Clinical Trials

Double-Blind Randomized Comparative Study of Naftifine Cream and Clotrimazole Cream in the Treatment of Dermatophytosis

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Materials and Methods

The efficacy of naftifine cream applied once daily was compared with clotrimazole applied twice daily in the first well-controlled study in the Middle East.

Data of 76 patients with clinical signs and symptoms of dermatophytosis were evaluated. The clinical diagnoses were confirmed by microscope examination and culture. Patients pretreated with systemic or topical antimycotic agents were instructed to stop such treatment for 4 weeks or 1 week, respectively, before being included in the study.

The patients were allocated to one of the two treatment groups with naftifine cream (1%) once daily or clotrimazole cream (1%) twice daily on a randomized double-blind basis. The course of healing and tolerability were checked after 1, 2, and 4 weeks. The antimycotic efficacy was assessed by 1) frequency of the negative cultures, and 2) regression of the clinical symptoms as scored on a four-point rating scale (0 = none; 2 = mild; 4 = moderate; 6 = severe).

At the end of each treatment the investigating physician carried out a global assessment of the therapy in each patient. It was further documented whether each individual patient was healed after a 4-week therapy.

Results

There were no statistically significant differences between the two groups with regard to their basic and anamnestic data.

Table 1 illustrates the increase in mycologic healing rates in the two patient groups.

After 1 week of treatment 51% of the naftifine-treated patients showed a negative culture compared to 43% of the clotrimazole-treated patients. With naftifine this percentage increased to 77% after 2 weeks and to 92% after 4 weeks. The corresponding results for clotrimazole were 64 and 78%, respectively.

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Clinical symptoms disappeared after 1 week in 48% of the naftifine group and in 38% of the clotrimazole group. After 4 weeks the values reached 90% with naftifine and 74% with clotrimazole ($2\ p \leq 0.05$).

The overall assessment of the results (Table 2) indicates a superiority of naftifine over clotrimazole.

Tolerability

Two patients in the naftifine and three patients in the clotrimazole group reported local side effects of minimal burning and erythema. The side effects occurred mainly during the initial phase of the treatment. None of the patients discontinued treatment because of side effects.

Discussion

Naftifine is a new antifungal allylamine-derivative exhibiting good activity against dermatophytes, yeasts, and moulds.[1,2] Several comparative studies with naftifine (1%) and clotrimazole (1%) have been performed in Europe, the United States, and Japan.[3-6]

Table 1. *Mycological Cure Rate*

	Negative Culture and Negative Native Preparations					
	After 1 Week		After 2 Weeks		After 4 Weeks	
Naftifine	20	51%	30	77%	36	92%
Clotrimazole	16	43%	24	64%	29	78%

TABLE 2. *Final Evaluation of Efficacy of Naftifine and Clotrimazole after 4 Weeks of Therapy*

Results	Very Effective	Effective	Not Effective
Naftifine	91%	9%	—
Clotrimazole	75%	16%	9%

A superiority of naftifine over imidazols has been found when used only once daily.[7,8]

The results of treatment with imidazole derivatives (clotrimazole) are sometimes unsatisfactory. This may be the result of poor patient compliance. Consequently, a reduced frequency of application would be advantageous. Naftifine was found to have a retention time of 24 hours[9] and can thus be used once daily. This and other studies have proven that there is no difference in efficacy whether naftifine is applied once or twice daily.[8,9]

Furthermore, it has been shown that the efficacy of naftifine applied once daily is superior to that of imidazol derivatives applied twice daily in the treatment of dermatomycosis.[7] After the 4-week trial comparing the efficacy of naftifine applied once daily and clotrimazole applied twice daily, 91% of the patients treated with naftifine had both mycological and clinical healing compared to 75% of the clotrimazole group.

Although the differences between the two topical agents was not statistically significant ($2\ p < 0.05$), the compliance factor with once daily application favors naftifine.

References

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