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A COMPARATIVE STUDY OF THE THERAPEUTIC EFFICACY OF ITRACONAZOLE VERSUS TERBINAFINE IN THE TREATMENT OF TINEA CORPORIS AND TINEA CRURIS INFECTION.

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ABSTRACT Dermatophytosis is a disease condition characterized by the infection of keratinized tissues such as the epidermis, hair and nails. We planned a comparative study to provide the insight into the therapeutic efficacy of Itraconazole and Terbinafine, the two preferred drugs for the treatment of T. corporis and T. cruris.

METHOD- Recruited subjects were assigned alternatively between 2 groups each to receive Itraconazole 100 mg OD or Terbinafine 250mg OD for 2 weeks. Therapeutic efficacy was evaluated at completion of therapy i.e at 2nd and 4th weeks. Mycological samples (skin scrapings) were examined by preparing 10% KOH mounts.

RESULTS- The patients with no clinical signs or symptoms with negative mycology (effective therapy) were 69 in Itraconazole group and 55 in Terbinafine group. The patients who had ineffective cure (improvement and treatment failure) were 26 in Itraconazole group and 39 in Terbinafine group showing Itraconazole to be a better drug.

KEYWORDS : Tinea, Itraconazole, Terbinafine, Dermatophytes.

INTRODUCTION

Dermatophytosis is a disease condition characterized by the infection of keratinized tissues such as the epidermis, hair and nails. Dermatophytes are among the common fungal agents implicated in superficial skin infections worldwide. The typical infections of dermatophytes are generally referred to as ringworm infections due to their ring like appearance. These infections are also known as 'Tinea infections' and are named according to the location of the lesions on the body.

Recently there has been an increase in the incidence of fungal infections.This increment may be a result of frequent usage of antibiotics, immunosuppressive drugs, persistent infections and various conditions which predispose an individual to an immunocompromised state like malignancies, organ transplantations and human immunodeficiency virus (HIV) infections. Dermatophytes are a group of fungi that cause superficial fungal infections in the humans.

This comparative study is planned to provide the insight into the therapeutic efficacy of Itraconazole and Terbinafine, the two preferred drugs for the treatment of T. corporis and T. cruris.

MATERIAL AND METHODS

It included all patients diagnosed with T. corporis and T. cruris who attended the outpatient department. The study was planned over a period of 12 months (from April 2016 to March 2017). The subjects who satisfied the Inclusion and Exclusion criteria were included in the study.

INCLUSION CRITERIA-

- Age more than 18 years.
- Both male and female subjects.
- Patients newly diagnosed with Tinea corporis and cruris infection.

EXCLUSION CRITERIA-

- Patients with immune compromised infections.
- Pregnant and lactating females.
- Patients with pre-existing hepatic dysfunction.
- Patients with pre-existing renal dysfunction.
- Patients with known history of allergy to these drugs.

Direct microscopy of KOH wet mount of skin scrapings was done at the baseline (to confirm the diagnosis) and was repeated at the end of study period.

Other relevant investigations such as hematological (Hb, TLC, DLC), bio chemical (blood sugar, serum creatinine, LFT) and HIV were done at the baseline and at the end of study period.

Recruited subjects were assigned alternatively between 2 groups each to receive Itraconazole 100 mg OD or Terbinafine 250mg OD for 2 weeks. Topical antifungal Ciclopirox was prescribed to the patients of both the groups.

Patients were advised to take the medication at the same time of the day after food. The study drugs were continued for 2 weeks and treatment response was assessed at the end of 2 weeks.

If any patient did not respond to the treatment after 2 weeks than the drugs were given for further 2 weeks and results were seen at the end of 4 weeks.

The treated subjects were followed up at 8 weeks following the discontinuation of medications.

At each visit clinical assessment was made and material was taken for mycological examination.

Therapeutic efficacy was evaluated at completion of therapy i.e at 2^{nd} and 4^{th} weeks. Mycological samples (skin scrapings) were examined by preparing 10% KOH mounts.

The assessment of efficacy was based on combined evaluation of mycological results and sum of clinical score at the completion of therapy according to following scheme-

Effective therapy included: a) **Complete cure** – non residual clinical sign and symptoms except post inflammatory hyper pigmentation with negative microscopic findings.

b) **Mycological cure**- minimal residual sign and symptoms (score less than 2) with negative mycology.

Ineffective therapy included: a) **Improvement**- positive mycology in microscopy with significant (> 50%) clinical improvement or negative mycology with no clinical improvement.

b) **Failure**- neither clinical nor mycological improvement. [1]

A total of 200 patients were enrolled in this study. 100 patients were assigned to Terbinafine group and were given 250mg of the drug daily and other 100 were assigned to Itraconazole group and were given

Itraconazole 100mg daily.
The study population was matched according to the baseline characteristics.
Most of the patients in both the groups were between the age group of 20 to 40 years. The mean age in Terbinafine group was 33.42 ± 11.60 years and in Itraconazole group it was 35.29 ± 9.59 years.

Table 1: Distribution According To The Diagnosis-

DRUG GROUP	T. CRURIS	T. CORPORIS	T.CRURIS & CORPORIS
TERBINAFINE	30	18	52
ITRACONAZOLE	25	19	56
TOTAL	55(27%)	37(18%)	108(54%)

The mean duration of therapy in Terbinafine group was 3.06 ± 1.22 weeks and 3.02 ± 1.18 weeks in Itraconazole group with no statistically significant difference (p>0.05).

In the end of the therapy it was observed that out of 100 patients, 35 had achieved complete cure, 20 achieved mycological cure, 21 had shown improvement and 18 had treatment failure in the Terbinafine group. 2 patients abandoned therapy due to development of AE and 4 patients did not attend the follow up.

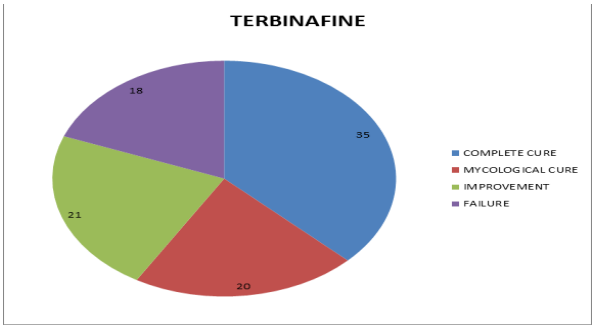

FIG.1: CURE ACHIEVED AT THE END OF 4 WEEKS.

In the Itraconazole group, 46 patients achieved complete cure, 23 achieved mycological cure, 11 patients had improvement and 15 patients had treatment failure. 4 patients were lost to follow up and 1 patient left therapy due to adverse event

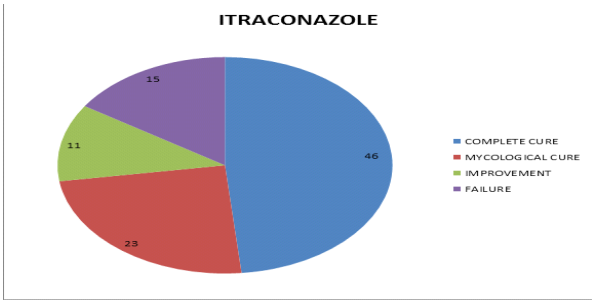

FIG.2: CURE ACHIEVED AT THE END OF 4 WEEKS.

The result was compared using Chi square test and the difference between the number of patients achieving effective cure in Itraconazole group was statistically significant when compared to the Terbinafine group with p value of 0.04 (p<0.05).

DISCUSSION

The Tinea infections are prevalent globally but they are common in tropics and may reach epidemic proportions in geographical areas with higher humidity, over-population and poor hygienic living conditions. Hot and humid climate of India makes dermatophytoses a very common superficial fungal infection of the skin. Since these infections are often confused with other skin disorders, it is therefore necessary to make early laboratory diagnosis for better management of these conditions. [2,3,4,5]

Tinea conditions are consequence of exhaustive physical work and prolonged exposure to sun leading to excessive sweating. In addition the tight fittings and synthetic clothing particularly in males provide damp, sweaty and warm skin conditions. All these factors favour the growth of dermatophytes. [6,7,8,9]

The primary efficacy parameter in our study was mycological cure at the follow up end point of week 8. Adverse events were recorded at weeks 1st, 2nd & 8th. Routine haematological and bio chemical tests were performed at the start and end of the study.

In our study Itraconazole was prescribed at the dose of 100mg per day and Terbinafine was prescribed at 250mg per day.

In a comparative study between Itraconazole and Terbinafine in the treatment of Tinea cruris/corporis by Sakya et al, a fall in positive mycology from 100% to 8.6% and 17.1% in Itraconazole and Terbinafine groups respectively was noted at the end of 4 weeks therapy. After 4 weeks, 91.4% and 82.9% patients were considered to be having effective therapy in the Itraconazole and Terbinafine groups respectively.[1]

In our study the number of patients achieving effective cure (complete cure and mycological cure) in Itraconazole group were more than the Terbinafine group with statistically significant difference (p<0.05). The patients with no clinical signs or symptoms with negative mycology (effective therapy) were 69 in Itraconazole group and 55 in Terbinafine group. The patients who had ineffective cure (improvement and treatment failure) were 26 in Itraconazole group and 39 in Terbinafine group.

In a study between Itraconazole pulsed and Terbinafine continuous therapy in toe nail dermatophytoses by Gupta et al, the better mycological cure was attained by patients in Itraconazole group (88.2%) as compared to Terbinafine and (79.3%).

Similarly in a study of the treatment of toe nail dermatophytoses by Mishra et al, a clinical cure rate of 82% and mycological cure rate of 90% in the group of patients treated with Itraconazole and 79% of clinical and 87% of mycological cure rate with Terbinafine group was achieved. [11]

In terms of adverse events, Terbinafine group had slightly higher number of patients (17) reporting with different types of adverse effects in comparison to Itraconazole group in which 15 patients reported with adverse events. There was no statistically significant difference between the two groups. Two patients in Terbinafine group and one patient in Itraconazole group had left the therapy due to the adverse events.

CONCLUSION

The dermatophyte infections of Tinea cruris and Tinea corporis are relatively common among the individuals who belong to the younger age groups even in the absence of co- morbid conditions and the present treatment options with oral antifungal agents provide a satisfactory cure for the condition. But the number of patients showing failure of therapy and subsequent relapses is also a cause of concern. The patients, who show small improvements or no cure at all after the recommended therapy period, must be looked in for the presence of antifungal resistance. Antifungal agents should preferably be started after the demonstration of fungal elements in the microscopic examination and the mycological cure should be demonstrated at the conclusion of the therapy.

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