MYCOSES 35, 157–159 (1992) ACCEPTED: FEBRUARY 1, 1992

Recurrent tinea pedis: a double blind study on the prophylactic use of fenticonazole powder*

Rezidivierende Tinea pedis: Eine Doppelblindstudie zur prophylaktischen Anwendung von Fenticonazol-Puder*

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Key words. Dermatophytoses, tinea pedis, antifungal powder, fenticonazole, prophylaxis.
Schlüsselwörter. Dermatophytosen, Tinea pedis, antimyzetischer Puder, Fenticonazol, Prophylaxe.

Summary. Tinea pedis is a common and frequently recurring dermatophytic infection, which is extremely difficult to eradicate. The often inevitable persistence of predisposing conditions, especially maceration, suggests that application of powders containing antifungal medication to the affected area could be effective in preventive therapy against recurrence. For this study we used one of the most recent azole antifungal agents, fenticonazole. Thirty patients affected with tinea pedis were cured with topical antifungal treatment; both the diagnosis and the cure were confirmed by microscopic and cultural mycological analyses. The results of subsequent double blind antifungal versus placebo treatment (controlled with clinical and mycological tests over a period of 4 months and with a final statistic evaluation) confirmed the effectiveness of such therapy in reducing the frequency of tiresome relapses in such patients.

Zusammenfassung. Tinea pedis ist eine verbreitete und oft rezidivierende Dermatophyten-Infektion, die schwierig zu beseitigen ist. Die oft unvermeidbare Persistenz disponierender Faktoren, insbesondere Mazeration, legt die Vermutung nahe, daß die Anwendung antimyzetischer Puder am befallenen Bereich eine präventive Wirkung auf solche Rezidive haben könnte. In der vorliegenden Studie wurde Fenticonazol, eines der jüngst entwickelten Azol-Antimykotika, eingesetzt. Dreißig Patienten mit Tinea pedis wurden mittels topischer antimykotischer Behandlung geheilt; Diagnose und Heilung wurden mikroskopisch und kulturell-mykologisch abgesichert. Die Ergebnisse der anschließenden Doppelblindstudie: Fenticonazol gegen Plazebo, die klinisch und mykologisch über den Zeitraum von vier Monaten hinweg kontrolliert und statistisch ausgewertet wurden, belegen die Wirksamkeit einer solchen Prophylaxe in der Reduktion der Häufigkeit der Rezidive an diesen Patienten.

Introduction

Among the skin infections caused by dermatophytes, tinea pedis (t. pedis) occupies a prominent place, accounting for 30% of all dermatophytoses in humans [1].

There are numerous factors that help fungi to adhere to and penetrate the skin. One major factor is the increasingly widespread use of shoes made exclusively of artificial fibres, which prevent the foot from perspiring properly. Hence, a really effective therapeutic approach, quite apart from solving the individual episode, should aim at removing the predisposing factors.

From the prophylactic point of view, correct personal hygiene, apart from washing, includes keeping the foot dry, since t. pedis, apart from frequently being exudative, flourishes in moist conditions. Medicated dusting powders appear to

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* Presented in part at the XIth Congress of the International Society for Human and Animal Mycology ISHAM, Montreal, Canada, June 24–28, 1991.

be effective in preventing relapses, which are a problem in this type of mycosis.

For some time new imidazole derivatives have occupied an important place in the topical treatment of t. pedis; of these, in order to study our series of cases, we chose fenticonazole [2–5], one of the most recent and most effective imidazole derivatives [6–8].

Materials and methods

Our study involved two stages, open for the curative stage and double blind controlled with placebo for the subsequent preventive stage. The patients who took part were of both sexes and of all ages, with fungus infections not requiring systemic therapy; subjects already being treated with other oral drugs that may have interfered with the final assessment of the therapeutic effects of the imidazole derivative were excluded.

With their oral informed consent, 30 patients were treated with 2% fenticonazole cream and with 2% powder once daily [9, 10] for a month, or until cured. Subsequently, the patients were split at random into 2 groups and were prescribed with the antifungal powder only, or with placebo, for a period of 4 months. They were seen approximately every 2 months, and checked for relapses. For both stages of the study, we used a tolerability score ranging from 0 to 3 (0 = null: interruption of treatment due to side effects; 1 = moderate: side effects requiring changes in the treatment; 2 = good: mild side effects; 3 = excellent: no side effects) and an overall efficacy score with a 4-point scale (0 = very bad; 1 = moderate; 2 = good; 3 = excellent).

The 30 patients selected for the clinical study (21 males and 9 females, aged between 14 and 70 years) had been suffering from t. pedis for an average of 25 months, and the condition was confirmed by both microscopic and cultural mycologic examination. The species of fungus responsible were: *Trichophyton rubrum* (16 patients), *Trichophyton mentagrophytes* (12 patients), *Microsporum canis* (1 patient) and *Epidermophyton floccosum* (1 patient) (Table 1). The clinical picture consisted mainly of itching, peeling and fissuring. The result were assessed critically and subjected to statistical analysis with the SPSS-PC+ program on an IBM-AT computer.

Results

Treatment with fenticonazole cream and powder continued up until clinical and mycological recovery. This result was achieved within the month foreseen, except for one patient who had to undergo a further 15 days' treatment. In this initial stage of the study, no adverse reactions were recorded; tolerability scores were excellent or good in all cases. At the end of treatment the efficacy of the therapy rated excellent or good in 23 cases and moderate in the remaining 7 cases.

Table 1. The species of fungi responsible in our patients

Species	No. of cases	%
T. rubrum	16	53
T. mentagrophytes	12	40
E. floccosum	1	3
M. canis	1	3

The second stage of the study included clinical and mycological checks performed every 2 months in order to detect any relapses.

Twenty-seven patients reported for the first check after two months (13 had received the drug and 14 the placebo); the only relapse was recorded in a patient using the placebo (Table 2). Of the 24 patients who reported for the second check after four months (12 using the drug and the other 12 using the placebo), 8 relapses were recorded, 2 in patients on the drug and 6 in patients using the placebo (Table 3).

The chi-square statistical test used to analyse the rate of recurrence recorded at the second follow-up showed $P = 0.08$ in favour of the group treated with powder containing fenticonazole.

At the preventive stage, the tolerability score awarded to the active principle and to the placebo was excellent or good in all cases.

Discussion

The open stage of our study reflected results already reported in previous studies. Fenticonazole confirmed its excellent pharmacological

Table 2. Second stage: 1st check-up after two months

Group	No. patients	Present	Relapses	%
Verum	15	13	0	0
Placebo	15	14	1	7

Table 3. Second stage: 2nd check-up after four months

Group	No. patients	Present	Relapses	%
Verum	15	12	2	17
Placebo	15	12	6	50

record, leading to clinical and mycologycal recovery within 4 weeks of treatment (6 weeks for one patient).

As far as the main aim of our study is concerned, the results would appear to point to a possible protective role for the antifungal powder. The absolute figures (7 relapses in the placebo group as opposed to 2 in the group that received the drug) and the moderately significant statistical datum confirm that the active product protected the patients to a greater degree than the placebo.

In conclusion, our study showed that the antifungal powder used is a valuable means for preventing recurrences of pedis, due to its intrinsic activity and to its formulation.

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