, KOH-positive tinea corporis attending a tertiary care hospital. The study demonstrated a higher clinical cure rate and markedly lower relapse rate with terbinafine compared with fluconazole.

The primary endpoint—clinical cure at completion of therapy—was achieved in 100% of patients in the terbinafine group compared with 79% in the fluconazole group. This difference, although derived from a small sample, is clinically meaningful in the context of extensive dermatophytosis[6,9,10,11–13]. Furthermore, relapse during the four-month follow-up period was observed in 36% (5/14 evaluated patients) in the fluconazole arm, whereas no relapses were documented in the terbinafine group.

Terbinafine is a fungicidal agent that inhibits squalene epoxidase, leading to ergosterol depletion and intracellular squalene accumulation, ultimately resulting in fungal cell death. In contrast, fluconazole is primarily fungistatic, inhibiting 14-α-demethylase and suppressing ergosterol synthesis without immediate fungal killing.

The fungicidal nature of terbinafine likely contributes to more complete eradication of dermatophytes in keratinized tissues. Additionally, terbinafine's lipophilicity and keratinophilicity result in high and sustained concentrations in the stratum corneum and sebum. This tissue persistence may explain the absence of relapse in the terbinafine group during the four-month follow-up period[10,14]

Fluconazole, although possessing excellent oral bioavailability and tissue penetration, is water-soluble and may not achieve the same degree of prolonged retention within keratinized tissue compartments. The once-weekly dosing regimen, while convenient and potentially improving adherence, may also contribute to intermittent drug exposure, possibly allowing fungal persistence and subsequent relapse.

Resolution of erythema and scaling occurred in both groups. However, itching showed complete resolution in the terbinafine group, while minimal residual symptoms persisted in the fluconazole group (post-treatment mean score 0.21 ± 0.43).[10,13] These findings indicate that although both agents improve inflammatory parameters, terbinafine provides more consistent symptomatic relief.

Safety outcomes were favorable in both arms. One patient in the fluconazole group developed a maculopapular rash after the first dose and was withdrawn. No clinically significant abnormalities were observed in liver function tests, renal function tests, complete blood picture, or ECG parameters in either group.

Limitations

This single-center study had a small sample size, male predominance, an open-label design, and a clinical (rather than mycologic) primary endpoint. Relapses were ascertained based on return visits within four months.

CONCLUSION

Oral terbinafine 250 mg once daily for 2 weeks produced higher clinical cure and zero relapse versus fluconazole 150 mg once weekly for 4 weeks in adults with tinea corporis, with good tolerability. These findings support terbinafine as a preferred short-course systemic option in similar patients.

Declarations

Ethics approval and consent to participate: Approved by the Institutional Human Research Ethics Committee; written informed consent obtained from all participants.

Consent for publication: Not applicable.

Availability of data and materials: Available from the corresponding author on reasonable request.

Conflict of interest: Nil.

Funding: Self, No external funding.

Authors' contributions: Drafting, data collection, analysis and interpretation by the study team; all authors reviewed and approved the final manuscript.

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