

ITRACONAZOLE THERAPY IN TINEA VERSICOLOR

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The efficacy of itraconazole was assessed in an open trial in 60 patients with wide spread disseminated lesions of Tinea versicolor confirmed by direct microscopy. The patients were allocated randomly to one of the two treatment regimens. 200 mg once daily for 7 days or 100 mg once daily for 15 days. On assessment 3 weeks after the end of the treatment. 50 patients were healed. 4 had mild residual lesions. 4 had considerable residual lesions, and 2 had relapsed. Two patients reported pain in the abdomen. Two patients reported nausea, vomiting and dyspepsia. Two patients had mild elevation of SROT, and SOT. Conclusion: Treatment of tinea versicolor with itraconazole 200mg day for 7 days or 100 mg day for 15 days is recommended.

INTRODUCTION

Tinea versicolor is the most common superficial, chronic fungal infection of the skin which is caused by *Malassezia furfur*,¹ characterized by discrete or confluent scaly discoloured or depigmented or hyperpigmented areas mainly on the trunk, arms, neck, abdomen, axillae, groins, thighs, genitalia, and even face and legs.

The normal flora of skin has two yeasts which are lipophilic namely *Pityrosporum orbiculare* and *Pityrosporum ovale*. *Malassezia furfur* is the filamentous form of *P. orbiculare* and *P. ovale*. The predisposing factors, for conversion of the commensals to the pathogenic form are seborrheic dermatitis,² hyperhidrosis,³ genetic factors, steroid therapy, immuno-suppressive therapy and malnutrition. Pregnancy and oral contraceptives may have some influence. If untreated Tinea versicolor can persist for many months or years. Cool weather can improve the condition but most of the patients need therapy. Various topical therapies such as selenium sulphide ketoconazole, 20% sodium hyposulphide solution and 50:50 propylene glycol in water and other broad spectrum topical anti-fungal. Since topical applications are messy and difficult to apply with the result that there is poor patient compliance, systemic therapy is more acceptable to the patients.

Oral ketoconazole 200 mg/day for 1-5 days gives satisfactory results.¹ The major problem with ketoconazole is its hepatotoxicity.

Itraconazole is a triazole derivative, which is active in vitro against *Pityrosporum* species. It is 5-10 times more potent than ketoconazole. Though

the drug is comparatively safe but should not be used in pregnancy.

We report results of an open randomized study of two treatment regimens with Itraconazole in patients with extensive Tinea versicolor.

PATIENTS AND METHODS

60 patients with wide spread tinea versicolor, who were seen in the skin department of Ayub Medical College and Hospital Complex, over a period of 20 months, were included in the trial. The criteria for inclusion were skin lesions typical of this condition (erythema, scaling, hypo and hyper pigmentation). Fluorescence in wood's light and positive KOH examination.

All patients were clinically assessed. Four parameters of clinical disease activity (hypo, or hyper pigmentation, scaling, itching) were observed and scored as 0=none, 1=mild, 2=moderate, 3=severe. Pregnant women, children, nursing mothers, and patients with other systemic diseases were excluded. The following tests were done on the first visit.

FBC

Blood Sugar

Serum Creatinine, Alkaline phosphatase

Serum bilirubin

SGPT, SGOT, LDH Cholesterol and

Triglycerides.

The patients were divided randomly into two groups. I and II having thirty (30) patients in each. Patients in group I were given 200 mg OD itraconazole after food for 7 consecutive days.

Patients in group II were given 100 mg itraconazole OD after food for 15 days. All other medications were stopped during the study.

The patients were asked to return one day after the end of therapy and again 3 weeks later. At these visits the patients were tested as pre-treatment time. At the end of the study the patient's condition was rated as healed, mild residual lesions, considerable residual lesions, unchanged, deteriorated, and unevaluable. Adverse

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effects were recorded. Haematological and Bio-chemical evaluation were repeated.

RESULTS

All patients in both groups had nummular lesions but 20 had confluent lesions. The sites affected were trunk, neck, upper arms, thighs, groin and face. The lesions were hypopigmented, or hyperpigmented with a few having erythematous lesions. Twenty-one (21) patients complained of itching. All patients had scaling (20 mild, 28 moderate, 12 severe).

Table-2 shows the results of the treatment one day after the end of therapy. Itching had disappeared in both groups of patients. Table-3 shows the results, 3 weeks after finishing therapy. 28 patients (93%) in Group-I had responded to treatment. 26 patients (87%) in Group-I 1 had responded to therapy.

All the patients found the treatment simple, easy and acceptable, though expensive. Compliance was good.

Some patients complained of mild side effects such as dyspepsia or pain in the abdomen.

No haematological and biochemical abnormality was detected but in two patients who had raised SGOT and SGPT, which returned to normal in two months' time.

DISCUSSION

At the assessment, one day after the end of therapy itching and erythema had disappeared in all patients in both groups. However mild scaling persisted in 14 patients in Group-I and 20 patients.

in group-11. Almost all had KOH positive. Wood's lamp test was still positive in these patients.

Comparing the results one day and 3 weeks after the cessation of therapy, it becomes evident that the patients treated with itraconazole, who had tinea versicolor should be evaluated at least three weeks after cessation of therapy.

Clinically mild side effects (mild dyspeptic symptoms and stomachaches) only appeared in 4 patients in group-1 that could have been due to the higher dose of itraconazole.

Though tinea versicolor can be treated with topical therapy but the problems faced are areas that are not assessable and presence of the yeasts in the follicles.

Itraconazole is more active in vitro and is absorbed systemically after oral intake and distributed as the active substance to the areas involved. The in vitro activity of itraconazole is about 100 and about 10 times more potent than those of miconazole and ketoconazole respectively.³

It is suggested that patients should be monitored for liver functions if taking itraconazole for longer periods.

Since tinea versicolor is a chronic disease and if not treated can persist for years. Our study suggests that systemic therapy with itraconazole[^] of the above mentioned disease is better than the topical and other modalities as regard compliance, convenience and safety.

Table-1 The Patients Characteristics and History.

	GROUP-I(30 patients)	GROUP-11 (30 patients)
Sex: Male	10	22
Female	20	8
Age(Years): Mean(range)	25.3(16-73)	23.2(15-56)
Weight(Kg) Mean(Range)	50.2(40-70)	55.5(42-60)
1st episode of tinea versicolor No of patients	14	14
Duration of 1st episode (months) mean(Range)	20(1-90)	40(1 -240)
Recurrent pitrysis versicolor No of patients	8	8
Recurrent versicolor duration (months) mean(Range)	50(4-68)	30(10-100)
Duration of last episode of recurrent tinea versicolor (months) mean(Range)	2(1-5)	4(1-9)

Table-2: Results Of the Treatment One Day After The End of Treatment

PARAMETER	NO OF PATIENT (MEAN CLINICAL SCORE) Group-I (30 patients)	NO OF PATIENT (MEAN CLINICAL SCORE) Group-II (30 patients)
Pruritis	0(0)	0(0)
Scaling	14(1) and 16(0)	20 (1) and 10(0)
Erythema	0(0)	0(0)
Hyperpig-mentation	12(1)	10(1)
Hypopig-mentation	18(2)	28 (2)
KOH +tive	30	26
Woods light	28	26

Table-3: Assessment 3 Weeks After the End of Therapy.

PARAMETERS	NO OF PATIENTS		
	Group-I	Group-II	Total
Responders Healed	26	24	50
Mild residual lesion	2	2	4
Total %	28(93)	26(87)	54(90)

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