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Original Research Article

Comparative Study of Efficacy of Oral Terbinafine and Oral Itraconazole in Treatment of Tinea Corporis Infection

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Abstract:

Background: Tinea corporis is a common superficial dermatophyte infection affecting keratinized tissues of the skin. Oral antifungal therapy is indicated in extensive, recurrent, or treatment-resistant infections. Terbinafine and itraconazole are widely used systemic antifungal agents, but their comparative efficacy and cost-effectiveness remain important considerations in clinical practice.

Aim: To compare the efficacy and cost-effectiveness of oral terbinafine and itraconazole in the treatment of patients with tinea corporis.

Methods: A prospective, randomized, single-blinded interventional study was conducted over one year in the Dermatology outpatient department of Government General Hospital, Kadapa. One hundred patients with KOH-positive tinea corporis were randomly allocated into two groups of 50 each. Group A received oral terbinafine 250 mg once daily, while Group B received oral itraconazole 100 mg once daily for four weeks. Clinical parameters including erythema, scaling, itching, lesion size, lesion margins, KOH microscopy, mycological cure, adverse effects, and overall clinical scores were assessed weekly. Statistical analysis was performed using SPSS version 21, with $p<0.05$ considered statistically significant.

Results: Both terbinafine and itraconazole produced significant clinical and mycological improvement. However, itraconazole demonstrated significantly greater reductions in erythema, scaling, itching, lesion size, and total clinical scores during the third and fourth weeks of therapy. At four weeks, KOH negativity was achieved in 84% of patients receiving itraconazole compared with 66% receiving terbinafine. Itraconazole also showed superior overall clinical response and excellent tolerability, whereas terbinafine was more economical, costing approximately ₹252 per patient compared with ₹300 for itraconazole.

Conclusion: Both oral terbinafine and itraconazole are effective treatments for tinea corporis. However, itraconazole provides superior clinical and mycological cure with excellent tolerability, making it the preferred therapeutic option. Terbinafine remains a cost-effective alternative, particularly for patients from lower socioeconomic groups. Larger multicentric studies are recommended to validate these findings.

Keywords: Tinea Corporis; Itraconazole; Terbinafine; Dermatophytosis; Antifungal Therapy.

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Introduction

Dermatophytes are fungi that invade and multiply within keratinized tissues (skin, hair, and nails) causing infection. [1] Based upon their genera, dermatophytes can be classified into three groups: Trichophyton (which causes infections on skin, hair, and nails), epidermophyton (which causes infections on skin and nails), and Microsporum (which causes infections on skin and hair). [2]

Based upon mode of transmission, these have been classified as anthropophillic, zoophilic and geophilic. Tinea corporis and tinea cruris infections may present as an annular erythematous plaque with a raised leading edge and scaling. Clearance occurs in the center of the lesion; however, resolution is often incomplete, because nodules may be left scattered throughout the infected area .The clearance in the center of the lesion may be the manifestation of an immune response of the host to the infecting organism. [3] Pruritus is a common symptom, and pain may be present if the involved area is macerated or secondarily infected. [4,5]

Tinea corporis can also present in a non-ringworm fashion, where it may manifest as an erythematous papule or a series of vesicles. [6] When a zoophilic dermatophyte, such as Trichophyton verrucosum, is the responsible organism, an intense inflammatory

reaction can result in large pustular lesions or a kerion. [4] In addition, occasionally frank bullae may appear as an expression of the inflammation, causing tinea corporis bullosa. [7]

Other factors such as increased urbanization including the use of occlusive footwear and tight fashioned clothes, has been linked to higher prevalence. [8] Over the last few years, studies on epidemiology of dermatophytic infection from different parts of India have shown a rising trend in the prevalence of cutaneous dermatophytosis with change in spectrum of infection and isolation of some uncommon species. [9-12] Few studies also showed isolation of rare species like Microsporum gypseum in non-endemic part of the world. [11]

The pathogenesis of dermatophyte infection involves complex interaction between the host, agent and the environment. The factors which predispose to such an infection are underlying diseases such as diabetes mellitus, lymphomas, immunocompromised status, or Cushing's syndrome, older age, which could produce severe, widespread, or recalcitrant dermatophytosis.

Some areas of the body are more susceptible to the development of dermatophyte infections such as intertriginous areas (web spaces and groins) where excess sweating, maceration, and alkaline pH favour the growth of the fungus. After inoculation into the host skin, suitable condition favor the infection to progress through adherence followed by penetration mediated by proteases, serine-subtilisins, and fungolysin, which causes digestion of keratin network into oligopeptide or amino-acid and also act as a potent immunogenic stimuli. [13]

Because of the broad range of differential diagnosis of dermatophyte infections, it is important to perform a mycologic examination, consisting of a10% to 15% KOH preparation, from skin scrapings, and a fungal culture on Sabouraud's agar media. When tinea corporis or tinea cruris infection is suspected, examination of the infected scales from the leading edge of the lesion may reveal septate hyphae coursing through the squamas.4 Cultures incubated at room temperature should grow the causative organism within 2 weeks.

Systemic treatment is necessary when large areas of the body are involved, the incidences chronic or recurrent, or when the infection is in immunocompromised patients. [14]

Tinea corporis and tinea cruris respond satisfactorily to topical therapies, such as the Azoles (sulconazole, oxiconazole, miconazole, clotrimazole, econazole, and ketoconazole); the allylamines (naftifine and terbinafine); benzylamine derivatives (butenafine); and hydroxypyridones (ciclopirox olamine). Repeated application to large areas of the skin may not always be feasible or convenient for the patient. Thus, oral treatments may be preferred by the patient. The use of oral ketoconazole has been limited by its rare association with hepatotoxicity. [15]

Griseofulvin has a rapid disappearance from the stratum corneum after administration because it is not very keratophilic with poor binding with keratin. Patients may be at a higher risk of relapse. [16]

The dosage of terbinafine is 250 mg/d given for 2 to 4 Weeks. The triazoles, fluconazole and itraconazole, are also safe and effective treatments for tinea corporis and tinea cruris. [17]

Fluconazole has shown high clinical and mycologic cure rates with once weekly therapy. Itraconazole is effective when given a regimen of 200 mg daily for 7days. [18]

In this study treatment options considered were Terbinafine among allylamines and itraconazole among triazoles. These two drugs are in frequent use in these infections as a treatment. So, I want to compare Terbinafine among allylamines and Itraconazole among triazoles for the efficacy and cost effectiveness. So that it may useful to the patients.

Aims & Objectives

1. To compare the efficacy of two oral antifungal agents –Terbinafine and Itraconazole in 50 each among 100 Tinea corporis patients in GGH, Guntur.
2. To identify the cost effective treatment among Terbinafine and Itraconazole.

Patients & Methods: This was a prospective, randomized, single blinded, interventional study conducted in outpatient division, Dermatology department of GGH, Kadapa in 100 patients with tinea corporis for a period of one year.

Inclusion Criteria: Age: 15-60 yrs, Both males and females, Patients who were not responding to topical therapy for > 2 wks, Positive KOH microscopy and culture, Patients ready for therapy after knowing adverse effects.

Exclusion Criteria: Age: >60 yrs, < 15 yrs, Pregnant and lactating women, Evidence of hepatic or renal disease, Patients who takes other drugs with possible interactions. Eg; cisapride, Hypersensitivity or intolerance to treatment.

100 patients who were diagnosed with Tinea corporis were taken into the study, on the basis of inclusion and exclusion criteria. They were divided into two groups A and B by randomization, each group containing 50 patients.

Ethical issues: Institutional Ethical committee approval was taken before starting the study and consent was taken from each patient before the study in local language.

Methodology: The study was single blinded study. The patient does not know the drug prescribed to him/her. The label on the back of tablet strips of both the drugs was removed to conceal the identity of drug and its dose.

Diagnosis of Tinea corporis: Microscopic examination is very important for the diagnosis of any tinea infection. Material is scraped from an active area of the lesion, placed in a drop of potassium hydroxide solution and examined under a microscope. The examination, which can be done quickly and easily, was highly sensitive and specific for dermatophyte identification. The highest yield was obtained from skin scrapings taken from the active border of a plaque. A fungal culture was an alternative, albeit slower method for diagnosis. In the present study patients were diagnosed as Tinea corporis based on KOH microscopy.

After diagnosis data collected by the proforma in both groups. Parameters like signs: Severity of redness, erythema, size of the lesion, scaling. Symptoms: pruritus, burning and scaling, KOH microscopy, culture on sabouraud's medium, adverse effects, were taken into the study. KOH Microscopy was done at the starting of the study and again at the end of treatment course.

Researcher knew the drug given .Drug given for Group 'A' patients -Terbinafine 250 mg. Drug given for Group 'B' patients –Itraconazole 100 mg. All the patients in Group 'A' were informed to take the given drug daily at morning time after breakfast for 4 weeks. All the patients in Group 'B' were informed to take the given drug once daily immediately after meals for 4 weeks. Patients were explained the whole procedure, advantages, probable adverse effects of drugs included in the study. After he/she accepted an informed consent form (Annexure-III) was given in local language (Telugu) and the person was asked to sign it or put a thumb impression. The study was non-invasive and drugs used in the study were safe. There were not life threatening to patient or imposed any serious hazards. Patient was educated about the possible adverse effects and asked to discontinue the drug immediately if there was any allergic reaction to the drug.

All the patients were given identical instructions for local hygienic care and advised to clean with soap when bathing, avoid the use of any other topical agents and always keep the infected areas dry and clean.

Patients should be encouraged to wear loose fitting garments made of cotton or synthetic materials designed to wick moisture away from the surface. Patients should also be advised to avoid walking barefoot and sharing garments. Each patient was asked to come to O.P at the end of 1st, 2nd, 3rd and 4th week to check all the parameters and adverse effects were checked.

Parameters taken in the study were: 1) Clinical improvement of signs and symptoms (signs: severity of redness, erythema, size of the lesion, scaling. symptoms: pruritus, burning and scaling). 2) KOH microscopy 3)Culture on sabouraud's medium 4) Adverse effects 5) Investigations like Hb%, TLC, DC, ESR, blood sugar, Weight, SGPT, SGOT, Blood urea and serum creatinine.

Efficacy parameters: The patients were monitored for the following signs.

Colour of the lesion: Change in colour from erythema to normal skin colour was noted. The scoring was given in following manner: 0=absent, 1=mild, 2=moderate, 3=severe.

Scaling of the lesion: The Scoring was given in the following manner: 0=absent, 1=Mild, 2=Moderate, 3=Severe. Itching: The scoring was given in the following manner: 0=no itching, 1=Mild itching not affecting daily activities, 2=Moderate itching affecting daily activities, 3=Severe itching disturbing the sleep.

Margins of the lesion: Whether the lesion shows progressive (presence of papules, vesicles) or regressive pattern (return to normal skin pattern). Scoring was given in following manner: 0=Regressive, 1=Stagnant, 2=Progressive.

Size of the lesion: Whether there was increase or decrease in size. Scoring for lesion size was as follows: 0=size less than 5cms in circumference, 1=size 5-10cms, 2=size 10-20cms, 3=size > 20cms.

KOH mount: The scoring was given as: 0=KOH negative, 2=KOH positive.

The efficacy of the treatment is determined by shifting of patients from grade 3 to grade 2, grade 2 to grade 1, grade 1 to grade 0 with each parameter. Grade 0 is the highest level of cure that can be attained by any patient. So the primary aim of treatment was to bring the patient to grade 0.

The total score includes the scores of colour of the lesion, scaling of the lesion, itching, and margins of the lesion, size of the lesion and KOH mount.

Statistical analysis: All the data entered in Microsoft Excel sheet (Annexure-IV) and analysed by statistical software SPSS version 21. Results of the study were analyzed statistically by using paired and unpaired student 't' test and the significance of results was tested by taking probability value at 0.05.sample size in each group was 50.so the degree of freedom was 49. After applying 't' test the obtained t value was compared with 't' value in t table at probability 0.05 at 49 degrees of freedom to evaluate whether the result is significant or not.

Results

Table 1: Age Distribution of Patients in Each Group

Age (Yrs)	Terbinafine Group(n=50)	Itraconazole group(n=50)	Total (n=100)
15-30	23 (46%)	21 (42%)	44 (44%)
31-40	15 (30%)	18 (36%)	33 (33%)
41-50	8 (16%)	6 (12%)	14 (14%)
51-60	4 (8%)	5 (10%)	9 (9%)

Table 2: Gender Distribution of Patients in Each Group

Gender	Terbinafine group(n=50)	Itraconazole group(n=50)	Total
Male	30	26	56
Female	20	24	44

Table 3: Comparison of Pre and Post Treatment Erythema in Terbinafine and Itraconazole Group

Erythema grade	Terbinafine group(n=50)		Itraconazole group(n=50)	
	Pretreatment patients	Post treatment patients	Pretreatment patients	Post treatment Patients
	No. (%)	No. (%)	No. (%)	No. (%)
0	0 (0)	13 (26.0)	0 (0)	32 (64.0)
1	7 (14.0)	33 (66.0)	6 (12.0)	18 (36.0)
2	21 (42.0)	4 (8.0)	23 (46.0)	0 (0)
3	22 (44.0)	0 (0)	21 (42.0)	0 (0)

Table 4: Comparison of Mean Scores of Erythema in Terbinafine and Itraconazole Group

Erythema	Terbinafine group(n=50)		Itraconazole group(n=50)		P value
	Mean	Std. deviation	Mean	Std. deviation	
Baseline	2.3	0.71	2.3	0.68	1.0 (NS)
1st week	1.42	0.61	1.64	0.72	0.1 (NS)
2nd week	1.16	0.47	1.12	0.38	0.64 (NS)
3rd week	1.0	0.49	0.64	0.52	0.0006(S)
4th week	0.82	0.56	0.36	0.48	0.0001(S)

Table 5: Comparison of Pre and Post Treatment Scaling In Terbinafine and Itraconazole Group

Scaling grade	Terbinafine group(n=50)		Itraconazole group(n=50)	
	Pretreatment patients	Post treatment patients	Pretreatment patients	Post treatment Patients
	No. (%)	No. (%)	No. (%)	No. (%)
0	0 (0)	35 (70.0)	0 (0)	44 (88.0)
1	18 (36.0)	15 (30.0)	10 (20.0)	6 (12.0)
2	17 (34.0)	0 (0)	30 (60.0)	0 (0)
3	15 (30.0)	0 (0)	10 (20.0)	0 (0)

Table 6: Comparison of Mean Scores of Scaling In Terbinafine and Itraconazole Group

Scaling	Terbinafine group(n=50)		Itraconazole group(n=50)		P value
	Mean	Std. deviation	Mean	Std. Deviation	
Baseline	1.94	0.82	2	0.64	0.68 (NS)
1st week	1.52	0.73	1.64	0.63	0.38 (NS)
2nd week	1.22	0.51	1.24	0.43	0.83 (NS)
3rd week	0.8	0.64	0.88	0.56	0.5 (NS)
4th week	0.3	0.46	0.12	0.33	0.02 (S)

Table 7: Comparison of Pre and Post Treatment Itching In Terbinafine and Itraconazole Group

Itching grade	Terbinafine group(n=50)		Itraconazole group(n=50)	
	Pretreatment patients	Post treatment patients	Pretreatment patients	Post treatment Patients
	No. (%)	No. (%)	No. (%)	No. (%)
0	0 (0)	32 (64.0)	0 (0)	46 (92.0)
1	11 (22.0)	18 (36.0)	12 (24.0)	4 (8.0)
2	28 (56.0)	0 (0)	22 (44.0)	0 (0)
3	11 (22.0)	0 (0)	16 (32.0)	0 (0)

Table 8: Comparison of Mean Scores of Itching In Terbinafine and Itraconazole Group

Itching	Terbinafine group(n=50)		Itraconazole group(n=50)		P value
	Mean	Std. deviation	Mean	Std. deviation	
Baseline	2	0.67	2.08	0.75	0.57 (NS)
1st week	1.58	0.57	1.72	0.73	0.28 (NS)
2nd week	1.28	0.45	1.42	0.61	0.19 (NS)
3rd week	1.16	0.37	1.02	0.55	0.13 (NS)
4th week	0.36	0.48	0.08	0.27	0.0005 (S)

Table 9: Comparison of Pre and Post Treatment Margins in Terbinafine and Itraconazole Group

Margins Grade	Terbinafine group(n=50)		Itraconazole group(n=50)	
	Pretreatment patients	Post treatment patients	Pretreatment patients	Post treatment Patients
	No. (%)	No. (%)	No. (%)	No. (%)
0	0 (0)	35 (70.0)	0 (0)	44 (88.0)
1	3 (6.0)	15 (30.0)	4 (8.0)	6 (12.0)
2	47(94.0)	0 (0)	46 (92.0)	0 (0)
3	0 (0)	0 (0)	0 (0)	0 (0)

Table 10: Comparison of Mean Scores of Margins in Terbinafine and Itraconazole Group

Margins	Terbinafine group(n=50)		Itraconazole group(n=50)		P value
	Mean	Std. deviation	Mean	Std. deviation	
Baseline	1.94	0.24	1.92	0.27	0.69 (NS)
1st week	1.58	0.5	1.46	0.5	0.23 (NS)
2nd week	1.32	0.47	1.22	0.42	0.26 (NS)
3rd week	0.76	0.62	0.72	0.45	0.71 (NS)
4th week	0.3	0.46	0.12	0.33	0.02 (S)

Table 11: Comparison of Pre and Post Treatment Size in Terbinafine and Itraconazole Group

Size grade	Terbinafine group(n=50)		Itraconazole group(n=50)	
	Pretreatment patients	Post treatment patients	Pretreatment patients	Post treatment patients
	No. (%)	No. (%)	No. (%)	No. (%)
0	0	2 (4.0)	0 (0)	23 (46.0)
1	4 (8.0)	33 (66.0)	10 (20.0)	27 (54.0)
2	25 (50.0)	15 (30.0)	16 (32.0)	0
3	21 (42.0)	0	24 (48.0)	0

Table 12: Comparison of Mean Scores of Size in Terbinafine and Itraconazole Group

Size	Terbinafine group(n=50)		Itraconazole group(n=50)		P value
	Mean	Std. deviation	Mean	Std. Deviation	
Baseline	2.34	0.63	2.28	0.78	0.67 (NS)
1st week	1.9	0.71	1.8	0.81	0.51 (NS)
2nd week	1.68	0.68	1.5	0.76	0.21 (NS)
3rd week	1.54	0.64	1.02	0.14	0.0001 (S)
4th week	1.26	0.53	0.54	0.5	0.0001 (S)

Table 13: Comparison of Pre and Post Treatment Koh Mounts Investigation in Terbinafine and Itraconazole Group

KOH mount grade	Terbinafine group(n=50)		Itraconazole group(n=50)	
	Pretreatment patients	Post treatment patients	Pretreatment patients	Post treatment patients
	No. (%)	No. (%)	No. (%)	No. (%)
0	0 (0)	33 (66.0)	0 (0)	42 (84.0)
1	0 (0)	0 (0)	0 (0)	0 (0)
2	50 (100)	17 (34.0)	50 (100)	8 (16.0)
3	0 (0)	0 (0)	0 (0)	0 (0)

Table 14: Comparison of Mean Scores of Koh in Terbinafine and Itraconazole Group

KOH grade	Terbinafine group(n=50)		Itraconazole group(n=50)		P value
	Mean	Std. Deviation	Mean	Std. Deviation	
Baseline	2	0	2	0	-
1st week	1.92	0.39	1.72	0.7	0.08 (NS)
2nd week	1.36	0.94	1.24	0.98	0.53 (NS)
3rd week	1.0	1.01	0.76	0.98	0.23 (NS)
4th week	0.68	0.96	0.32	0.74	0.038 (S)

Table 15: Comparison of Mean Clinical Scores in Terbinafine and Itraconazole Group

Mean total score	Terbinafine group(n=50)		Itraconazole group(n=50)		P value
	Mean	Std. Deviation	Mean	Std. Deviation	
Baseline	12.52	1.16	12.58	1.41	0.81 (NS)
1st week	9.92	1.35	9.98	1.38	0.82 (NS)
2nd week	8.02	1.54	7.74	1.61	0.37 (NS)
3rd week	6.26	1.65	5.04	1.5	0.0002 (S)
4th week	3.72	1.44	1.54	1.05	0.0001 (S)

Table 16: Mean Clinical Scores in Terbinafine Group

	Terbinafine group (n=50)				
	At Baseline	At 1st wk	At 2nd wk	At 3rd wk	At 4th wk
Mean ± SD	12.52±1.16	9.92±1.35	8.02±1.54	6.26±1.65	3.72±1.44
P value (comparing with Baseline)		<0.05 (S)	<0.05 (S)	<0.05 (S)	<0.05 (S)

Table 17: Mean Clinical Scores in Itraconazole Group

	Itraconazole group (n=50)				
	At Baseline	At 1st wk	At 2nd wk	At 3rd wk	At 4th wk
Mean ± SD	12.58±1.41	9.98±1.38	7.74±1.61	5.04±1.5	1.54±1.05
P value (comparing with Baseline)		<0.05 (S)	<0.05 (S)	<0.05 (S)	<0.05 (S)

Discussion

This study was a randomized, interventional, single blinded study conducted in out -patient division of Dermatology department of Government General Hospital, Kadapa, and Andhra Pradesh. In this study two drugs Terbinafine and Itraconazole were choosen because data comparing oral terbinafine with itraconazole were limited. Oral antifungal agents were important in the treatment of tinea infections that are widespread, which fail to respond to topical treatment, which involve the thick stratum corneum of the soles and palms, or which occur in immunosuppressed patients.

Short courses of oral itraconazole and terbinafine are safe and effective in treating tinea infections. Both itraconazole and terbinafine were display high anti dermatophyte activity,these agents had a better mycological cure rate and lower relapse rate and it was not necessary to treat any patient for more than four weeks. These drugs improved patient compliance. They were well tolerated. The results in the present study proved that both itraconazole and terbinafine display high anti dermatophyte activity. Faster onset and longer post therapy activity were demonstrated in the itraconazole treatment group. These results were consistent with the study of J.Decroix, P.Fritsch, A.Picoto, W.Thurlimann, H.Degreef et al conducted a study in a tertiary care hospital which was a double blind, multi centre trail conducted with 230 patients. Patients were given Itraconazole 200mg/day for 7 days, Terbinafine 250 mg/day for 7 days. Their results concluded that after 5 weeks of follow up, 81% of itraconazole-treated patients and 68% of terbinafine-treated patients were mycologically cured ($p < 0.05$).19 This mycological cure rate was similar to our study results which were, 66%, 84% patients in Terbinafine and Itraconazole groups showed absence of hyphae in KOH mount test after 4 weeks of treatment.

In our study mycological cure rate by Itraconazole was statistically significant than terbinafine. ($p < 0.05$). The clinical response rate was 84% in itraconazole-treated patients and 71 % in terbinafine-treated patients ($p < 0.05$). Similarly In our study at the end of 3rd and 4th week significantly better reduction ($P<0.05$) of overall scores was observed by Itraconazole than Terbinafine. This showed Itraconazole drug showed better efficacy than Terbinafine.

In our study both medications displayed good safety profiles, but tolerability was rated significantly higher in the itraconazole group than in the terbinafine group ($p=0.001$).This explains that both Terbinafine, Itraconazole is highly effective in treatment of superficial dermatomycosis. But Itraconazole is significantly better than Terbinafine in terms of mycological, clinical cure and also tolera-

bility. These results were also consistent with the study of G.E. Pierard, MD, PhD, J.E. Arrese, MD, PDe Doncker, et al conducted a study on ‘’Antifungal activity of itraconazole and terbinafine in human stratum corneum. In this study three groups of 10 healthy volunteers entered the open comparative trial. Results were evaluated in a blinded manner. 200 mg itraconazole daily and twice daily and 250 mg/day terbinafine were given to all three groups. 200 mg itraconazole twice daily appeared to be more fungitoxic than 250 mg/day terbinafine and 200 mg/day itraconazole. Their study concluded that both itraconazole and terbinafine display high anti dermatophyte activity. Faster onset and longer post therapy activity were demonstrated in the itraconazole treatment groups. [20]

The results were also consistent with Susan M. Grant, Stephen P. Clissold et al conducted a study on “Itraconazole A Review of its Pharmacodynamic and Pharmacokinetic Properties, and Therapeutic Use in Superficial and Systemic mycoses. This article explains that itraconazole 100mg once daily has proven to be the optimal dosage in dermatophytoses, producing ⩾ 80% clinical and mycological response (cure or marked improvement) against tinea corporis, tinea cruris, tinea pedis and tinea manuum. [21] These results were similar to our study.

In the present study itraconazole100 mg was given for a period of 4 weeks. Itraconazole showed significant clinical response and mycological cure than terbinafine. This shows Itraconazole was preferred drug for tinea corporis. These results were supported by following studies.

Boonk. W, de Geer. D de Kreek. E, Remme. J, van Huystee. B conducted a study on “Itraconazole in the treatment of tinea corporis and tinea cruris: comparison of two treatment schedules”. This is a multicentre, randomized, double-blind parallel-group trail. 54 patients were given 100mg daily for 2weeks. 60 patients were given 200 mg daily for 1 week. After a 6-week follow-up period, mycological cure was achieved in 70% of patients in the 100 mg/2 weeks group and in 60% of cure in the 200 mg/1 week group (not significantly equivalent); Clinical response was seen in 80% of 100 mg/2 weeks group and in 73% in the 200 mg/1 week group at the end of follow-up (borderline equivalent). [22] Noppakun N, Phuphaibool K conducted a study on “Treatment of dermatophytosis with new systemic antifungal agent, itraconazole’’. It is a open non-comparative clinical trial, Itraconazole was given orally in the dosage of 100 mg per day for 14 consecutive days. Their study concluded that Itraconazole was highly effective in treatment of dermatophytosis with a shorter treatment period than other conventional antifungal agents. [23] Malini Haria, Harriet M. Bryson, Karen L. Goa et al conducted a study on ‘’Itraconazole A Reappraisal of its Pharmacological Properties and Therapeutic Use in the Management of Superficial Fungal Infections’’. Their study concluded that itraconazole 100 mg/day demonstrate that 2-week treatment courses generally produce clinical and mycological cure/marked improvement in /≥80% of patients with dermatophyte infections affecting body areas, groin, and interdigital areas of the hand and foot; complete healing (clinical cure and negative mycology) may be observed in ≈ 50 to 80% of patients. [24]

Amado saul, Alejandro Bonifaz MB et al conducted a study on ‘’Itraconazole in common dermatophyte infections of the skin: Fixed treatment schedules’’. Their study concluded that Itraconazole is an effective medication against the most common dermatophytoses. It has been shown to be more active than griseofulvin and ketoconazole. [25]

De Doncker P, Cauwenbergh G et al conducted a study on “Management of fungal skin infections with 15 days itraconazole treatment: a worldwide review.’’ Their study concluded that Itraconazole shows 80% mycological cure and a 90% clinical response at a daily dose of 100 mg for 15 days. [26]

In the present study males (56%) outnumbered females (44%) with a male to female ratio of 1.3:1. This show Males were more suffering from dermatophyte infections than females which were consistent with other studies like Agarwal US, Saran J, Agarwal P et al study [11], Sahai S, Mishra D et al study [12]. In their studies male to female ratio was 2.16:1 in Agarwal etal study and 2:1 in Sahai S etal study.

In the present study by analysing the age pattern, it was found that the incidence of Tinea corporis is (44%) more among younger population in15-30 yrs age group. This finding is consistent with Bindu V, Pavithran K et al study. In their study, maximum patients were seen in the second decade with males outnumbering females. The higher incidence in young males could be due to greater physical activity and increased sweating. [27]

In the present study there were no adverse effects noted with itraconazole. This is in consistence with Michael s, Saag, et al study [28]. This article states that Itraconazole and fluconazole show much promise as orally active agents, with less potential for toxicity than the currently available azoles. The present study compared efficacy and cost effective treatment of two drugs Terbinafine, Itraconazole and concluded both terbinafine and itraconazole are quite effective in the treatment of tinea corporis patients in terms of Mycological cure. Itraconazole shows slightly better results than Terbinafine ($P > 0.05$). The terbinafine is more cost effective than itraconazole.

Benefits and Strengths of the study: Both Terbinafine and Itraconazole were given for shorter therapy as both are fungicidal. Studies with fewer subjects like present study were quick to conduct –short duration of treatment is needed to enroll the patients. Easy to review the patient case sheets at any time. Research questions were addressed in relatively short span of time.

Collection of scrapings from the lesion and KOH microscopy was possible for each and every patient in both the groups with fewer subjects. Obtaining institutional ethics committee approval is easy for small studies like this when compared to large multi centre trials. Appropriate focus on each subject to receive exact number of medicines and exact dose was given.

Randomized study: Randomization was done to reduce the subjective errors confounding factors which made this study more accurate. Both the drugs were given to patients with financial assistance of researcher. KOH microscopy was done in microbiology department of GMC, Kadapa. Culture in SDA agar also was done in microbiology department GMC, Kadapa

Conclusions

Tinea corporis is a common problem encountered in dermatology practice. It is more common in males than females. It mainly involves Lower extremities and trunk. T. rubrum is the most common causative organism. Hot and humid climates, occlusive clothing, increased hydration and maceration of skin are most common predisposing factors.

Most patients with tinea corporis are diagnosed clinically. To avoid a misdiagnosis, identification of dermatophyte infections requires both a fungal culture on Sabouraud's agar media, and a mycological examination, consisting of a 10% to 15% KOH preparation, from skin scrapings.

Although topical antifungals may be sufficient for treatment of tinea corporis, but systemic medications are used for patients with severe infection, for infections that do not respond to topical therapy, when the infected areas are large, macerated with a secondary infection, or in immunocompromised individuals. Common systemic antifungal agents used are oral griseofulvin, terbinafine, fluconazole and itraconazole. Azole and Allylamine agents appear to have greater efficacy and fewer side effects. The most commonly prescribed drugs Allylamines, Azoles were included in our study. Itraconazole showed promising results when compared to Terbinafine.

The response rate and the mycological cure rate in the itraconazole treatment group continued to increase in the 15 days following treatment and this can be explained by the high affinity that itraconazole has for the skin. There were no serious adverse effects in both the groups. Cost of treatment 252 rupees per patient in Terbinafine group (For 4 weeks) and 300 rupees per patient in Itraconazole group (for 4 weeks). In conclusion Itraconazole is more effective than terbinafine in clearing the symptoms, signs and the infection. But as per the cost, terbinafine is suitable to lower socio economic groups of patients.

Limitations of the study

In this study the sample size was 100 indicating that the study sample was small. Results for small studies were less reliable when compared to larger studies. Larger studies with more subjects produce narrow confidence of intervals (95% to 99%) and so produce more precise results. It was difficult to distinguish between a real effect and a random variation in smaller studies.

This study was done only with dose of 250 mg Terbinafine and 100mg Itraconazole varying doses and dose titrated effects comparison was not done in this study. Dose was not titrated in this study as patients responded to the actual proposed dose. Limitations of standard microscopy and culture methods have been recognized. There is a high false negative culture rate, and thus there is a question of whether new episodes of infection or new infections, or relapses of previous infection. Culture is time consuming.

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