

Treatment of Seborrhoeic Dermatitis of the Scalp with Ketoconazole Shampoo

A Double-blind Study

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Thirty-six patients with seborrhoeic dermatitis of the scalp and culture positive for *Pityrosporum ovale* were treated in a double-blind placebo controlled study with ketoconazole shampoo twice weekly for 4 weeks. In the ketoconazole group, 16 of 18 patients (89%) became free of lesions or improved, compared with only 8 of 18 ($p < 0.01$) in the placebo group. The patients found the shampoo effective, easy to use and cosmetically attractive. Key word: *Pityrosporum ovale*.

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Seborrhoeic dermatitis of the scalp is characterized by yellowish adherent greasy scales. The lipophilic dimorphic yeast *Pityrosporum ovale* is a member of the normal human cutaneous flora (1, 2). It is also the etiological agent of pityriasis versicolor (3) and *Pityrosporum* folliculitis (4). Several studies have demonstrated a causative role for *P. ovale* in seborrhoeic dermatitis (5, 6).

Ketoconazole has earlier been effective in the treatment of seborrhoeic dermatitis. Ford et al. treated patients with ketoconazole tablets (7) and Skinner et al. treated patients topically with a 2% cream (8). In two earlier studies involving small numbers of patients ketoconazole shampoo has been found effective (9, 10).

In the present double-blind controlled study, 38 patients with seborrhoeic dermatitis of the scalp were treated either with ketoconazole shampoo, or placebo shampoo twice weekly for 4 weeks.

MATERIALS AND METHODS

Patients

Thirty-eight patients, culture-positive for *P. ovale*, with seborrhoeic dermatitis of the scalp were included. Nineteen (17 men and 2 women; mean age 38 years) were treated with ketoconazole shampoo and 19 (11 men and 8 women; mean

age 41 years) were treated with the placebo shampoo. No topical or systemic treatment with antimycotics or corticosteroids was allowed for 3 weeks prior to the start of the study. The patients did not shampoo their hair for 3 days prior to assessment of lesions.

Treatment

The patients applied the test shampoo twice weekly for 4 weeks. The shampoo remained in the hair for 2 min before showering. If the patients shampooed their hair more often than twice weekly, they used a mild indifferent shampoo (Lactacyd, Famaco AB, Stockholm, Sweden). Patients were assessed before treatment and after 4 weeks, 3 days after the last day of treatment.

Assessment of lesions

Lesions were examined and scored on a quadrant-area-severity scale. The scalp was divided into four quadrants. The area of involvement of each quadrant was measured on a 1-5 scale where 1 means less than 10% involvement and 5 more than 70% involvement. Severity was measured by a 0-3 scale where 0 indicates healed and 3 erythema with thick confluent plates of yellowish white scales. The whole scalp score was then obtained by multiplying the total area of involvement by the total severity score.

Statistics

The numbers of cured patients in the two groups were compared using the χ^2 -test with Yates' correction.

RESULTS

Two patients, one in each group did not return for follow-up.

The results of treatment are shown in Table I. Keto-

Table I. Treatment of seborrhoeic dermatitis of the scalp with ketoconazole shampoo

	Cured	Improved	Failure
Ketoconazole	14	2	2
Placebo	2	6	10

conazole shampoo was significantly better than placebo shampoo ($p < 0.01$), with 16 of 18 patients (89%) free of lesions or improved after 4 weeks of treatment. The mean score dropped, in the ketoconazole group, from 25 before treatment to 3 after treatment, compared with the placebo group, whose mean score was 27 before treatment and 19 after treatment. No side effects were found and the patients found the treatment easy to use and cosmetically attractive.

DISCUSSION

There are now several published studies indicating the etiological significance of *P. ovale* in seborrhoeic dermatitis. Experimental infections in both humans and animals have been described (11, 12). Treatment of seborrhoeic dermatitis has earlier been with corticosteroids which, though effective, do not prevent the lesions from recurring very soon after treatment is stopped or reduced (6). However, a combination of miconazole and hydrocortisone has proved effective as prophylaxis when used twice monthly (6).

In the present study, ketoconazole shampoo was very effective in the treatment of seborrhoeic dermatitis of the scalp, with 89% of patients free of lesions or improved after 4 weeks of treatment twice weekly. The patients found the shampoo effective, easy to use and cosmetically attractive.

REFERENCES

1. Roberts SOB. *Pityrosporum orbiculare*: Incidence and distribution on clinically normal skin. *Br J Dermatol* 1969; 81: 264–269.

2. Faergemann J, Bernander S. *Tinea versicolor* and *Pityrosporum orbiculare*: A mycological investigation. *Sabouraudia* 1979; 17: 171–179.
3. Faergemann J, Fredriksson T. Experimental infections in rabbits and humans with *Pityrosporum orbiculare* and *P. ovale*. *J Invest Dermatol* 1981; 77: 314–318.
4. Bäck O, Faergemann J, Hörnquist R. *Pityrosporum folliculitis*: A common disease of the young and middle aged. *J Am Acad Dermatol* 1985; 12: 56–61.
5. Shuster S. The aetiology of dandruff and the mode of action of therapeutic agents. *Br J Dermatol* 1984; 111: 235–242.
6. Faergemann J. Seborrhoeic dermatitis and *Pityrosporum orbiculare*: treatment of seborrhoeic dermatitis of the scalp with miconazole-hydrocortisone (Daktacort), miconazole and hydrocortisone. *Br J Dermatol* 1986; 114: 695–700.
7. Ford GP, Farr PM, Ive FA, Shuster S. The response of seborrhoeic dermatitis to ketoconazole. *Br J Dermatol* 1984; 111: 603–609.
8. Skinner RB, Noah PW, Taylor RM, Zanolli MD, West S, Guin JD, Rosenberg EW. Double-blind treatment of seborrhoeic dermatitis with 2% ketoconazole cream. *J Amer Acad Dermatol* 1985; 12: 852–857.
9. Carr MM, Pryce DM, Ive FA. Treatment of seborrhoeic dermatitis with ketoconazole: I. Response of seborrhoeic dermatitis of the scalp to topical ketoconazole. *Br J Dermatol* 1987; 116: 213–216.
10. Green CA, Farr PM, Shuster S. Treatment of seborrhoeic dermatitis with ketoconazole: II. Response of seborrhoeic dermatitis of the face, scalp and trunk to topical ketoconazole. *Br J Dermatol* 1987; 116: 217–221.
11. Goodfield MJD, Saihan EM, Crowley J. Experimental folliculitis with *Pityrosporum orbiculare*: The influence of host response. *Acta Derm Venereol (Stockh)* 1987; 67: 445–450.
12. Drouhet E, Domp martin D, Papachristou-Moraiti, Ravissi P. Dermatite experimentale *Pityrosporum ovale* et (ou) *Pityrosporum orbiculare* chez le cobaye et le souris. *Sabouraudia* 1980; 18: 149–154.