

MICONAZOLE VERSUS SALICYLIC-BENZOIC ACID OINTMENT IN THE TREATMENT OF DERMATOPHYTOSIS

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Summary

In 18 cases of tinea corporis, which were KOH positive, a comparative therapeutic trial with miconazole nitrate 2% gel-cream and salicylic-benzoic acid ointment were made. On culture 25 of these cases gave positive results. (*T. mentagrophyte* 13 cases, *T. rubrum* 11 cases and *Epidermophyton floccosum* 1 case). Miconazole gave 100% cure rate in four weeks as compared to 73.7% with salicylic-benzoic acid ointment. Response with miconazole was quicker than with Salicylic-benzoic acid ointment.

Miconazole nitrate, an imidazole derivative is by now a well established drug in the treatment of dermatophytosis. Clinical cure rates with this drug in 1 to 2 percent topical preparations have been claimed to be 60 to 100 percent in various types of ring-worms with duration of treatment varying from 14 to 90 days^{1, 2, 3, 4, 5}. However, clinical trials are nearly lacking to adjudge the comparative efficacy of this drug to old time topical applications, such as salicylic - benzoic acid ointment (Whitfield ointment).

Methods

Thirty-eight cases of tinea corporis were selected at random, from Skin and STD department of Medical College, Amritsar during the years 1977-1978, which showed at least two lesions with

positive scrapings in KOH for fungi. In each case before the start of treatment, the scraping material was subjected to culture on Sabouraud's dextrose agar medium for the identification of the causative dermatophyte.

In each case, to one patch miconazole nitrate 2% Gelcream (Daktarin by Ethnor Ltd.) and to the other patch Benzoic acid 6%, salicylic acid 3% ointment (Whitfield ointment) were applied morning and evening by the investigator. A weekly follow-up was conducted for four weeks so as to make a clinical evaluation of the lesions and to examine the scrapings from the lesions for the presence of fungi. The clinical assessment was graded as follows :

GO — no improvement

GI — persistence of few papular lesions with mild to moderate prurigo.

GII — Scaly lesions with or without mild prurigo.

GIII — Cured completely with or without residual pigmentation.

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Observations

General :

Among 38 cases studied, 13 cases (34.2%) were females and 25 cases (65.8%) were males. Their ages ranged between 15 years and 70 years - 27 cases (71.1%) were in the age group of 21 to 50 years. These patients had been suffering from tinea corporis for the last 5 months to 15 years. In majority (78.9%) of them illness was of 1 to 5 years duration. Multiple sites were involved in all the cases.

25 cases (65.8%) gave positive result with culture - in 13 cases *Trichophyton mentagrophyte*, in 11 cases *Trichophyton rubrum* and in one case *Epidermophyton floccosum*. Areas treated were on an average 90.0 sq. cm. (range 30 to 288 sq. cm.) and 68.2 sq. cm. (range 6 to 250 sq. cm.) for miconazole gel-cream and salicylic-benzoic acid ointment respectively.

Follow-up :

Scrapings in KOH from areas under miconazole became negative at first week's follow-up in all the cases and persisted so throughout the period of study. Scrapings from lesions under salicylic-benzoic acid ointment for fungi became negative in 2 cases, 9 cases, 29 cases and 38 cases at 1st, 2nd, 3rd and 4th week's follow-up respectively.

At one week's follow-up all cases treated with miconazole showed some improvement-4 cases had GIII response, 18 cases GII and 16 cases GI response.

At second week's follow-up, out of 34 cases, who had shown less than GIII improvement at first week's follow-up, 27 cases had shown further improvement. Among 7 cases who had not further improved, six cases continued to be stable at GI and one case at GII. At third week's follow-up all the cases showed GIII response except one case who also had GIII improvement at 4th week's follow-up (Table 1).

With salicylic-benzoic acid ointment at first week's follow-up no improvement was observed in 29 cases. At second week's follow-up 3 cases had not shown any improvement, whereas other cases showed some response and in one case GIII improvement was observed. At third week's follow-up 8 cases had GIII response and at fourth week's follow-up 28 cases showed GIII improvement (Table 1).

In *T. mentagrophyte* cases, no case was cured at first week's follow-up with either of the drugs. With miconazole at second week's follow-up 10 cases were cured and by the third week all cases were cured, whereas by that time no case got cured with salicylic-benzoic acid ointment. In *T. rubrum* cases at first week's follow-up 3 cases were cured with miconazole and none with salicylic-benzoic acid ointment. By fourth week's follow-up all the cases were cured with miconazole, whereas salicylic-benzoic acid ointment gave cure in 7 cases (63.6%). The single case of *Epidermophyton floccosum* took one week and four weeks for cure

TABLE 1
Showing cure rate with duration of treatment.

Drug	DURATION OF TREATMENT							
	1st week		2nd week		3rd week		4th week	
	No. of cases cured	Percent-age	No. of cases cured	Percent-age	No. of cases cured	Percent-age	No. of cases cured	Percent-age
Miconazole	4	10.5	27	71.1	31	81.6	38	100
Salicylic benzoic acid oint.—	—	—	1	2.6	8	21.1	28	73.7

TABLE 2

Showing cure rate in various dermatophytes with duration of treatment

Fungal Species	No. of cases	Drug tried	1st week		2nd week		3rd week		4th week	
			No. of cases cured	Percent- age	No. of cases cured	Percent- age	No. of cases cured	Percent- age	No. of cases cured	Percent- age
T. mentagrophyte	13	Miconazole	0	0	10	76.9	13	100	13	100
		Salicylic-benzoic acid oint.	0	0	0	0	0	0	7	53.9
T. rubrum	11	Miconazole	3	27.3	6	54.6	10	96.9	11	100
		Salicylic-benzoic acid oint.	0	0	1	9.1	4	36.4	7	63.6
Epidermophyton floccosum	1	Miconazole	1	100	1	100	1	100	1	100
		Salicylic-benzoic acid oint	0	0	0	0	0	0	1	100

with miconazole and salicylic-benzoic acid ointment respectively (Table 2).

Statistically difference in clinical improvement for various periods of treatment with these two drugs has been found to be highly significant in favour of miconazole ('P' being less than 0.01 or 0.05).

Discussion

Both vitro and vivo studies cast no doubt about the efficacy of miconazole against various dermatophytes. This drug in vitro studies had been shown to have fungicidal and in low concentration, fungistatic activity⁶. The primary effect of miconazole appears to be on a microbial cell wall and plasma lemma making them permeable to intracellular amino-acids, phosphatase and potassium, thus inhibiting intracellular macromolecular synthesis^{7,8,9}. This drug has stood the test of clinical trials for the treatment of dermatophytosis in various formulations of 1 to 2% concentration^{1,2,3,4,5}.

Whitfield ointment which contains benzoic acid and salicylic acid in the ratio of 2:1 (usually 6% and 3% respectively) combines the fungistatic action

of benzoate with keratolytic action of salicylate. Since benzoic acid is only fungistatic, eradication of the infection occurs only after the infected stratum corneum is shed and salicylates accelerate this condition¹⁰.

The present study has been conducted to find out the effectiveness of miconazole as compared to salicylic-benzoic acid ointment (Whitfield ointment). It has been found that miconazole is superior to salicylic-benzoic acid ointment in the treatment of dermatophytosis. Whereas the former drug gave 100% cure rate with four weeks' treatment, the latter gave only 73.7% cure rate. Further, response with miconazole had started much earlier as compared to salicylic-benzoic acid ointment. Both *T. mentagrophyte* and *T. rubrum* gave similar response to the drugs.

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