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ORIGINAL ARTICLE

Ciclopirox nail lacquer for the treatment of onychomycosis: An open non-comparative study

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ABSTRACT

Onychomycosis is a relatively common disease accounting for up to 50% of all nail disorders. Topical treatment, although less effective than systemic, is usually preferred by patients. Topical antifungal nail lacquers have been formulated to provide better delivery of the antifungal agent to the nail unit. The purpose of this research is to evaluate the efficacy and safety of ciclopirox nail lacquer in the treatment of onychomycosis. Patients suffering from distal and lateral subungual toenail onychomycosis (DLSO) and lateral subungual onychomycosis (LSO) were treated by ciclopirox nail lacquer once daily for 9 months. Every week the nail lacquer was removed using acetone. Clinical nail status, KOH examination and mycological culture were recorded by the same investigator at 0, 3, 6 and 9 months. Thirty-six patients completed the 9-month regimen. *Trichophyton rubrum* was the most common pathogen. At the end of the study, good improvement to complete cure was observed in 13 patients (36%), 12 patients showed only mild to moderate improvement and 11 patients (31%) had no clinical improvement. No adverse effects were noted throughout the treatment period. Ciclopirox nail lacquer seems to be slightly more effective than other topical modalities and could be used in patients who cannot or do not want systemic treatment.

Key words: antifungal nail lacquer, ciclopirox, onychomycosis.

INTRODUCTION

Onychomycosis is a common disease accounting for up to 50% of all nail disorders. Factors that influence the choice of therapy include the presentation and severity of the disease, current medications the patient is taking, previous therapies for onychomycosis and their effectiveness, physician and patient preference, and the cost.[1,2] In this study the efficacy of ciclopirox nail lacquer for the treatment of onychomycosis caused by dermatophyte was evaluated.

METHODS

Forty patients suffering from distal and lateral subungual toenail onychomycosis (DLSO) and lateral subungual onychomycosis (LSO), which involved two to four toenails, entered the study. Onychomycosis was confirmed by both KOH examination and mycological culture, and samples were taken from the distal parts of the involved nail. Nail samples were divided into two parts; one was used for direct KOH examination and the second for fungal culture using Sabouraud's Dextrose agar (Novamed, Jerusalem, Israel) which contains chloramphenicol or streptomycin and penicillin to prevent contamination. The identification of the fungus is done on the basis of morphological characteristics of the different fungi.

Patients were treated by ciclopirox nail lacquer once daily for 9 months. Every week the nail lacquer was removed using acetone. Clinical nail status, KOH examination and culture were performed by the same

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investigator at 0, 3, 6 and 9 months. The patients were instructed to remove the nail lacquer with acetone during the evening before the examination. The target nail was the big toe. Clinical response to treatment was assessed based on the nail change from initiation of the study by a score of 0–4 of improvement noted: 4, both clinical and mycological cure; 3, marked clinical improvement of more than 75% of the affected area of the nails; 2, moderate improvement of 50–75%; 1, mild improvement of 25–49%; and 0, failure that was determined when less than 24%.

RESULTS

Thirty-six of 40 patients (aged 21–57 years, 24 women and 12 men) completed the 9-month regimen; four patients were lost to follow up. All 36 patients had had toenail onychomycosis for a mean of 8 years. Two patients also had fingernail onychomycosis. The causative organism was *Trichophyton rubrum* in 35 patients and *Trichophyton mentagrophytes* in one patient. The most common clinical presentation of the toenail onychomycosis was DLSO (32/36 patients).

After 9 months of treatment, eight of 36 patients (22%) had complete cure (clinical and mycological) of the toenails. Five patients (14%) had both marked clinical improvement of their toenails and mycological cure. Nine patients had mild improvement and three patients had moderate improvement of their toenail status. However, eight of 12 patients (66%), of which 6 patients had mild improvement and 2 had moderate improvement, still showed fungal hyphae at KOH examination and/or positive culture. Eleven patients (31%) had no clinical improvement in their toenails and all had positive mycological cultures at the end of the study. The results of the treatment outcome are shown in Table 1 and in Figures 1 and 2.

Table 1. Clinical toenail status after 9 months and its correlation to mycological cure

Clinical toenail status	No. of patients (%)	Mycological cure
No improvement	11/36 (30.5)	0/11 (0)
Mild improvement	9/36 (25)	3/9 (33.3)
Moderate improvement	3/36 (8.3)	1/3 (33.3)
Marked improvement	5/36 (13.9)	5/5 (100)
Total cure	8/36 (22.2)	8/8 (100)

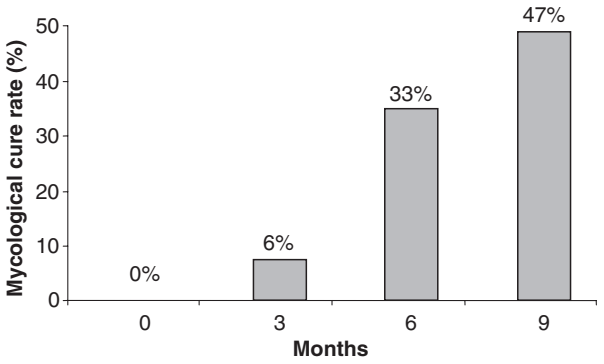

Figure 1. Mycological cure rate during the treatment.

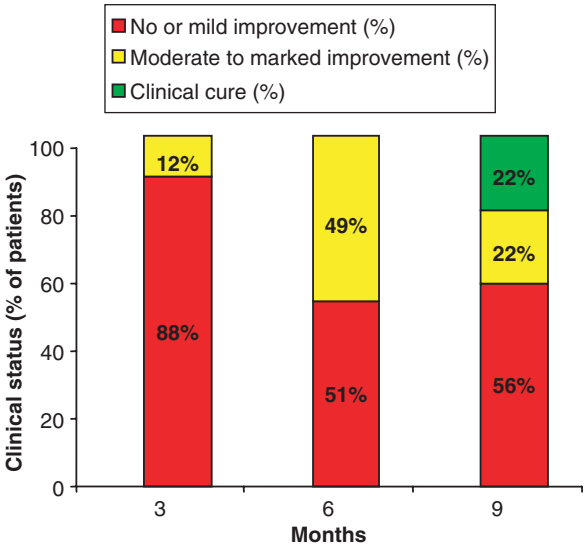

Figure 2. Clinical status during treatment.

We also found that the success of treatment was influenced by two parameters: patient age and duration of the disease. The mean age of patients who achieved complete cure was 31 versus 42 years in cases of treatment failure. Duration of the disease was 4.25 years for the cured versus 9.68 years for the non-cured patients.

No adverse effects were noted throughout the treatment period.

DISCUSSION

Systemic antifungal drugs are effective, but also increase the risk of side-effects. Topical agents have

generally been perceived as ineffective, mainly because of poor penetration into the nail. However, newer topical agents, such as ciclopirox and amorolfine, have been formulated to provide efficient delivery of the antifungal agent to the nail unit.[1,2]

Nail keratin is both compact and hard and, as such, is somewhat impermeable, thus restricting drug access to the organisms causing onychomycosis. Although topical agents allow greater proximity to the infection site, some areas may still prove relatively inaccessible and maintaining effective drug concentrations can be difficult. Moreover, topical solutions and creams are easily removed by washing or wiping, which further reduces delivery of the drug to the subungual tissue. The effectiveness of topical antifungals can be enhanced when applied as a nail lacquer, as is the case with amorolfine and ciclopirox.[1,2]

Topical antifungal agents show low cure rates in cases of onychomycosis.[1] Hay *et al.*[3] reported a 22% complete cure rate in patients using tioconazole nail solution twice daily for 12 months. Combination therapy of 40% urea for removal of the nail plate followed by application of 1% bifonazole also gave disappointing results. Tsuboi *et al.*[4] reported 50% mycological cure and 22% marked clinical improvement after 12 weeks of treatment with combined 40% urea and 1% bifonazole solution once daily. Similar results were reported by Shemer *et al.*[5]

The introduction of topical formulations of antifungal agents as nail lacquers allows the active ingredient to remain in contact with the nail plate for a longer duration, and theoretically may increase the potential for successful treatment. Previous trials of ciclopirox nail lacquer for onychomycosis have demonstrated mycological cure rates of 47–67%[5] and a complete cure rate of up to 25%.[6,7] These results are similar to our findings in this study.

Ciclopirox nail lacquer is a safe regimen for onychomycosis, and is effective in younger patients whose disease duration is shorter. Despite its low cure rate, it can be used as a treatment option for those patients who would not or cannot tolerate oral therapy.

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