

TO COMPARE THE EFFECTIVENESS OF DIFFERENT REGIMEN IN MANAGEMENT OF DERMATOPHYTE INFECTION AT TERTIARY CARE CENTER BIKANER RAJASTHAN

Anil Babani¹, R D Mehta², B C Ghiya³, Prasoon Soni⁴

¹ Resident Doctor, ² Senior Professor & HOD, ³ Associate Professor, ⁴ Assistant Professor
Department of Dermatology, Venereology and Leprosy, S.P. Medical College and A.G. of Hospitals Bikaner, Rajasthan

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Corresponding Author: R D Mehta, Senior Professor & HOD, Department of Dermatology, Venereology and Leprosy, S.P. Medical College and A.G. of Hospitals Bikaner, Rajasthan

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Abstract:

Background: The dermatophytoses are caused by a group of fungi known as ringworm or Tinea. These are from genera *Microsporum*, *Trichophyton* and *Epidermophyton*. Amongst Five to six species which are prevalent globally, *Trichophyton rubrum* happens to be the commonest.

Methods: A hospital based comparative prospective study included 600 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 3 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. Group C received Tablet Griseofulvin 10mg per kg body weight in two divided doses daily. Treatment to all groups was given for a period of 4 weeks. The data were analyzed on EPI-Info-6 Software.

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

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

Keywords: Fluconazole, Griseofulvin, Mono Therapy, Dual therapy, Tinea Cruris and Tinea Corporis.

Introduction

The dermatophytoses are caused by a group of fungi known as ringworm or tinea. These are from genera *Microsporum*, *Trichophyton* and *Epidermophyton*.¹ Amongst Five to six species which are prevalent globally, *Trichophyton rubrum* happens to be the commonest². It is estimated that superficial fungal infections affect roughly 20-25% of the world population³

Clinical manifestations may vary depending on the causative agent and on the immune response of the host; they may last for months to years and may be asymptomatic or manifest as pruritus only.⁴ In the majority of cases, however, infection manifests itself

as erythematous annular lesion with central clearing and some times as fissures, blistering and scales.⁵

The varied clinical presentation of tinea is often confused with other skin diseases. It may be due to misuse of combination creams containing steroid that lead to misdiagnosis and mismanagement and probably the reason for clinical resistance to available topical and oral antifungal drugs hence any such clinical diagnosis needs to be supported by laboratory diagnosis.⁶

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.⁷

Nowadays we have observed that patients with dermatophytoses do not respond to conventional treatment regimens. So in the present study we have compared the different drug regimen for treatment of tinea corporis and cruris and advantage of using combination treatment of fluconazole and griseofulvin 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.

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 3 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.

Group C received Tablet Griseofulvin 10mg per kg body weight in two divided doses daily.

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

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 600 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 three groups randomly by simple randomization method. Group A received combination of Fluconazole and Griseofulvin, Group B received Fluconazole and Group C received Griseofulvin for a period of 4 weeks. Thirty patients in Group A, while 27 patients each in Group B and C were lost to follow up.

Table 1: Patients Response at 1st week

Response	Group A		Group B		Group C	
	No.	%	No.	%	No.	%
Complete clinical cure	1	0.59	1	0.58	0	0.00
Partial cure	169	99.41	172	99.42	173	100.00
No response	0	0.00	0	0.00	0	0.00
Total	170	100	173	100	173	100

$\chi^2=1.013n$ $p = 0.603$

Table 1, demonstrates the condition of patients at 1 week of treatment. Complete clinical cure was seen in 1 (0.59%) patients in group A, 1(0.58%) patients in group B, none had any response in group C. Partial cure was seen in 169(99.41%),172(99.42%) and 173(100%) patients in group A, group B and groupC respectively.
There was no statistically significant difference in all the three groups ($p>0.05$).

Table 2: Patients response at 2nd week

Response	Group A		Group B		Group C	
	No.	%	No.	%	No.	%
Complete clinical cure	3	1.76	1	0.58	3	1.73
Partial cure	167	98.24	172	99.42	170	98.27
No response	0	0.00	0	0.00	0	0.00
Total	170	100	173	100	173	100

$\chi^2=1.179$ $p = 0.554$

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, 1(0.58%) patient in group B and 3(1.73%) patients in group C. Partial cure was seen in 167(98.24%), 172(99.42%) and 170(98.27%) patients in group A, group B and group C respectively.
There was no statistically significant difference in all the three groups ($p>0.05$).

Table 3: Patients Response at 3rd week

Response	Group A		Group B		Group C	
	No.	%	No.	%	No.	%
Complete clinical cure	25	14.71	23	13.29	21	12.14
Partial cure	145	85.29	150	86.71	152	87.86
No Response	0	0.00	0	0.00	0	0.00
Total	170	100	173	100	173	100

$\chi^2=0.489$ $p = 0.783$

Table 3shows the condition of patients at the end of 3 weeks. Complete clinical cure was seen in 25(14.71%) patients in group A, 23(13.29%) patients in group B and 21(12.14%) patients in group C. Partial cure was seen in 145(85.29%), 150(86.71%) and 152(87.86%) patients in group A, group B and group C respectively.
There was no statistically significant difference in all the three groups ($p>0.05$).

Table 4: Patients Response at 4th weeks

Response	Group A		Group B		Group C	
	No.	%	No.	%	No.	%
Complete Clinical Cure	148	87.05	125	72.25	119	68.78
Partial cure	22	12.95	48	27.75	54	31.22
No Response	0	0	0	0	0	0
	170	100	173	100	173	100

$\chi^2=17.649$ $p=0.0001$

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, 125(72.25%) patients in group B and 119(68.78%) patients in group C. Partial cure was seen in 22(12.95%), 48(27.75%) and 54(31.22%) patients in group A, group B and group C respectively.

There was statistically significant difference in all the three groups ($p<0.05$).

Table 5: Patients Response at 4 (b) weeks (Mycological Cure)

Response	Group A		Group B		Group C	
	No.	%	No.	%	No.	%
Complete cure	137	80.58	105	60.69	93	53.76
	KOH	Culture	KOH	Culture	KOH	Culture
Negative	141	139	107	118	95	108
Positive	7	9	18	7	24	11
Total	148	148	125	125	119	119

$\chi^2=6.016$ $p = 0.049$

Table 5 shows the condition of patients at the end of 4 weeks (end of treatment). Complete mycological cure was seen in 137(80.58%) patients in group A, 105(60.69%) patients in group B and 93(53.76%) patients in group C among the totally clinically cured patients. There was statistically significant difference in all the three groups ($p<0.05$)

Table 6: Patients Response at 8 weeks

Response	Group A		Group B		Group C	
	No.	%	No.	%	No.	%
Complete clinical cure	128	75.29	93	53.76	83	47.98
Partial cure	22	12.94	48	27.75	54	31.21
Relapse	20	11.76	32	18.50	36	20.81
	170	100.00	173	100.00	173	100.00

$\chi^2=29.874$

$p = 0.0001$

Table 6 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, 93(53.76%) patients in group B and 83(47.98%) patients in group C. Partial cure was seen in 22(12.94%), 48(27.75%) and 54(31.21%) patients in group A, group B and group C respectively.

Clinically relapse was seen in 20 (11.76%) patients in group A, 32(18.50%) patients in group B and 36(20.81%) patients in group C.

There was statistically significant difference in all the three groups ($p<0.05$).

DISCUSSION

The present study was conducted in an attempt to compare the efficacy and safety of three different 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. Group C received Tablet Griseofulvin 10mg per kg body weight in two divided doses daily. A total of 516 patients (170 in Group A, 173 in Group B, 173 in Group C) were analysed to compile the results.

In our study we compared efficacy and safety of three 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 or Griseofulvin. It is needed

to combine two antifungals to get better clinical and mycological cure rates. Patients should be advised to avoid steroid containing combination creams, adopt proper cleaning and ironing of clothes and treatment of all family members who are suffering from same ailment simultaneously.

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