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Dermatophytosis: Clinical profile and resistance to itraconazole and terbinafine

Shivank Shrivastav[1], Suneel Singh Sengar[2], Varun Kumar[1,*]& Amardeep Malviya[1]

[1]Department of Dermatology, AIMS, Dewas, Madhya Pradesh, India; [2]Department of Dermatology, SSMC, Rewa, Madhya Pradesh, India; *Corresponding author

Affiliation URL:
https://amaltasmedicalcollege.in/
https://ssmcrewa.ac.in/

Author contact:
Shivank Shrivastav- E-mail: shivank24@gmail.com
Suneel Singh Senger- E-mail: suneelsinghsengar@gmail.com
Varun Kumar- E-mail: varunkumarshobha@gmail.com

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Amardeep Malviya- E-mail: amardeepmlv97@gmail.com

Abstract:
Globally, 20-25% of the population suffers from dermatophytosis. In India, there is an increase in treatment resistance and an epidemiological shift towards *Trichophyton mentagrophytes*. This was a prospective study, which randomized 500 patients of dermatophyte infection to either oral itraconazole or terbinafine to find out the rising treatment failure. Tinea cruris was the prevalent diagnosis (37.2%, M:F ratio 2.16:1), with *Trichophyton mentagrophytes* the commonest pathogen isolated. The clinical resistance of terbinafine was significantly higher than itraconazole (24.4% versus 5.2%, $p < 0.0001$). With no real mycological resistance found, clinical failure was mainly due to non-compliance (44.6%), diabetes and co-existing onychomycosis. Thus, data show the best first-line therapy is likely itraconazole and dealing with host co-morbidities probably overcomes treatment failure.

Keywords: Dermatophytosis, itraconazole, terbinafine

Background:
Dermatophytosis is present in about one quarter of the global population at any time **[1]**. In 2019, the global incidence of fungal skin diseases amounted to 1.65 billion cases **[2]**. Every year, millions of people around the globe visit the dermatologist for skin infections **[3]**. India is presently undergoing an unprecedented and serious epidemic of recalcitrant Dermatophytosis **[4]**. In Indian tertiary care, the most common presentation still remains tineacruris and tineacorporis **[5]**. Diagnostic fungal culture positivity rates usually range between 30% and 70% depending on laboratory protocols **[6]**. According to a study, Terbinafine performs its action by inhibiting squaleneepoxidase **[7]**. Itraconazole usage affects lanosterol 14α-demethylase and depletes ergosterol **[8]**. Although both are very active, itraconazole has a more rapid onset of activity in the stratum corneum **[9]**. Currently, approximately 30% of worldwide cases of terbinafine-resistant *Trichophyton* are found in India **[10]**. The ongoing resistance crisis is fuelled by irrational usage of OTC steroid-antifungal creams **[11]**. Inability to maintain hygiene and a delay in seeking treatment worsen the disease severity **[12]**. The rate of dermatophytosis is much higher in male than female due to occupational exposure outdoor **[13]**. Tinea cruris and corporis are clinically the most common dermatophytoses, as per the multi-centric studies **[14]**. Tinea corporis etcruris has been officially accepted as the current Indian epidemic's hallmark presentation **[15]**. According to earlier evidence; *Trichophytonrubrum* was the main causative organism of the subcontinent **[16]**. Epidemiological data indicates there is a large shift in this microbiota recently **[17]**. In recent years, the most common dermatophyte isolate is rapidly emerging as *mentagrophytes* **[18]**. In addition, non-dermatophytemoulds are of increasing clinical importance in diabetic patients **[19]**. First-line systemic antifungal therapies include terbinafine and itraconazole **[20]**. For instance, it has been shown in clinical trials that itraconazole leads to higher complete remission rates than terbinafine **[21]**. Patients treated with itraconazole show markedly better mycological cure rates **[22]**. According to the results of comparative studies, itaconazole appears to be superior to both terbinafine and fluconazole **[23]**. Treatment failure in the absence of *in vitro* antifungal resistance is a common occurrence **[24]**. According to research patient non-compliance is the number one global cause of continuing infection and treatment failure **[25]**. Diabetic patients often develop extensive, chronic dermatophytosis, requiring prolonged therapy **[26]**. The presence of onychomycosis has been noted to be effective in yielding a fungal reservoir which leads to a reduction in clinical cure rates **[27]**. Therefore it is of interest to compare the clinical and mycological efficacy of oral itraconazole versus terbinafine in dermatophyte patients owing to the changing epidemiological set-up and increasing concern of antifungal resistance in India.

Materials and Methods:
Study design and setting:
This prospective observational study was conducted in the Department of Dermatology, Venereology and Leprology (DVL), Index Medical College Hospital and Research Centre, Indore, Madhya Pradesh, India, over a period of 18 months (September 2016 to February 2018). The study was approved by the Institutional Ethics Committee of Index Medical College Hospital and Research Centre, Indore (IEC approval obtained prior to enrolment). All procedures were performed in accordance with the Declaration of Helsinki guidelines for research involving human subjects.

Study population:
A total of 500 patients attending the DVL outpatient department (OPD) who were clinically diagnosed with dermatophytosis were enrolled consecutively after obtaining written informed consent.

Inclusion criteria:
Patients of either sex presenting with clinically diagnosed dermatophytosis.

Exclusion criteria:
[1] Patients who did not provide valid informed consent
[2] Patients who had received any antifungal treatment within the preceding 2 weeks
[3] Immunocompromised patients (including those with HIV, malignancy, or on immunosuppressive therapy)
[4] Patients who did not return for follow-up (n = 131; excluded from final analysis)

Clinical assessment and sample collection:
Detailed history was recorded for all enrolled patients, including age, sex, and duration of illness and site of infection. Epidermal

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scrapings were collected from the active border of the lesion under aseptic conditions and transported to the Department of Microbiology for fungal identification, culture and susceptibility testing. A 10% potassium hydroxide (KOH) wet mount preparation was performed for each patient; only KOH-positive samples were submitted for culture and sensitivity testing.

Treatment protocol:
Patients were randomized into two equal treatment groups of 250 patients each:
[1] Group A: Oral itraconazole 100 mg once daily for 14 days
[2] Group B: Oral terbinafine 250 mg once daily for 14 days

Treatment response was evaluated at the end of 14 days based on the following clinical parameters:
[1] Relief of itching
[2] Activity of the lesion
[3] Change in size of the lesion
[4] Presence or absence of adverse drug effects

Patients who failed to show satisfactory clinical improvement on all above parameters at 14 days were classified as clinically resistant. In such cases, the drug therapy was interchanged between the two groups for further management.

Mycological methods:
Fungal culture was performed on Sabouraud dextrose agar (SDA) supplemented with cycloheximide and chloramphenicol and incubated at 28°C for up to 4 weeks. Species identification was performed by standard macroscopic and microscopic morphological criteria. Antifungal susceptibility testing was performed using the Itraconazole Hi Comb™ MIC Strip (HiMedia Laboratories, Mumbai, India), which provides a gradient of 16 serial concentrations for determination of the minimum inhibitory concentration (MIC) in micrograms per milliliter (µg/mL). As commercially prepared terbinafine discs were unavailable, terbinafine susceptibility discs were prepared in-house using the method described by Santos *et al.* **[28].** Patients with positive culture for dermatophytes whose isolates showed no inhibition at the breakpoint concentration were classified as mycologically resistant. Patients in whom no growth was obtained or in whom non-dermatophyte organisms were grown were classified as not applicable for mycological resistance assessment.

Outcome measures:
The primary outcomes assessed were:

[1] Clinical response- resolution of symptoms (itching, lesion activity, lesion size) at 14 days
[2] Mycological response- absence of growth on repeat culture at 14 days
[3] Attributable causes of clinical non-response- non-compliance, diabetes mellitus, onychomycosis, or no identifiable cause

Statistical analysis:
Data were entered and managed using Microsoft Excel 2.0since all study variables were categorical in nature; Pearson's chi-square (χ^2) test was applied for comparison between groups. Yates' continuity correction was applied when the expected cell frequency was less than 5. A p-value of < 0.05 was considered statistically significant.

Table 1: Demographic distribution by sex

Sex	N	%
Male	342	68.4
Female	158	31.6
Total	**500**	**100.0**

Male preponderance observed; M:F ratio = 2.16:1.

Table 2: Distribution by type of dermatophytosis

Type of Infection	n	%
Tineacruris	186	37.2
Tineacruris + corporis	112	22.4
Tineacorporis	89	17.8
Tineafaciei	48	9.6
Tineapedis	34	6.8
Tineamanuum	21	4.2
Tineacapitis	10	2.0
Total	**500**	**100.0**

Tineacruris was the most prevalent clinical variant (37.2%).

Table 3: Fungal species isolated on culture

Species	n	%
Trichophytonmentagrophytes	92	18.4
Trichophytonrubrum	39	7.8
***Aspergillus* spp.**	10	2.0
***Candida* spp.**	10	2.0
Trichophytonviolaceum	9	1.8
Microsporumgypseum	5	1.0
***Mucor* spp.**	5	1.0
No growth	330	66.0
Total	**500**	**100.0**

Overall culture positivity rate: 34.0%. T.mentagrophytes was the predominant isolate among positive cultures.

Table 4: Distribution by treatment administered

Drug	n	%
Itraconazole	250	50.0
Terbinafine	250	50.0
Total	**500**	**100.0**

Patients were equally allocated between the two antifungal drug groups.

Table 5: Clinical and mycological response by drug given

Drug	Clinical Response n (%)	Clinical Resistance n (%)	Mycological Response n (%)	Mycological Resistance n (%)
Itraconazole	237 (94.8%)	13 (5.2%)	90 (36.0%)	0 (0.0%)
Terbinafine	189 (75.6%)	61 (24.4%)	55 (22.0%)	0 (0.0%)
Total	**426 (85.2%)**	**74 (14.8%)**	**145 (29.0%)**	**0 (0.0%)**

Clinical resistance: $\chi^2 = 36.544$, df = 1, $p < 0.0001$ (significant). Mycological resistance: $\chi^2 = 11.899$, df = 1, $p = 0.0006$ (significant). No mycological resistance was detected in either group.

Table 6: Attributable causes of clinical non-response by drug group

Cause of Non-Response	Itraconazole n (%)	Terbinafine n (%)	Total n (%)
Non-compliance	8 (61.5%)	25 (41.0%)	33 (44.6%)

Diabetes mellitus	0 (0.0%)	6 (9.8%)	6 (8.1%)
Onychomycosis	0 (0.0%)	3 (4.9%)	3 (4.1%)
Diabetes + onychomycosis	2 (15.4%)	11 (18.0%)	13 (17.6%)
No identifiable reason	3 (23.1%)	17 (27.9%)	20 (27.0%)
Total non-responders	**13 (100%)**	**61 (100%)**	**74 (100%)**

Non-compliance was the leading cause of treatment failure in both groups. Comorbidities (diabetes, onychomycosis) were exclusive to the terbinafine non-responder group.

Results and Discussion:

In the current study, males occupied 68.4% of all 500 patients with an M:F ratio of 2.16:1 indicating male preponderance (**Table 1**). This result is in agreement with the study being done by Grover and Roy, **[11]** as they also found more incidence of dermatophytosis in male as compared to female due to more outdoor activities and sweating and occupational exposure. Mahajan *et al.* **[12]** penned similar male dominance; health-seeking behaviour and poor hygiene further aggravate the sex-ratio of the disease in males. Lohariwala *et al.* **[29]** also reported incidence is higher among the male sex, possibly due to more occupational exposure and more physical activities and other socio-cultural factors as well that influence the access to the health care system. An Indian study has also shown that the number of male is greater than female in the study population (ratio 1.5:1). This proves our study findings **[13]**. In our study, tineacruris made up the most common type (186 patients, 37.2%), followed by tineacruris with corporis (112 patients, 22.4%) (**Table 2**). The large multicentric study by Verma and Madhu **[14]** done in 13 Indian centres likewise shows tineacruris (79.99%) and tineacorporis (75.69%) as the most frequently involved clinical types in chronic and recurrent dermatophytosis pattern. In their editorial for the IJDVL, Dogra and Uprety **[15]** also state that tineacorporisetcruris is the most common presentation in the current Indian epidemic of dermatophytosis. The lower tineacapitis (2.0%) and tineapedis (6.8%) incidence in our series, which is similar to nationwide frequency, suggests there has been no concomitant increase in tineacapitis or tineapedis despite rising truncaldermatophytosis. Culture positivity was obtained in 34.0% of the patients. The predominant isolate was *Trichophytonmentagrophytes* (18.4%) followed by *T.Rubrum* accounts for 7.8% An epidemiological shift is taking place in India with respect to *T.mentagrophytes* has been gradually displaced by *T.rubrum*. as the prime pathogen. India saw this reversal first reported by Chakrabarti *et al.* **[16]** and Jerajani *et al.* **[17]**. As *T.Mentagrophytes* are the most common isolate. A clinicomycological study done by Nenoff *et al.* **[18]** reported *T.mentagrophytes* was the most common dermatophyte which is in accordance with the present epidemic-like scenario on the Indian subcontinent subsequent studies in India have shown *T.mentagrophytes*. The rate of positive cultures in tertiary care settings is 75.9%-77.5% for mentagrophytes. Non-dermatophytemoulds are *Aspergillus* spp, *Mucor* spp and *Candida* spp. In our research, Hazarika *et al.* **[19]** it is noted that 4.0% of cultures are non-dermatophytemould infections of increasing importance in immunocompromised and diabetic patients. The patients were proportionately allocated into two antifungal groups, namely, itraconazole and terbinafine (250 each, 50.0%) for a balanced comparative analysis (**Table 4**). According to Agrawal *et al.* **[20]**, the two main drugs presents the first-line systemic antifungal drugs in dermatophytosis recommended, their mechanism is different at the ergosterol biosynthesis pathway. Compared to terbinafine (24.4%), itraconazole had significantly lower clinical resistance (5.2%) in the present study ($\chi^2 = 36.544$, $p < 0.0001$) (**Table 5**). The results obtained were similar to those obtained by Kumar *et al.* **[21]** who compared both drugs in 145 patients. The results showed that itraconazole elicited complete remission in 72.5% as compared to 67.6% in terbinafine group. Bhatia *et al.* **[22]** similarly found mycological cure in 91.8% of the patients on itraconazole compared to 74.3% in terbinafine group ($p<0.05$) and concluded that itraconazole is superior in tineacorporis and cruris. One comparative study with three arms concluded that itraconazole was the best followed by terbinafine and fluconazole **[23].** Importantly, there was no mycological resistance in either treatment group in this study. This was also found by Sardana *et al.* **[24]**. They noted that *in vitro* antifungal resistance (>1 µg/ml MIC) was absent in patients with recalcitrant tineacorporis and cruris. Host-fungal interaction may be behind clinical treatment failure rather than real resistance. The common factor for clinical treatment failure among non-responders was non-compliance with a rate of 44.6% (**Table 6**). According to Mukherjee *et al* **[25]** non-compliance is the primary global cause for antifungal treatment failure. Non-compliance leads to sub-therapeutic drug levels and thus continues infection. Only in the terbinafine group diabetes mellitus was noted as a contributory factor. The study of Rajagopal *et al.* **[26]** also showed that diabetic patients are known to have more chronic recurrent extensive dermatophytosis requiring prolonged treatment. The identification of onychomycosis as another co-factor causing failure of treatment in our study tallies with Scher *et al.* **[27]** who showed onychomycosis being a lasting reservoir of re-infection and a key factor in lowering clinical cure rates despite being systemic antifungal.

Conclusion:

We show the resistance of itraconazole was considerably lower at 5.2% as compared to terbinafine which was 24.4%. The main isolate of Indian dermatophytes was seen to be *Trichophyton mentagrophytes* indicating the epidemiological shift. There is no mycological resistance and non-compliance, diabetes and onychomycosis itraconazole are the first choice oral antifungal in present Indian epidemic.

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