Clinical Trials

Naftifine Cream 1% Compared with Miconazole Cream 2% in Dermatophytosis

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cumulation of the mycologic and clinical cure rates. Naftifine proved to be very effective in 92% of the cases and miconazole in 84%. No side effects were observed.

Materials and Methods

In this trial the antimycotic efficacy of naftifine cream, applied once daily, in the treatment of dermatophytosis was determined. Miconazole cream, applied twice daily, was used as the reference substance in this trial.

Forty patients were entered into a comparative trial of naftifine cream 1% versus miconazole cream 2%. Patients, whose ages ranged from 4 to 70 years, had potassium hydroxide scraping and fungal culture positive dermatophyte infection. Patients were only considered for the protocol if they had had no antifungal treatment for the previous 4 weeks. The patients were assigned to one of the two treatment groups with naftifine cream 1% and miconazole cream 2%, respectively. The course of healing and tolerability were checked after 1, 2, and 4 weeks. The antimycotic efficacy was assessed by determining the frequency of negative cultures, and the regression of clinical symptoms (eg, itching, erythema, vesiculation, or scaling) was scored by a 4-point rating scale (0 = none, 2 = mild, 4 = moderate, and 6 = severe). At the end of each treatment the investigating physician carried out a global assessment of the therapy in each patient.

Results

Thirty-three patients completed the study (Table 1). The two groups were homogenous with respect to their basic and amnestic data. The mycologic cure rate in the two patient groups is shown in Table 2. After week 1, 53% of the naftifine-treated patients showed a negative culture compared with 50% of the miconazole-treated patients. The difference between the two groups increased in week 2 with naftifine at 78% and miconazole at 70%. This trend continued to week 4 when the mycologic cure rate of naftifine amounted to 90% and that of miconazole to 81%.

The clinical symptoms regressed with a similar trend. The final evaluation (Table 3) represents the

Table 1. *Basic and Amnestic Data*

Data	Naftifine	Miconazole
Median age (yr)	37	14
Sex		
M	12	10
F	5	6
Median size of lesion (cm^2)	64.5	79.6
Causative agent		
Trichophyton mentagrophytes	5	6
Trichophyton verrucosum	4	4
Epidermophyton flocossum	4	3
Trichophyton violaceum	2	1
Microsporum canis	1	—
Trichophyton rubrum	1	2
Site of lesion		
Head and neck	4	3
Trunk	4	4
Extremities	2	3
Groin	7	6

Table 2. *Mycologic Cure Rate*

	Negative Culture and Negative KOH		
	After 1 wk	After 2 wks	After 4 wks
Naftifine	9 (53%)	13 (78%)	15 (90%)
Miconazole	8 (50%)	11 (70%)	13 (81%)

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TABLE 3. *Final Evaluation*

	Results		
	Very Effective	Effective	Not Effective
Naftifine	15 (92%)	2 (8%)	—
Miconazole	13 (84%)	3 (16%)	—

Discussion

A large number of studies have been performed to determine the clinical efficacy of the new allylamine derivative naftifine.[1] Naftifine cream shows anti-inflammatory attributes. In a study comparing it with imidazole/triamcinolone, itching and erythema were reduced or eliminated at the same rate.[2]

In the present study, the antimycotic activity of naftifine showed a superior trend over miconazole; however, this trend was not statistically significant. There also was the advantage of once daily application over the traditional twice daily application of miconazole.[3,4]

Drug Names

miconazole
naftidine

References

1. Mykosen: Diagnosis, therapy and prophylaxis of fungal diseases. 1987.
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3. Tronnier H. Inflammatory dermatomycoses—comparative study of naftifine and a combination of a corticosteroid and an imidazole derivative, mykosen. 1987;78–87.
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The Great Omni, perhaps the most famous of all the tattooed. Facial tattoos are usually not done by most tattoo artists today (courtesy H. Beerman, M.D.). From the World of Tattoos collection, Honolulu, HI. Submitted by Norman Goldstein, M.D., Honolulu, HI.