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A Clinical Evaluation of Two Shampoos in the Treatment of Seborrheic Dermatitis

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Synopsis—The relative EFFICACIES of a commercially available ZINC PYRITHIONE SHAMPOO; a commercially available SULFUR, SALICYLIC ACID, and HEXACHLOROPHENE SHAMPOO; and a control shampoo in the "over the counter" treatment of frank SEBORRHEIC DERMATITIS were measured using a visual technique. Both the zinc pyrithione shampoo and the shampoo based on the combination of active ingredients produced better results than the unmedicated control shampoo. Further, the zinc pyrithione shampoo was significantly more effective in controlling this disease process than the shampoo containing the combination of active ingredients. A supplementary evaluation of the relative efficacies of the test products in suppressing itching of the scalp also indicated the zinc pyrithione product to be superior; however, the data do not give any evidence of better long-term reduction of scalp oiliness with this shampoo compared to the other active ingredient shampoo.

Introduction

Commercial preparations for the treatment of seborrheic dermatitis† of the scalp generally include the use of a shampoo, a postshampoo treatment (rinse), or a hair dressing containing one or more active ingredients. Some of the more commonly used materials have been sulfur, salicylic acid, resorcinol, coal tar, selenium sulfide, quaternary ammonium compounds, and hexachlorophene (1–7).

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† Seborrheic dermatitis: an erythemoto squamous dermatitis with a predeliction for areas with a heavy sebaceous gland population.

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Nearly all of the published clinical studies deal with a single active preparation; almost without exception, they report the tested system to be efficacious. The absence of comprehensive comparative studies does not permit firm conclusions as to the relative effectiveness of available treatments although certainly not all of the available treatments are equally effective!

This paper presents the results obtained in a controlled clinical study with two active systems, both of which are currently being used in commercially available shampoos. This is the first time that comparative data on the efficacies of these two active systems on frank seborrheic dermatitis have been published.

Materials and Methods

The preparations involved in the test were (A) a zinc pyrithione shampoo;* (B) a shampoo containing sulfur, salicylic acid, and hexachlorophene;† and (C) a placebo shampoo, identical to (A) except for the omission of the zinc pyrithione.

All three products were packed in identical 6.5-fl. oz. plastic bottles. Label instructions called for at least once-a-week use at home and gave the following instructions in product usage: "Lather-Rinse-Repeat." In addition, the lable of product (B) instructed the user to leave each lather on the scalp for 5 min before rinsing.

The shampoos were used by men and women, assigned in a balanced fashion to three groups on the basis of the pretest severity of their dermatitis. In that way, each group included the same percentage of subjects with various degrees of dermatitis.

The grading was done visually and the entire scalp was graded on a 0–4 scale. The criteria used in evaluating seborrheic dermatitis of the scalp were as follows:

0 is no dermatitis.

1 is minimal dermatitis, subjectively not a problem to the patient, objectively detectable by the examining physician. A small percentage of these patients would have glabrous skin involvement.

2 is moderate dermatitis, both subjectively and objectively detectable by the examining physician, as well as the patient. Approximately half of these patients would have glabrous skin involvement.

* Head and Shoulders, The Procter & Gamble Co., Cincinnati, Ohio 45224.

† Sebulex, Westwood Pharmaceuticals, Buffalo, N. Y. 14213.

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3 is moderately severe dermatitis, and usually both cosmetically and medically a problem. Most of these patients would have glabrous skin involvement.

4 is severe dermatitis involving the entire scalp intensively, and is invariably a real medical problem. All of these patients would have glabrous skin involvement.

Eligibility requirements were such that all subjects included in the study: (a) had minimum initial dermatitis grade of 2.0; (b) regularly washed their hair at home at least once per week; (c) had washed their hair approximately 1 week (7 ± 2 days) prior to the initial examination; and (d) had not used an antiseborrheic preparation within the 4-week period preceding the initial examination.

This test ran 8 weeks with examinations initially, after 4 weeks, and after 8 weeks of product use. Once again, subjects were required to wash their hair 7 ± 2 days prior to each examination, to use the test product at least once a week, and to avoid the use of any other antiseborrheic preparation during the test period. If any of the requirements were not met, the subject was rejected.

The test was conducted as a double-blind study, except to the extent that the products might have been unavoidably recognized by some subjects and that the zinc pyrithione and placebo shampoos were similar to each other and different from the sulfur–salicylic acid–hexachlorophene system.

As an attendant part of the study, the effect of the test products on scalp oiliness and itching were also determined. A single grade, from 0 (dry) to 4 (very oily), was assigned according to the examiner's assessment of the oiliness of the subject's scalp and a similar 0–4 scale was used by the subjects in grading itching. No attempt was made to balance groups on the basis of either initial oiliness or itching grades.

Results

One hundred and seventy individuals were present for clinical evaluations initially and at the 4- and 8-week examinations.

The data were evaluated by an analysis of covariance of the 4-week and 8-week grades, using the initial grades as the covariate.

As the data in Table I show, the zinc pyrithione shampoo and the sulfur–salicylic acid–hexachlorophene shampoo were significantly more effective in controlling seborrheic dermatitis than the control shampoo after both 4 and 8 weeks of product use. The zinc pyrithione shampoo

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Table I
Effect of Test Products on Seborrheic Dermatitis

	Zinc Pyrithione Shampoo	Sulfur–Salicylic Acid–Hexachlorophene Shampoo	Control Shampoo
No. of subjects	57	56	57
Average starting grade	2.5	2.6	2.5
Adjusted mean (4 weeks)	1.0[a]	1.6[b]	2.3
Adjusted mean (8 weeks)	0.6[a]	1.3[b]	2.2

[a] Significantly greater product effect ($\alpha = 0.05$) than all other treatments.
[b] Significantly greater product effect ($\alpha = 0.05$) than control.

Table II
Relative Efficacy of Test Products

	Zinc Pyrithione Shampoo	Sulfur–Salicylic Acid–Hexachlorophene Shampoo	Control Shampoo
Number of subjects	57	56	57
No effect			
No. of people	3	17	41
Percentage	5%	30%	71%
Good effect			
No. of people	13	24	16
Percentage	24%	42%	29%
Excellent effect			
No. of people	41	15	0
Percentage	71%	28%	0%

was also significantly more effective than the sulfur–salicylic acid–hexacholorophene shampoo after both 4 and 8 weeks of product use.

The data can also be looked at in another way, and this is shown in Table II. Any individual whose final grade was 2 or more grade points lower than the initial grade was considered to have had an excellent effect. If the reduction was 1 grade point or more, but less than 2, the effect was judged to be good. A reduction of less than one full grade point was considered no effect. It can be seen from the table that the zinc pyrithione shampoo produced a good or excellent result in 95% of the subjects. This is considerably better than the sulfur–salicylic acid–hexachlorophene shampoo in which this figure is 70%. Both, obviously, are

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Table III
Effect of Test Products on Subjective Scalp Itching[a]

	Zinc Pyrithione Shampoo	Sulfur–Salicylic Acid–Hexachlorophene Shampoo	Control Shampoo
Average starting grade	0.9	0.7	0.9
Adjusted mean (4 weeks)	0.2[b,c]	0.5[c]	0.5[c]
Adjusted mean (8 weeks)[d]	0.1[c,e]	0.3[b,c]	0.5[c]

[a] Numbers of subjects/product/period same as in Table I.
[b] Significant product effect, $\alpha = 0.05$ compared to control.
[c] Significant product effect, $\alpha = 0.05$ compared to initial grade.
[d] Relative to initial grade.
[e] Significant product effect, $\alpha = 0.05$ compared to control and compared to the sulfur–salicylic acid–hexachlorophene shampoo.

better than the placebo in which a good or excellent result is seen in only 29% of subjects.

Evaluation of oiliness turned out to be not very rewarding and the data are, therefore, not presented here. None of the products had a significant effect on scalp oiliness. However, the two therapeutic shampoos did show a small directional effect toward reducing the level of scalp oil over that seen with the control product.

The subjective itching data (Table III) indicate that while the use of all three shampoos lowered the awareness of itching, the zinc pyrithione shampoo users reported significantly less subjective itching than did the users of the sulfur–salicylic acid–hexachlorophene shampoo or the control shampoo after 8 weeks' use.

Conclusions

Both zinc pyrithione in a shampoo vehicle and a combination of sulfur, salicylic acid, and hexachlorophene in a shampoo vehicle were effective in controlling seborrheic dermatitis. The zinc pyrithione shampoo was more effective than the shampoo containing the combination of sulfur, salicylic acid, and hexachlorophene in reducing the seborrheic dermatitis and accompanying itching, but showed no long-term advantages in terms of reducing oiliness.

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