Original Article

A study to compare efficacy of various oral antifungals (Fluconazole, Terbinafine, Itraconazole) in treatment of Onychomycosis

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ABSTRACT

Background: Onychomycosis is accounting for upto 50% all nail disorders. It causes not only physical but also psychosocial and emotional distress to the patient. Treatment of the disease is far from satisfactory mainly due to high cost and long duration of therapy with poor patient compliance.

Objective: to compare the efficacy of pulse therapy of oral Fluconazole, Terbinafine and Itraconazole.

Methods: 90 patients of Onychomycosis were randomly divided into 3 treatment groups and followed up regularly. KOH smear and culture were done of all patients. Group A was given tablet Fluconazole 150 mg per week for 6 months in fingernail and 12 months in toenail onychomycosis. Group B was given tablet Terbinafine 250 mg and group C was given capsule Itraconazole 200 mg twice daily for 1st 7 days/month for 3 or 4 months in finger or toe nails involvement respectively.

Results: Male Female ratio was 1:2.46 with Mostly housewives (53.33%). Distal & Lateral Subungual Onychomycosis was the most common type in 82.22% patients. Grade IV improvement was seen in 46.66% patients in group B, 40% patients in group C and 33.33% patients in group A at the end of the study.

Conclusion: Both Terbinafine and Itraconazole pulse therapy is equivalent in terms of clinical cure and relapse. But Terbinafine being cost effective and having minimal drug interaction appears to be the best drug.

Keywords: Onychomycosis, fluconazole, terbinafine, itraconazole

INTRODUCTION

Onychomycosis includes all infection of nail caused by any fungus including Non-Dermatophytes and Yeast. It represents 30% of all mycotic infections of the skin [1, 2]. Its incidence is rising due to increased average age of population [3], uses of occlusive shoes and the numbers of the immune-compromised patients. Now it accounts for upto 50% of all nail disorders [4]. Onychomycosis occurs commonly in adults [5] and is commonly associated with Tinea Mannum or Tinea Pedis [6]. It may lead to pain, discomfort and impaired tactile or motor functions. It may also affect patient psychosocially or emotionally. Treatment of onychomycosis has been a challenge for dermatologists because of longer duration of therapy, high cost of therapy and inherent slow growth of the nail plate requiring a long time to see observable effects of treatment [7]. The most commonly used agents for treatment are fluconazole, terbinafine and itraconazole. They have ability to penetrate the nail apparatus easily and persist there for months after stopping therapy. High cost of conventional therapy has lead to formation of different therapeutic schedules of these drugs which minimizes the cost with affecting the efficacy. And this study was conducted to compare the efficacy of the pulse therapy among fluconazole, terbinafine and itraconazole.

MATERIAL AND METHODS

Single blinded, randomized, clinical comparative study was conducted in the department of Skin V.D. & Leprosy, MP Shah Medical College, Jamnagar during the period from August 2012 to July 2014. 90 patients of 18 years or above were selected randomly from out-patient department having clinical features of

Onychomycosis either in finger or toenail or both. Patients having known hypersensitivity to drugs, pregnant or lactating woman, having abnormal CVS, Hepatic or Renal function, patients of uncontrolled DM, immune-compromised state, concomitant nail lesions of other dermatoses, already taken antifungal treatment in recent past were excluded from the study. All patients were subjected to KOH smear study and culture on Sabourad's agar. They were randomly assigned into one group regimen. Group A was given tablet Fluconazole 150 mg per week for 6 months in fingernail and 12 months in toenail onychomycosis. Group B was given tablet Terbinafine 250 mg and group C was given capsule Itraconazole 200 mg twice daily for 1st 7 days/month for 3 or 4 months in finger or toe nails involvement respectively. Written consent, clinical photographs were taken. Patients were followed up regularly monthly till completion of the study. Treatment response <30% were given grade 1, 30-60% improvement (grade 2), 60-90% improvement (grade 3) and >90% improvement was given grade 4 and that was considered clinically cured. At end repeat KOH smear and Culture study was also done to check cure and relapse.

Ethical clearance

Ethical permission was taken from ethical committee of institute.

RESULTS

90 patients of onychomycosis were randomly selected and divided into any of 3 treatment groups. The age distribution of the study was as following. Maximum no. of patients 38(42.22%) belonged to 31-40 years of age while minimum 2(2.22%) were seen above 50 years of age as shown in table-1.

Table 1: Distribution of patients according to age

Age (in yrs)	Group A	Group B	Group C	Total (%, n=90)
18-30	8	14	10	32(35.55%)
31-40	14	10	14	38 (42.22%)
41-50	8	4	6	18 (20%)
51-60	0	2	0	4(2.22%)
Total	**30**	**30**	**30**	**90 (100%)**

Table 2: Distribution of patients according to sex

Male (%)	Female (%)	Total (%, n-90)
26 (28.88)	64 (71.12%)	90 (100%)

Female patients 64(71.12 %) outplayed male patients 26(28.88%) in our study as shown in table-2.

Occupation distribution of the study was varied with maximum numbers 48(53.33%) of patient were housewife followed by laborer 16(17.77%), service person 10 (11.11%), students & businessmen were 6 (6.66%) from each group & 4 (4.44&) were from other job as shown in table-3.

Table 3: Distribution of patients according to occupation

Occupation	Number of patients	Percentage (%, n=90)
Student	6	6.66%
Laborer	16	17.77%
housewives	48	53.33%
Businessmen	6	6.66%
Service	10	11.11%
miscellaneous	4	4.44%

Among various clinical patterns of onychomycosis DLSO (Distal & Lateral Subungual Onychomycosis) accounts for 74 (82.22%) of patients while minimum patients 2(2.22%) were of PSO (Proximal Subungual Onychomycosis) as shown in table-4.

Table 4: Distribution of patients according to clinical types

Sr. No.	Clinical types	Present study	Gupta et al [9]	Neerja et al [8]
1.	DLSO	74(82.22%)	95(73.1%)	57(76%)
2.	WSO	10(11.11%)	6(4.6%)	3(4%)
3.	PSO	2(2.22%)	7(0.7%)	1(1.33%)
4.	TDO	4(4.44%)	9(7.7%)	14(18.66%)

At the end of the study 46.66% patients in group B (i.e. terbinafine pulse therapy) while 40% in group C (i.e. itraconazole pulse therapy) and 33.33% patients in group A (i.e. fluconazole pulse therapy) were clinically cured (i.e. grade 4 improvement) as shown in table-5.

Table-5: Clinical cure rate following treatment

Regimen	At 12 months of therapy				At end of study			
	Grade of improvement				Grade of improvement			
	1	2	3	4	1	2	3	4
Group A	0	12 (40%)	8 (26.66%)	**10 (33.33%)**	0	16 (53.33%)	6 (20%)	**8 (26.66%)**
Group B	0	2 (6.66%)	14 (46.66%)	**14 (46.66%)**	0	4 (13.33%)	12 (40%)	**14 (46.66%)**
Group C	0	0	18 (60%)	**12 (40%)**	0	2 (6.66%)	16 (53.33%)	**12 (40%)**

DISCUSSION

Maximum no. of patients 38(42.22%) belonged to 31-40 years of age while minimum 2(2.22%) were seen above 50 years of age as shown in Table-1. These findings are comparable with study done by Neerja Puri et al [8] which had maximum number of patients 28(37.2%) in age group 31-40 years of age.

Female patients 64(71.12 %) outplayed male patients 26(28.88%) in our study as shown in table-2. The finding is consistent with study by Neerja Puri et al [8] where females were 57(76%) and males were 18(24%).

In present study maximum numbers 48(53.33%) of patient were housewife, that is consistent with the study Neerja Puri et al [8] where 39(52%) numbers of patients were housewife. Exact reason for more prevalence of onychomycosis in housewife is not identified but it may be due to wet work.

Most numbers of cases were from DLSO category about 74 (82.22%) while minimum patients 2 (2.22%) were of PSO category. These findings were also consistent with other studies as shown in table-4 [8, 9].

Clinical cure rate of present study is shown in table-5. According to Minati Mishra et al [10], who studied the efficacy of pulse therapy of terbinafine v/s itraconazole, clinical cure rate (>70%) were 79% and 82% respectively. In Arca E et al [11], clinical cure was 37% in Fluconazole group.

CONCLUSION

In our study Female preponderance was noticed. Among them most of were housewives. This suggested that in housewives contact with water and detergent favors the fungal invasion. Clinically Distal Lateral Subungual Onychomycosis was the commonest diagnosis. Both Terbinafine and Itraconazole have not only significantly higher clinical and mycological cure rate but also have lower relapse rate than Fluconazole. There is no significant difference in between terbinafine and itraconazole in terms of clinical cure. Terbinafine being the cost effective than Itraconazole ensures that patients are more likely to complete therapy. So in our study we found that both Terbinafine and Itraconazole have comparable cure rate clinically and mycologically, but as we take cost effectiveness, lesser drug interactions as per literature into consideration, Terbinafine appears to be the best drug.

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