

A DOUBLE-BLIND COMPARISON OF 2% KETOCONAZOLE AND 1% CLOTRIMAZOLE IN THE TREATMENT OF PITYRIASIS VERSICOLOR

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Forty adult patients of pityriasis versicolor were treated with either topical 2% ketoconazole cream (20 patients) or topical 1% clotrimazole cream (20 patients). In global assessment of treatment after 2 weeks, 18 (90%) out of 20 patients treated with ketoconazole cream were cured while 2 cases had considerable residual lesions. In clotrimazole treated group, 17 (85%) out of 20 patients were cured and 3 still had considerable lesions. No significant difference was observed in response rates in the two groups. No side effects were reported in either groups.

Key Words : Ketoconazole, Clotrimazole, Pityriasis versicolor

Introduction

Imidazole derivatives are widely used for the treatment of pityriasis versicolor and ketoconazole can be used both topically and systemically. Because of hepatotoxicity with systemic ketoconazole, an alternative topical formulation in the form of 2% ketoconazole cream has been developed and is found to be very effective for treatment of pityriasis versicolor.^{1,2}

The aim of the present study was to compare the efficacy of 2% ketoconazole cream with 1% clotrimazole cream in treatment of pityriasis versicolor.

Materials and Methods

Material of the present study comprised of 40 patients of pityriasis versicolor. All patients after a detailed history and clinical examination were confirmed by microscopic KOH and Wood's lamp examination. Dermatophyte infections were ruled out by culture in each case. Patients were excluded if they had received systemic antifungal therapy within 1 month or topical antifungal therapy within 1 week of the start of study. Also

excluded were those who had systemic mycotic or serious concurrent disease. Consent of each patient was taken before entering into the study.

Twenty patients were treated with 2% ketoconazole cream and 20 with 1% clotrimazole cream. The patients were assigned tubes of either 2% ketoconazole or 1% clotrimazole cream in a randomised fashion. They were instructed to apply cream once a day for 2 weeks.

Dermatological, KOH and Wood's lamp examinations were done in each case before start of treatment and after 1 and 2 weeks of treatment. Clinical assessment in terms of erythema, scaling and pruritus was assessed on a scale of 0-3 (3-severe, 2-moderate, 1-mild and 0-absent). At the end of treatment phase, clinical response was assessed globally with the use of broad scale of healed, mild residual disease, considerable residual disease, not changed and deteriorated. Patients with assessment in the top 2 categories ie, healed (clinically and mycologically clear) and mild residual disease (mycologically clear) were considered cured. These patients were examined clinically and mycologically at a follow up visit 8 weeks later for any relapse. Adverse effects were recorded. In each case liver function tests were done at initial visit and

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at the end of the study.

Results

The two groups were similar with respect to sex and age. Clinical assessment of symptoms showed no significant difference between both treatment groups at any visit with respect to changes in the mean scores for pruritus, erythema and scaling. After 2 weeks of treatment, 18(90%) and 17(85%) patients of ketoconazole and clotrimazole groups had negative fluorescence results respectively. Mycological cure (KOH-negative) was recorded for 18 (90%) and 17 (85%) patients of ketoconazole and clotrimazole groups respectively. Fisher's exact test showed no significant difference in response rates between 2 groups.

Table I shows the results of global

Table I. Global assessment of treatment after 2 weeks

Parameters	Number of patients	
	Ketoconazole	Clotrimazole
Cured		
Healed	18	16
Mild residual lesions	-	1
Considerable residual lesions	2	3
Unchanged	-	-
Deteriorated	-	-
Total	20	20
Percentage of cured (healed and mild residual lesions)	90%	85%
p-value	>0.05	

assessment of treatment after 2 weeks. Eighteen (90%) of 20 patients treated with ketoconazole cream were cured while 2(10%) cases had considerable residual lesions. In clotrimazole group, 17(85%) cases were to cured and 3(15%) cases still had considerable lesions. Fisher's exact test showed no

significant difference in global evaluation between 2 groups at the end of treatment.

Sixteen of 18 cured patients of ketoconazole group returned for a follow up visit, 8 weeks latter and all 16 remained cured. In clotrimazole group, only 1 patient was defaulter while the rest 16 patients returned for follow up visit and all remained cured.

No side effects were reported in either group. In both the groups, values for the various biochemical parameters to assess liver functions were within normal limits before and after the treatment.

Discussion

Imidazoles are widely used for the treatment of pityriasis versicolor.^{3,4} Recently it has become possible to treat pityriasis versicolor systemically with a new imidazole derivative, ketoconazole.⁵ Oral ketoconazole is generally a safe and well tolerated medication but its most important adverse effect is hepatotoxicity.⁶ Because of hepatic toxicity with oral ketoconazole an alternative topical formulation of 2% ketoconazole cream was developed and has found to be effective in the treatment of pityriasis versicolor.¹ Results of the present study suggested that 2% ketoconazole cream is almost as safe and effective as 1% clotrimazole cream in the treatment of pityriasis versicolor.

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