NAFTIFINE TREATMENT FOR DERMATOPHYTOSIS: MULTICENTER CLINICAL INVESTIGATIONS IN TURKEY

TURKISH MULTICENTER DERMATOPHYTOSIS STUDY GROUP

The following Clinical Trial was previously published in the *International Journal of Dermatology* (1991; 30:584–585). The Editors have chosen to republish the entire article due to several misprints in naming the members of the Turkish Multicenter Dermatophytosis Study Group.

The efficacy of naftifine has been shown in a large number of clinical trials. In comparison with antimycotics such as clotrimazole,[1,2] econazole,[3] bifonazole,[4] miconazole,[5] and tioconazole, naftifine proved to be equal or superior. The studies were mostly performed in central Europe, but have recently been supplemented by trials in the United States,[6] tropical areas,[7] and Arabia.[8] The published reports verify the once daily treatment model[9,10] as well as the anti-inflammatory effect of naftifine.[11–13]

Materials and Methods

Six clinics, with locations in Istanbul, Izmir, Ankara, and Adana, participated in this trial that covered all climatic and ethnic differences in Turkey. One hundred and fifty-seven patients who were suffering from tinea cruris, t. pedis, and t. corporis were evaluated. Treatment with application of 1% naftifine cream once daily lasted for 4 weeks.

Inclusion criteria included a positive KOH scraping, positive culture, and microscopic determination of the causative agents. Patients pretreated with another preparation in the previous 4 weeks were excluded.

Clinical symptoms were checked at weekly intervals. The antimycotic efficacy was determined by the frequency of negative cultures and the regression of the clinical symptoms (e.g., erythema, pruritus, vesiculation, and scaling) and rated by a 4-point scale (0 = none, 2 = mild, 4 = moderate, and 6 = severe). At the end of each treatment a global assessment of the therapy was carried out.

RESULTS

One hundred and fifty-seven patients were included in this study (Table 1): 53 had t. cruris, 66 had t. pedis, and 38 had t. corporis. The clinical cure rate was 96%, and the mycologic cure rate, as shown by culture and microscopic examination, was 95%.

Negative culture was generally seen after 2 weeks. Pruritus disappeared completely after 2½ weeks and erythema after 3 weeks. The sum of all side effects (e.g., dryness, burning, etc.) was 6%.

DISCUSSION

The present study verifies the efficacy of 1% naftifine cream in the treatment of severe mycoses that, on the average, had persisted 29 weeks before treatment. No difference in efficacy as a function of the location of the infection could be found. The proportion of tinea

Table 1. Basic and Amnastic Data

Age (yr)	6–70
Sex	
M	118
F	39
Causative agents	
Trichophyton rubrum	45%
T. mentagrophytes	19.4%
T. verrucosum	1.8%
T. schoenleini	0.6%
T. violaceum	0.6%
Trichophytosis	0.6%
Microsporum	3.2%
Epidermophyton floccosum	6.3%
Candida albicans	15 %
Perineum	7.5%

Mean duration of infection before treatment: 29 weeks (maximum, 8 months).

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Table 2. Final Evaluation

Very effective	113 (72%)
Effective	38 (24%)
Not effective	6 (4%)

cruris and t. corporis was found to be higher than that in central Europe; however, no difference in the spectrum of causative agents could be found. Between the different centers, no differences were found in the spectrum of fungi or in the results of therapy.

It is possible that the relative severity of the infections had a positive effect on patient compliance.

The side effects (6%) found in this trial were in the range of the results found in other studies.[6] Most of the side effects were nonallergic (e.g., dryness in the case of interdigital mycoses).

Pruritus disappeared somewhat faster than erythema. This can be explained by the additional anti-inflammatory effect of naftifine.

DRUG NAME

1% naftifine: Exoderil

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The Use of Sutures

There are many interesting things said with regard to depressed fractures and the necessity for elevating the bone. If the depressed portion is wedged, then an opening should be made with the trephine and an elevating instrument called a spatumen used to relieve the pressure. Great care should be taken, however, in carrying out this procedure lest the bone of the cranium itself, in being lifted, should injure the soft structures within. The dura mater should be carefully protected from injury as well as the pia. Care should especially be exercised at the brow and the rear of the head and at the commissures (*proram et pupin et commissuras*), since at these points the dura mater is likely to be adherent. Perhaps the most striking expression, the word *infect* being italicized by Gurlt, is: "In elevating the cranium be solicitous lest you should infect or injure the dura mater."

For wounds of the scalp, sutures of silk are recommended because this resists putrefaction and holds the wound edges together. Interrupted sutures about a finger-breadth apart are recommended. "The lower part of the wound should be left open so that the cure may proceed properly." Red powder was strewed over the wound and the leaf of a plant set above it. In the lower angle of the wound a pledget of lint for drainage purposes was inlaid. Hemorrhage was prevented by pressure, by the binding on of *burnt* wool firmly, and by the ligature of veins and by the cautery. *From Walsh JJ. Old-time makers of medicine. New York: Fordham University Press, 1911:241.*