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A Study of Comparative Efficacy and Safety of Two Different Drug Regimen in the Management of Dermatophyte Infection

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Abstract

Background: Superficial fungal infections of the skin, hair and nail are a major cause of morbidity in the world, particularly in the tropics, where heat and humidity provide the ideal conditions for the growth of fungi that cause skin infections.

Methods: A hospital based comparative prospective study included 400 patients of dermatophytoses having Tinea cruris and Tinea corporis attending the outpatient department of Dermatology, Venereology and Leprosy in PBM hospital Bikaner. Patients randomly divided into 2 groups -i)Group A received Tablet Fluconazole 150 mg per week plus Tablet Griseofulvin 10mg per kg bodyweight daily in two divided doses, ii)Group B received Tablet Fluconazole 150 mg per week. Treatment to all groups was given for a period of 4 weeks. The data were analyzed on EPI-Info-6 Software.

Results: There was no statistically significant difference in both groups was observed at 1st, 2nd & 3rd weeks and statistically significant difference in both groups was observed at 4th & 8th weeks follow-up.

Conclusion: The combination of Fluconazole and Griseofulvin is a bettar treatment option to treat tinea cruris and corporis as compared to mono therapy with Fluconazole.

Keywors: Fluconazole ,Griseofulvin, Mono Therapy, Tinea Cruris and Tinea Corporis.

Introduction

Superficial fungal infections of the skin, hair and nail are a major cause of morbidity in the world, particularly in the tropics, where heat and humidity provide the ideal conditions for the growth of fungi that cause skin infections.1-3 Direct contact is sufficient to transmit the infection from a contaminated surface or host to another and the role of fomites in the transmission of infection has also been observed. Dermatophytoses are the most common cause of fungal infection in men, though candidiasis and pityriasis versicolor are also examples of major superficial myoses.3,4

The choice of treatment is determined by the site and extent of lesions, the fungal species involved and the efficacy, safety profile and pharmacokinetics of the available antifungal agents.5

Reason for unsuccessful antifungal management is poor adherence to long-term treatment regimens using topical antifungal drugs.[5,6] However, relapses following self

stoppage of the antifungal treatment by the patients is the major compliance issue. It may also be due to T.rubrum acquisition of resistance, especially in the case of infections involving prolonged treatment with relatively low drug concentrations.[7] There is evidence that some fungal strains are resistant to certain antifungal drugs which results in therapeutic failures.[8] Some reasons for failure of fungal treatment in clinical practice are peripheral vascular disease, resistant structures such as subungual dermatophytomas and the presence of dormant fungal spores.[9] Despite the increasing prevalence of cutaneous dermatophytosis across the world and especially in tropics, research in this area has often been neglected. In fact, one has to go back about two decades to find guidelines on the management of tinea corporis and cruris and these at best, appear inadequate in today's world.[10]

Now a days we have observed that patients with dermatophytoses do not respond to conventional treatment regimens. So in the present study we have compared the two different drug regimen for trement of tinea corporis and cruris and advantage of using combination treatment of fluconazole and giseofulvin for treatment of tinea cruris/corporis.

Materials and Method

Study design: A hospital based comparative prospective study.

Study duration: Study was done till the sample size was reached.

Study Place: Department of Dermatology, Venereology and Leprosy, Sardar Patel Medical College, PBM and associated group of Hospitals, Bikaner, Rajasthan.

Study population: Included patients of dermatophytoses having Tinea cruris and Tinea corporis attending the outpatient department of Dermatology, Venereology and Leprosy in PBM hospital Bikaner. Prior to carrying out the study, ethical approval was obtained from the Institute Ethics Committee of Sardar Patel Medical College, Bikaner.

Sampling method: Simple random sampling.

Sample Size:sample size was calculated as follows[11]

$n = 4pq/E^2$

$n = 4*0.34* 0.66/(.068)^2$

$n = 194.11$

Rounding off it to 200 so each group in our study contain 200 patients.

The cases were diagnosed by the typical clinical manifestations and confirmed either by 10% KOH smear examination or by culture in all the patients.

The study cases were divided into 2 groups

Group A received Tablet Fluconazole 150 mg per week plus Tablet Griseofulvin 10mg per kg bodyweight daily in two divided doses.

Group B received Tablet Fluconazole 150 mg per week.

Treatment to all groups was given for a period of 4 weeks. The patients in all the groups were given topical clotrimazole 2% and oral antihistaminics during the treatment period.

All patients were followed every week during the treatment period and four weeks after the completion of treatment to observe any relapse (i.e.till the end of 8th week).

Patient would visit the hospital six times during the study period, first baseline visit then four visit at the end of each week for the total treatment period of four weeks and a follow up visit at 8th week

Side effects and clinical response are recorded on every visit. History, clinical features, investigations, treatment given and follow-up were recorded in a printed performa (Enclosed)with photographs. Written consent was taken from all the patients, prior to initiation of therapy.

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Patient selection criteria

1. Patient with clinical diagnosis of tinea corporis and tinea cruris and mycological confirmation (positive KOH test or culture).
2. Patient with age of 15-50 years.

Patient exclusion criteria

1. Patients with systemic mycosis.
2. Tinea Manuum, Tinea Pedis, Tinea Capitis & onychomycosis.
3. History of hypersensitivity to study drugs.
4. Immunocompromised status.
5. Pregnant or lactating women.
6. Patient with history of any liver disease.

Data Analysis

1.Master chart was prepared from the details recorded on the proforma.

2.Epidemiological and clinico morphological data was obtained from master chart for making respective tables.

3.Statistical analysis was assessed by chi square test and p value less than 0.05 was considered significant.

Observations

Present study was conducted on 400 patients of Tinea cruris and corporis. The cases were diagnosed clinically and confirmed by 10%KOH mount and /or culture. The patients were divided into two groups randomly by simple randomization method. Group A received combination of Fluconazole and Griseofulvin and Group B received Fluconazole for a period of 4 weeks. Thirty patients in Group A and 27 patients in Group B were lost to follow up.

Thus 170 patients in Group A, 173 in group B were analysed to compile results.

Table 1

Patients Response at 1st week

Response	Group A		Group B	
	No.	%	No.	%
Complete clinical cure	1	0.59	1	0.58
Partial cure	169	99.41	172	99.42
No response	0	0.00	0	0.00
Total	170	100	173	100

χ^2=0.486 p = 0.486

Table 1, demonstrates the condition of patients at 1 week of treatment. Complete clinical cure was seen in 1 (0.59%) patient in group A and 1(0.58%) patient in group B. Partial cure was seen in 169(99.41%) and 172(99.42%) patients in group A and group B respectively. There was no statistically significant difference in both groups (p>0.05).

Table 2. Patients response at 2nd week

Response	Group A		Group B	
	No.	%	No.	%
Complete clinical cure	3	1.76	1	0.58
Partial cure	167	98.24	172	99.42
No response	0	0.00	0	0.00
Total	170	100	173	100

χ^2=0.271 p = 0.603

Table 2, demonstrates the condition of patients at 2 weeks of treatment. Complete clinical cure was seen in 3 (1.76%) patients in group A and 1(0.58%) patient in group B. Partial cure was seen in 167(98.24%) and 172(99.42%) respectively. There was no statistically significant difference in boths groups (p>0.05).

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Table 3

Patients Response at 3rd week

Response	Group A		Group B	
	No.	%	No.	%
Complete clinical cure	25	14.71	23	13.29
Partial cure	145	85.29	150	86.71
No Response	0	0.00	0	0.00
Total	170	100	173	100

χ^2=0.049 p = 0.825

Table3 shows the condition of patients at the end of 3 weeks. Complete clinical cure was seen in 25(14.71%) patients in group A and 23(13.29%) patients in group B. Partial cure was seen in 145(85.29%) and 150(86.71%) respectively. There was no statistically significant difference in boths groups (p>0.05).

Table 4

Patients Response at 4thweeks

Response	Group A		Group B	
	No.	%	No.	%
Complete Clinical Cure	148	87.05	125	72.25
Partial cure	22	12.95	48	27.75
No Response	0	0	0	0
Total	170	100	173	100

χ^2=10.48 p=0.001

Table 4 shows the condition of patients at the end of 4 weeks (end of treatment). Complete clinical cure was seen in 148(87.05%) patients in group A and 125(72.25%) patients in group B. Partial cure was seen in 22(12.95%) and 48(27.75%) patients in group A and group B respectively. There was statistically significant difference in boths groups (p<0.05).

Table 5

Patients Response at 8 weeks

Response	Group A		Group B	
	No.	%	No.	%
Complete clinical cure	128	75.29	93	53.76
Partial cure	22	12.94	48	27.75
Relapse	20	11.76	32	18.50
Total	170	100.00	173	100.00

χ^2=17.94 p = 0.0001

Table 5 shows the condition of patients at the end of 8 weeks (end of follow up). Complete clinical cure was seen in 128(75.29%) patients in group A and 93(53.76%) patients in group B.

Partial cure was seen in 22(12.94%) and 48(27.75%) patients in group A and group B respectively.

Clinically relapse was seen in 20 (11.76%) patients in group A and 32(18.50%) patients in group B

There was statistically significant difference in boths groups (p<0.001)

Discussion

The present study was conducted in an attempt to compare the efficacy and safety of two diffrent drug regimens, to determine predisposing factors as age, sex and occupational incidence of Dermatophytoses in clinically known cases of Tinea cruris and corporis attending outpatient department of Dermatology, Venereology and Leprosy of Sardar Patel Medical college and PBM group of Hospitals, Bikaner over a period of one year. Patients were divided into three groups randomly by simple randomization method. Group A received Tablet Fluconazole 150 mg per week plus Tablet Griseofulvin 10mg per kg bodyweight daily in two divided doses. Group B received Tablet Fluconazole 150 mg per week. A

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total of 343 patients (170 in Group A, 173 in Group B) were analysed to compile the results.

In our study we compared efficacy and safety of two different drug regimen with one regimen containing two drugs. It is one of the study being conducted for first time, as per scanning of the literature

Conclusion

This study proves that combination of Fluconazole and Griseofulvin is a better treatment option to treat tinea cruris and corporis as compared to mono therapy with Fluconazole.

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