

Sertaconazole in the Treatment of Pediatric Patients with Cutaneous Dermatophyte Infections

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ABSTRACT

Sertaconazole is a new topical anti-mycotic with demonstrated efficacy against dermatophyte infections in adults. An open-label, multicenter study was conducted to assess the efficacy and tolerability of sertaconazole in children in primary care. Twenty-nine children were initially included in the study and tolerability was assessed in all of them. The 16 children examined for efficacy (8 girls and 8 boys, aged 2 to 16 years) all had culture-confirmed cutaneous mycoses. Fourteen children had tinea corporis, 1 had tinea cruris, and 1 had tinea pedis. *Microsporum canis* was identified in 50% of cultures and *Trichophyton rubrum* in 42%. Patient lesions were treated with 2% sertaconazole cream during a 2-week period. Clinical cure was achieved in 31% of patients after 1 week, 75% after

2 weeks, and 100% after 4 weeks. No local or systemic adverse effects were observed. It is concluded that once-daily topical sertaconazole is an effective and well-tolerated treatment for pediatric patients with dermatophytosis.

INTRODUCTION

Cutaneous dermatophyte infections constitute a clinical problem that occurs fairly frequently in primary care. In a recent study¹ determining the incidence of dermatologic diagnoses in pediatric populations, it was found that tinea corporis (herpes circinatus) was among the 10 skin lesions most commonly diagnosed in pediatric patients between the ages of 4 and 7.

Dermatophytes are fungi that affect only the epidermis and appendages rich in keratin, such as hair and nails.² Tineas are classified according to the loca-

tion of the lesions: tinea corporis, tinea cruris, tinea capitis, tinea manuum, tinea pedis (athlete's foot), and tinea unguium. The lesions are usually annular with a raised edge corresponding to the area of active growth where the fungus is concentrated; the center of the lesion contains a smaller number of microorganisms. In everyday practice, treatment is generally empirical. In doubtful cases, however, it is better to examine a sample (using potassium hydroxide [KOH]) and to grow a culture to confirm the etiology of the lesion. Simplification of dosage schedules may lead to increased compliance and greater efficacy of the treatment. In the present study we used sertaconazole, an antimycotic preparation which is used only once or twice daily, thus requiring a less frequent application than other current regimens.

Sertaconazole is a new topical antimycotic drug with a chemical structure characterized by the presence of a benzothiophene. The efficacy of sertaconazole in the treatment of dermatophyte infections has already been demonstrated in studies with adult patients.^{3,4} The objective of the present study was to assess the efficacy and tolerability of sertaconazole in a group of pediatric patients with dermatophyte infections.

PATIENTS AND METHODS

This open-label, multicenter study was conducted at three pediatric primary care institutions, located in the province of Barcelona, from June to October 1993. Twenty-nine patients (14 boys, 15 girls), younger than 18 years of age and with dermatophytosis sus-

pected clinically, were initially included in the study. Informed consent to participate in the study was provided by the parents. Those patients who had previously been treated with an oral or topical antimycotic preparation were excluded. The physician could stop treatment in the event of an adverse reaction or ineffectiveness.

In all cases, a sample of the lesion, taken by scraping the active edge with a scalpel, was sent to a laboratory for direct examination and selective culture. In cases where sufficient sample material could not be taken, the preparation of the culture was given priority. A fresh sample of the lesion was processed with 20% KOH, and examined by direct observation under an optical microscope. It was considered positive if the presence of hyphae was detected. The cultures were grown in Sabouraud's chloramphenicol-actidione medium.⁵ The culture was considered positive if colonies of dermatophytes grew. Even when direct examination of the fresh specimen produced negative results, the sample was cultured in Sabouraud's chloramphenicol-actidione medium.⁵ Identification of the fungi isolated was performed by using the usual macroscopic and microscopic methods.⁶

After obtaining the results of the direct examination and mycologic culture, only 16 patients remained. Thirteen patients were dropped from the efficacy portion of the study because it was not possible to confirm the clinically suspected mycotic etiology. However, all 29 patients who were initially included in the study were assessed for tolerability. Before starting treatment, patient his-

Table. Distribution of patients according to diagnosis.

Diagnosis	n (%)
Tinea corporis	14 (87.5)
Tinea cruris	1 (6.3)
Tinea pedis	1 (6.3)
Total	16 (100.0)

tory was recorded: age, sex, clinical diagnosis of the type of mycosis, and occurrence, duration, number, and size of the lesions.

Antimycotic treatment consisted of the application of 2% sertaconazole cream once daily for 2 weeks. All patients were assessed at weeks 1 and 2, and a follow-up assessment was also made at week 4. At each follow-up visit, the presence or absence of each of the following symptoms was recorded: erythema, desquamation, vesicles, and pruritus. Attention was also paid to the possible appearance of any adverse reaction. Clinical cure was defined as the absence of any sign or symptom.

RESULTS

Sixteen patients, 8 girls and 8 boys, were eligible for the efficacy evaluation. The mean (\pm SD) age was 10.1 ± 3.9 years (range, 2 to 16 years). The duration of the lesions at the time of diagnosis was 12.1 ± 9.5 days (range, 3 to 30 days). The mean lesion size was 6.7 ± 7.0 cm² (range, 1 to 26 cm²). The majority of patients presented with a single cutaneous lesion, although two of them presented with up to seven lesions.

The table shows the clinical diagnoses of all patients. Tinea corporis

was the type most commonly found. The most common etiological agents were *Microsporum canis* and *Trichophyton mentagrophytes*, which were identified in 50% and 42% of the cultures, respectively.

Figures 1 and 2 show the results of remission of symptoms and overall clinical cure, respectively. Seventy-five percent of the patients were clinically cured after 2 weeks of treatment, and 100% of patients had no lesions at the 4-week follow-up visit.

None of the patients suffered local or systemic adverse effects; the drug appeared to be very well tolerated in all 29 patients who were included in the assessment of tolerability.

DISCUSSION AND CONCLUSION

The results obtained in this study concur with those obtained in previous studies evaluating sertaconazole in adult populations. Thus, in adults with dermatophytosis, treatment with sertaconazole 2% cream over 4 weeks yielded clinical cure in 20% of the patients at week 1 of treatment, in 60% at week 2, and in 100% at week 4.⁴ These results are similar to those obtained in our study. The clinical results of these studies may be correlated to the marked in vitro activity shown by

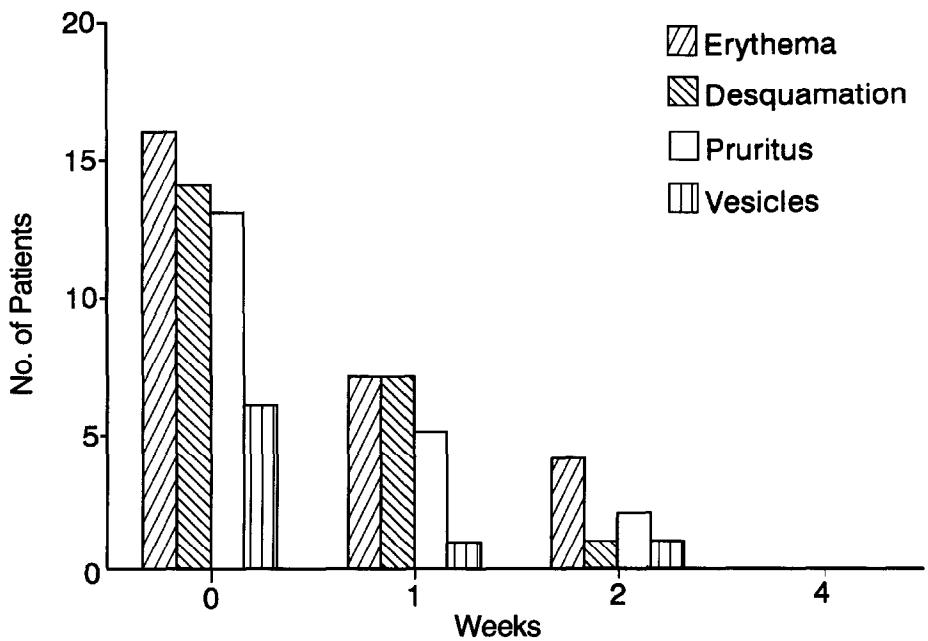


Figure 1. Remission of symptoms is shown by the number of patients who presented with each symptom at each of the follow-up visits. Patients were treated with 2% sertaconazole cream for 2 weeks, with assessments at weeks 1, 2, and 4.

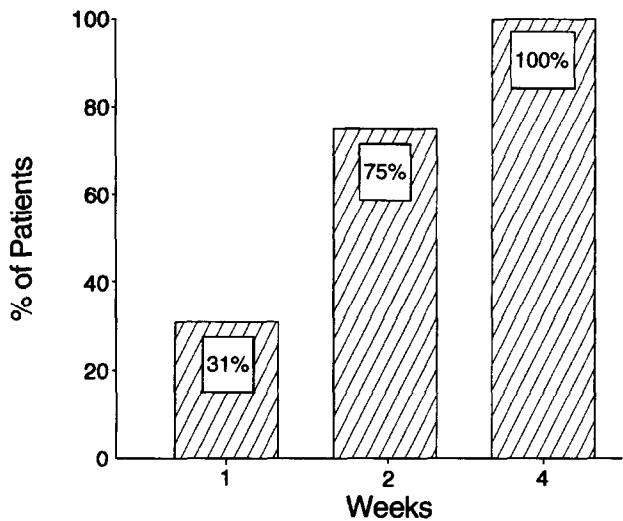


Figure 2. Clinical cure is shown by the percentage of patients (n = 16) who achieved remission at each of the follow-up visits. Patients were treated with 2% sertaconazole cream for 2 weeks, with assessments at weeks 1, 2, and 4.

sertaconazole in the presence of the species of infecting dermatophytes found in these studies.⁷

In our study, the cream was applied once daily as opposed to the schedule adopted for adults in the study mentioned above in which the frequency of application was twice daily.⁴ Consequently, our clinical results are indicative of good penetration and lengthy persistence of sertaconazole in the skin. When sertaconazole cream was applied to guinea pigs in the same concentration as used in our study, dermatophyte *T mentagrophytes* colonization was prevented when a suspension of this fungus was applied to the same area of skin 24 or 48 hours later.⁸ The excellent tolerance of sertaconazole by the pediatric patients in our study also concurs with that observed in the studies conducted in adult patients.^{3,4,9,10}

In summary, the results obtained suggest that sertaconazole, a new topical antimycotic applied once daily, is an effective and well-tolerated drug for dermatophyte infections in pediatric patients.

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REFERENCES

1. Casanovas JM, Clanxet J, Fernández I, Busquets C. Diagnòstics en dermatologia pediàtrica en un centre d'assistència primària. *But Soc Cat Pediatr*. 1994;54:81-84.
2. Hughes W. The dermatophytoses. In: Osaki F, De Angelis KD, Feigin RD, et al, eds. *Principles and Practice of Pediatrics*. 2nd ed. Philadelphia: JB Lippincott; 1994: 1371-1372.
3. Alomar C, Bassas S, Casas M, et al. Multi-centre double-blind trial on the efficacy and safety of sertaconazole 2% cream in comparison with miconazole 2% cream on patients suffering from cutaneous mycoses. *Arzneim-Forsch Drug Res*. 1992;42(I)5a: 767-773.
4. Pedragosa R, González B, Martín M, et al. Therapeutic efficacy and safety of the new antimycotic sertaconazole in the treatment of cutaneous dermatophytosis. *Arzneim-Forsch Drug Res*. 1992;42(I)5a:760-763.
5. Torres JM. Técnica micológica. In: Torres JM, ed. *Micosis que afectan piel y mucosas*. Barcelona: Ediciones Doyma; 1987:171-179.
6. Piédrola G. Hongos productores de micosis superficiales y cutáneas. In: Pumarola A, Rodríguez Torres A, García Rodríguez JA, Piédrola-Angulo G, eds. *Microbiología y Parasitología Médica*. Barcelona: Salvat Editores; 1984:712-724.
7. Palacín C, Sacristán A, Ortiz JA. In vitro activity of sertaconazole. *Arzneim-Forsch Drug Res*. 1992;42(I)5a:699-705.
8. Palacín C, Sacristán A, Ortiz JA. Actividad antifúngica de sertaconazol crema, polvo y solución en la prueba del tiempo de retención cutánea. *Rev Iberoamericana Micología*. 1994;11:17-20.

9. Umberto P, Nasarre J, Bello A, et al. Phase II study of therapeutic efficacy and safety of the new antimycotic sertaconazole in the treatment of superficial mycoses caused by *Candida albicans*. *Arzneim-Forsch Drug Res.* 1992;42(I)5a:757–760.
10. Nasarre J, Umberto P, Herrero E, et al. Therapeutic efficacy and safety of the new antimycotic sertaconazole in the treatment of pityriasis versicolor. *Arzneim-Forsch Drug Res.* 1992;42(I)5a:764–766.