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Comparative Study on Efficacy of Oral Itraconazole Vs Terbinafine in the Treatment of Dermatophytic Infections at Tertiary Care Hospital

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ABSTRACT:
Objectives: The most common fungal infections observed globally are Tinea infections. To treat these infections, itraconazole and terbinafine are widely used. Recently there exists a substantial increase in the resistance of these anti-fungal agents. Thus, the principle aim of our study was toobserve and compare the efficacy of oral itraconazole vs terbinafine in the treatment of dermatophytic infections and to rule out whether there is a development of resistance in either of the drugs.
Methodology:A prospective observational study was carried out in the Outpatient department of dermatology at Shadan Teaching and General Hospital, a tertiary care teaching hospital for a duration of 6 months. There were two groups enrolled in the study, Group 1 was prescribed terbinafine 250 mg OD, while the other Group 2 was prescribed itraconazole 100 mg OD. The data collection was done from OP cards and observing the patients physically. The data was recorded in Case Collection Form. The efficacy of the drugs was compared by assessing the clinical parameters during treatment. The parameters were change in erythema, pruritus, and scaling.
Results: The clinical cure rate was better in the itraconazole group as compared to the terbinafine group. 84% patients in Group 2 and 63% patients in Group 1 were completely cured of the tinea infection. Medication compliance was better in Itraconazole group when compared to Terbinafine group.
Conclusion: Itraconazole group had shown higher mycological and clinical cure rate when compared to terbinafine group. Patients who were prescribed terbinafine has indicated that there is a growing resistance to the drug and increased chances of treatment failure in dermatophytic infections, failure of therapy also leads to financial burden on patients.
KEYWORDS: Dermatophytic infection, Terbinafine, Itraconazole.

I. INTRODUCTION

The most common fungal infections are the dermatophytic infections affecting 20 - 25% population globally. In India, hot and humid climate favours dermatophytosis.

Over the past few years, it has been observed and recorded that dermatophyte infections have increased by many times in India. There is a remarked change in the disease presentation, severity, treatment response, and relapse rate. However, the causes may even be more diverse, from the irrational use of antifungal drugs to topical steroid usage and to the poor socioeconomic status of the population.[1]

Antifungal agent and antimycotic are unremarkably used oral antifungal agents for the same. However, resistance to those medication is being seen progressively once utilized in the standard doses and length.[2]

The first line of drug for the treatment of dermatophytic infections is Terbinafine due to its activity against the fungal infections and pharmacokinetic profile. Mechanism of action is by inhibiting the enzyme squalene oxidase, thereby inhibiting ergosterol synthesis.[3]

There has been an increase in resistance in the incidence of terbinafine recently with increasing numbers of clinical failures and relapses. Antifungal resistance is due to decrease in effective drug concentration. Terbinafine at higher doses of 500mg/day was reported to be efficacious and safe.

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Itraconazole is an orally active antifungal drugs which belongs to the triazole class and has demonstrated a broad spectrum of activity and a suitable pharmacokinetic profile. It acts by inhibiting cytochrome P450-dependent enzyme, hence interfering with demethylation of lanosterol to ergosterol. When given at a dose of 100mg once a day for 2 weeks and with 200mg once a day for 7 days it has shown good results and efficient in managing the dermatophytosis.

II. METHODOLOGY

Type of study:

Aprospective observational study for the Evaluation and comparison of efficacyof the two given drugs i.e., Terbinafine and Itraconazole.

Detailed method of study:

The patient who are diagnosed with dermatophytic infections who were prescribed Terbinafine or Itraconazole for the treatment of infection is included in the study. Written informed consent is taken from the subject population. Data is Collected from the case sheets of the patient at the outpatient department of Dermatology. Patients are assessed to know the severity of the infection based on the scale used. The subject populations are counseled about the disease and the importance of drugs for better improvement. The Data collected are Name, age, gender, phone number, other histories, type of dermatophytic infection. All these data are collected in the case collection form.

Study Site: Department of Dermatology at Shadan Institute of Medical Sciences Teaching Hospital and Research Centre.

Study Duration: The study was carried out for a period of 6 months.

Inclusion criteria:

- Patients above 18 years of age who have a clinical diagnosis of Dermatophytic Infection.
- Both men and women.
- Patients who are willing to participate in the study.
- Patients who are prescribed Itraconazole and Terbinafine.

Exclusion criteria:

- Patients below the age of 18 years.
- Female patients who are pregnant or breastfeeding.

Patient data will be collected from the case sheets, outpatient cards, and weekly follow-up of patients diagnosed with dermatophytic infection.

Clinical assessments

After initiating the therapy, the subject population is followed up every week for 4 weeks. At each follow up the subjects are assessed to know medication adherence, whether they are following precautionary measures if not, encouraging them to do so and also at each visit, clinical response is noted like:

1. Pruritus
2. Erythema
3. Scaling.

The data obtained are recorded in the Case Collection Forms (CCF).

After completion of 4-week therapy, the data obtained are compared with the initial complaints of the subject. The data are rated as clinical scores i.e., 0-3. The table below shows the Clinical scores.[4]

Clinical scores	Intensity
0	Absent
1	Mild
2	Moderate
3	Severe

Table 1: Clinical scores Scale

Considering the outcomes, the patients are classified as follows:

1. Healed
2. Marked Improvement (<50%)
3. Considerable Residual Lesions (>50%)
4. No change
5. Worse.[4]

Statistical analysis

The statistical analysis of the data was done by IBM SPSS software (version: 28.0.0.0). In which we have calculated the mean severity score of the three clinical parameters i.e., Erythema, Pruritus, and Scaling. The scores were compared from baseline to 2 weeks after therapy and 4 weeks after the therapy. The percentage change was also calculated.

III. RESULTS:

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A total of 38 patients were randomly assigned treatment and were a part of the study. Out of 38, Group-1 of 19 members were prescribed Terbinafine 250 mg once a day, while the other Group-2 of 19 members were prescribed Itraconazole 100mg once a day.

Table 2 below shows the demographic profile of patients containing age, gender, and diagnosis in both groups.

Parameters	Group1 Terbinafine (n=19)	Group 2 Itraconazole (n=19)
Age (mean ± S.D)	30.21± (8.48)	27.05± (7.314)
Gender(n%) Male Female	28.94% 21.05%	28.94% 21.05%
Diagnosis		
Tinea cruris	15(39.47%)	7(18.42%)
Tinea corporis	3(7.89%)	1(2.63%)
Tinea cruris and corporis	1(2.63%)	11(28.94%)

Table 1Demographic profile and diagnosis in both the groups

Scores	Group 1 (Terbinafine)		
	At baseline	After 2weeks	After 4weeks
Scaling (mean ± S.D)	2.63(0.59)	1.57(0.83)	1.21(1.18)
P	0.399	0.020	0.36
Pruritis (mean ± S.D)	2.47(0.77)	0.84(1.06)	0.68(1.05)
P	0.5	0.06	0.04
Erythema (mean ± S.D)	2.68(0.47)	1.52(0.77)	0.89(1.10)
P	0.50	0.17	0.42
Scores	Group 2 (Itraconazole)		
	At baseline	After 2weeks	After 4weeks
Scaling (mean ± S.D)	2.68(0.67)	1.10(0.56)	1.10(0.56)
P	0.399	0.020	0.36
Pruritis (mean ± S.D)	2.47(0.84)	0.42(0.60)	0.21(0.53)
P	0.5	0.06	0.04
Erythema (mean ± S.D)	2.68(0.67)	1.10(0.56)	0.94(0.60)
P	0.50	0.17	0.42

Table 2 Clinical parameters in Group 1 (n=19) and Group 2 (n=19)

The percentage improvement in the symptom scores was significantly more in both the groups from 0 to 4 weeks. The percentage change in scaling was more in from 0 to 2 weeks than 2 to 4 weeks. In Group 2 the percentage change was zero from 2 to 4 weeks. The percentage change in

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scores of pruritus and erythema was more in 0 to 2 weeks and less in 2 to 4 weeks.

Parameters	Mean (%) Group1 (n=19)	Mean (%) Group2 (n=19)
Scaling		
Baseline to 2weeks	40.30%	58.95%
2weeks to 4weeks	23%	0%
Baselinet-4 weeks	53.99%	58.95%
Pruritis		
Baseline to 2weeks	65.99%	82.99%
2weeks to 4weeks	19.04%	50%
Baseline to 4weeks	72.46%	91.49%
Erythema		
Baseline to 2weeks	43.28%	58.95%
2weeks to 4weeks	41.44%	48.18%
Baseline -4 weeks	66.79%	78.73%

Table 3 **Percentage change in clinical parameters in both the groups**

At the end of 4 weeks, the mycological cure was achieved in 12 patients (64%) in Group 1 and 16 patients (84%) in Group 2. No adverse effects were observed during treatment. Both the drugs were well tolerated with no adverse effects.

The clinical response was better in the Itraconazole group as compared to the Terbinafine group. Itraconazole group showed no worsened patients (0%), whereas Terbinafine group showed 10% patients.

Medication compliance was better in Itraconazole group when compared to Terbinafine group.

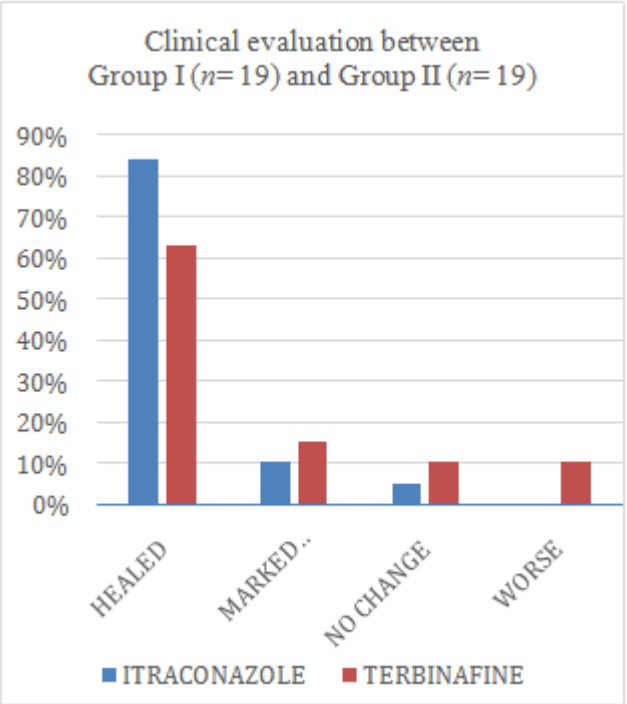

Figure 1Clinical evaluation between Group 1(n=19) and Group 2(n=19)

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Clinical outcomes of the therapy, 63% of patients were classified as healed, 16% as marked improvement, 10% as with no change and, 11% worse in Group 1.

Clinical outcomes of the therapy, 84% of patients were classified as healed, 10% as marked improvement, 5% as with no change and no patient's condition got worsen during therapy in Group 2.

IV. DISCUSSION:

In rural parts of Telangana there's widespread dermatophytic infection cases. Due to which an effective treatment plan should be made. Earlier terbinafine was used as a first-line agent in the treatment of dermatophytic infections. Recently, due to increased resistance of terbinafine, that is due to a decrease in effective drug concentration because of extensive accumulation of terbinafine in the skin and adipose tissue. (24) Due to this Itraconazole is used as first-line drug in the treatment, it belongs to the triazole class on anti-fungal drugs.

Our target subject size was 120 patients (60 in each group), based on the 6 months duration of the study; however, due to Covid-19, the study's duration was cut short, and the sample size was decreased to 38 patients only (19 in each group).

Nearly 20 patients did not show medication adherence at the beginning of the study due to the high expense of the therapy. They were not included in the study. After that, we provided physician samples to both groups to ensure medication adherence. The antifungal drugs in the market should be available at a lesser price so that medication adherence can be increased. As the treatment course is of longer duration and increased financial burden to the patients. This financial burden leads to the discontinuation of therapy.

The outcome of our study was that itraconazole is a better drug than terbinafine in efficacy and to treat dermatophytic infections. This result was similar to earlier studies in patients who were diagnosed with tinea cruris and who also found itraconazole to have higher cure rates as compared to terbinafine.

V. CONCLUSION:

Itraconazole has shown a higher mycological and clinical cure rate when compared to Terbinafine. Patients who were prescribed Terbinafine have indicated that there is a growing resistance to the drug and increased chances of failure of treatment of dermatophytic infections, failure of therapy also add to the financial burden on patients.

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