

Long-term Follow-up of Toe-nail Onychomycosis Treated with Terbinafine

Sir,

Previous studies have shown excellent results following the use of terbinafine for the treatment of onychomycosis. Mycological cure rates have ranged from 60–100% and clinical cure rates from 42–100% after treatment for 3 to 6 months and follow-up periods of approximately 1 year (1, 2). The aim of the present study was to follow a group of patients treated with 250 mg terbinafine daily for 3 to 6 months for approximately 2½ years, to determine the risk of relapse or reinfection, as well as the patients' satisfaction with the final result.

MATERIALS AND METHODS

The 22 patients in the current study had onychomycosis of the toenails (positive microscopy and culture) and had previously participated in a double-blind, controlled study of the treatment of onychomycosis with terbinafine (2). In the former study, the patients were randomized to receive either daily treatment with 250 mg terbinafine or a placebo for 3 months. Based on a clinical evaluation after 3 months, and without breaking the code, additional treatment with 250 mg terbinafine daily for 3 months was given to all the patients who had not responded satisfactorily during the first course of treatment. All the patients in the controlled study were followed for approximately 1 year after the initiation of the study.

Approximately 2½ years after the initiation of the study, the same patients were invited to participate in an additional follow-up. Those who participated in the latter follow-up were evaluated clinically, and specimens were taken for fungal culture and microscopy. The mycological investigations were performed at the Department of Dermatology, Odense University Hospital, Denmark.

During the additional 2½-year follow-up, one of the patients was treated with topical antifungal medications, but none received systemic antifungal treatment.

RESULTS

Twenty-one of the 22 patients were invited to take part in the additional follow-up and were evaluated clinically and mycologically. One patient had to stop treatment during the initial controlled study after 2 months due to tinnitus. The others were treated for 3–6 months according to the protocol.

Ten of the patients were clinically cured after participation in the controlled study, but only one of these had a mycological cure (mycological cure = negative microscopy and negative

culture). Three of 10 patients seen to be clinically cured at the initial evaluation were designated clinically "not cured" at the evaluation after approximately 2½ years. One of these patients had a mycological cure after 1 year but had a positive microscopy after 2½ years. The other had a positive microscopy after 1 year but had a negative culture after 2½ years, and the third had a positive microscopy after both 1 and 2½ years. Two of 11 patients among those not clinically cured 1 year after initiation of treatment were seen to be clinically cured at the later re-evaluation. One of these had a positive microscopy after 1 year and a negative culture after 2½ years. The other had a negative culture both after 1 and after 2½ years.

At a clinical evaluation 2½ years after initiation of treatment, many of the patients had only small remnants of fungal infection, and 68% of the patients were satisfied with the final result.

CONCLUSION

It is shown that although some patients changed status from cured to not cured and vice versa, nearly half of the patients had a clinical cure after 1 year and a clinical and a mycological cure after 2½ years. Patient satisfaction was high, suggesting that the cosmetic result of treatment with terbinafine was felt to be satisfactory.

REFERENCES

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Flemming Brandrup¹ and Poul Ølholm Larsen²

¹Department of Dermatology, Odense University Hospital, Sdr. Boulevard 29, DK-5000, Odense C and ²Private practice of dermatology, Guldsmødegade 1, DK-8000, Århus C.