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The antidandruff efficacy of a shampoo containing piroctone olamine and salicylic acid in comparison to that of a zinc pyrithione shampoo

M. LODÉN* and C. WESSMAN

ACO Hud AB, Research & Development, Box 622, S-194 26 Upplands Vàsby, Sweden

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Synopsis

Dandruff (pityriasis capitis) is a chronic scalp condition characterized by scaling and sometimes itching and redness. Shampoos containing antifungal agents are used to control the scaling condition. In the present study, two shampoos with different actives are compared in a double-blind, randomised and bilateral study on 19 subjects. One shampoo contained piroctone olamine (0.75%) combined with salicylic acid (2%) and the other contained zinc pyrithione (1%) as active ingredient. The subjects were treated twice weekly with the shampoos for almost 4 weeks. Before each treatment the degree of dandruff was evaluated.

Both shampoos were highly effective in reducing the dandruff. The combination of piroctone olamine and salicylic acid appeared to be slightly more effective than zinc pyrithione in reducing the severity and area affected by the scaling.

Résumé

L'état pelliculaire *pityraisis capitis* est une maladie chronique du cuir chevelu, caractérisée par des desquamations et dans certain cas des démangeaisons et des rougeurs. Les shampooings contenant des agents antifongiques sont utilisés pour contrôler l'état du cuir chevelu. Dans cette étude, deux shampooings aux actifs differents sont comparés dans un test bilatéral en double aveugle et au hasard sur 19 sujets. Un des shampooings contient de la piroctone olamine (0,75%) combinée avec de l'acide salicylique (2%). L'autre shampooing contient de la pyrithione zinc (1%) comme actif. Les sujets sont traités avec les shampooings deux fois par semaine pendant quatres semaines. Avant chaque traîtement, le degré de l'état pelliculaire a été évalué.

Les shampooings ont réduit de façon significative l'état pelliculaire dans les deux cas. Toutefois la combinasion piroctone olamine/acide salicylique semble être plus efficace que la pyrithione zinc tant au niveau de la severité de la maladie et de la surface affectée par la desquamation.

Introduction

Dandruff (pityriasis capitis) is a chronic scalp condition characterized by scaling and sometimes accompanied by itching and redness of the scalp. The areas of the scalp usually affected are the forehead and the back of the ears beyond the hairline and other parts of the face. Dandruff may gradually progress through redness, irritation and increasing scaling of the scalp to seborrhoeic dermatitis and both conditions are considered to be the same disorder but different severity. The common causative agent is now accepted to be

*To whom correspondence should be addressed. Tel: + 46 8 622 3650; fax: + 46 8 622 3680; e-mail: marie.loden@acohud.se

the lipophilic yeast *Malassezia furfur* (formerly known to be *Pityrosporum ovale*), which is increased in the scaly epidermis of both dandruff and seborrhoeic dermatitis sufferers.

Shampoos containing tars, ketoconazole, selenium sulphide, zinc pyrithione, and piroctone olamine as active ingredients are used to control the scaling condition by reduction of the lipophilic yeast. The ultimate goal of these shampoos is to remove scales and reduce multiplication of the resident lipophilic yeast. Removal of the scales may be facilitated by the addition of keratolytic agents, for example salicylic acid. Previous studies have shown 0.5% piroctone olamine to be slightly more effective than 0.5% zinc pyrithione (ZPT) [1]. However, to our knowledge the efficacy of the combination of piroctone olamine (PO) and salicylic acid (SA) has not yet been studied.

The aim of the present study was to compare the efficacy of a shampoo containing 0.75% PO and 2% SA as active compounds with a shampoo containing ZPT (1%) as active ingredient. The area involved and the severity of the scale pattern were combined into an overall dandruff score, which was considered as the primary efficacy variable [1].

Materials and methods

Study design and treatments

This was a randomised double-blind study in healthy volunteers who acted as their own controls by receiving both study shampoos on each side of the head in a randomized manner. This design allows the direct comparison of the two products in the same subject at the same time. Nineteen volunteers with dandruff were included in the study (eight women and 11 men, mean age 26 years) and all subjects finished the study. Inclusion criteria was dandruff on both sides of the head at day 1 (score > 4, see below).

Following a run-in period of minimum 1 week, during which the subjects used an ordinary non-dandruff shampoo, the subjects entered a 4-week treatment period. The test products were used twice weekly, Tuesdays and Fridays. Other shampoos were not allowed during the study period, but some subjects used hair conditioning products. Washing of the hair with the shampoos was performed by professional hairdressers supervised by the investigator (C.W.). The total shampoo contact time was 3–4 min on each side and care was taken to avoid cross-contamination of the treatment sites during shampooing. The study was approved by Uppsala University ethics committee.

One of the test products (Head & Shoulders, mot mjäll, normal, Procter & Gamble, Kista, Sweden) contained 1% ZPT as active ingredient. Other ingredients were aqua, ammonium laureth sulphate, ammonium lauryl sulphate, sodium chloride, sodium lauroyl sarcosinate, glycol distearate, PEG-12, polyquaternium-10, citric acid, sodium sulphate, tetrasodium EDTA, DMDM hydantoin, sodium polynaphtalenesulphonate, potassium sorbate, sodium benzoate, parfum, Cl 42090. The other test shampoo contained 0.75% PO and 2% SA as active ingredients (Special schampo mot mjäll, ACO HUD AB, Stockholm, Sweden). Other ingredients were aqua, sodium C12–15 pareth sulphate, propylene glycol, cocamidopropyl betaine, sodium citrate, PEG-120 methyl glucose diolate, PEG-7-glyceryl cocoate, disodium phosphate, citric acid, sodium chloride, parfum.

Method of assessment and data treatments

The scalp was divided into four sections and to allow close examination of the scalp, the hair was parted with a comb. The area of involvement within each quadrant of the scalp was scored on a 0–4 scale, and the severity on a 1–5 scale. The area scores were:

0 = < 10%, 1 = 10–< 30%, 2 = 30–< 50%, 3 = 50–< 70%, 4 = > 70%. The severity scores were: 1 = small flakes resembling a coarse greyish powder, 2 = intermediate, 3 = either large flakes very loosely attached to the scalp and giving an irregular whitish surface or small flakes partially adhering to the scalp, 4 = intermediate, 5 = flakes adhering to the scalp as white or yellow plates. The assessments were made immediately before the shampooing treatment. Results from each assessment were noted on a separate scalp chart and the investigator did not have access to any previous score while making the assessment. The same investigator (C.W.) made all the evaluations.

The dandruff score was calculated for each side of the scalp by adding the product of the two scores (area score multiplied by severity score) for each of the two quadrants (i.e. the maximum score for one side of the scalp was 40). The dandruff score was considered the primary efficacy variable, and area involved and severity signs were used as descriptive parameters. The area and severity scores were the mean value from the area and severity scores from the two quadrants (i.e. the maximum score of area and severity for one side was 4 and 5, respectively). The scores of the two scales were arbitrary and changes in severity were not regarded as being numerically comparable with changes in area [1].

Data are presented as mean values. The Wilcoxon signed rank test on paired data was used to test the differences between the two treatments. *P*-values are reported and $P < 0.05$ was adopted as the level of significance. Minitab® statistical software, Release 12 (PA, U.S.A.) for Windows was used for calculations and plots.

Results

The primary efficacy variable decreased progressively throughout the treatment period with the two treatments (Fig. 1). There was no difference in dandruff score between the two halves of the scalp at the start of the study, but at day 18 a significant difference was noted ($P = 0.024$) in favour of the PO + SA shampoo (Fig. 1). At days 8 and 18, the severity score was significantly lower at the PO + SA shampoo treated area ($P = 0.029$ and 0.023, respectively; Fig. 2). At days 18 and 25, a significantly smaller area was affected by treatment with the PO + SA shampoo ($P < 0.005$ for both days; Fig. 3). At the end of the study less than one-third of the scalp was affected by small dandruff flakes.

Discussion

The results of the present double-blind study demonstrated that both shampoos significantly reduce dandruff. There were no apparent differences in mechanism between the two preparations, as both the severity and area curve showed a similar time course for the two treatments. At the end of the treatment period less than one-third of the head was affected by small flakes resembling coarse greyish powder. The combination of 0.75% PO + 2% SA appeared to be slightly more effective than 1% ZPT in reducing dandruff. The numerical difference in efficiency between the products was not large, but the high sensitivity in the study due to the bilateral double-blind treatment, showed small differences in favour of the PO + SA shampoo. Differences in severity were detected at days 8 and 18 and in area affected at days 18 and 25.

ZPT has bacteriostatic and fungistatic properties and is used at 1–2% in the control of seborrhoeic dermatitis and dandruff [2] and also as preservative at a maximum level of 0.5% in Europe (78/768/EEC). Some articles have addressed contact sensitivity to ZPT [3]

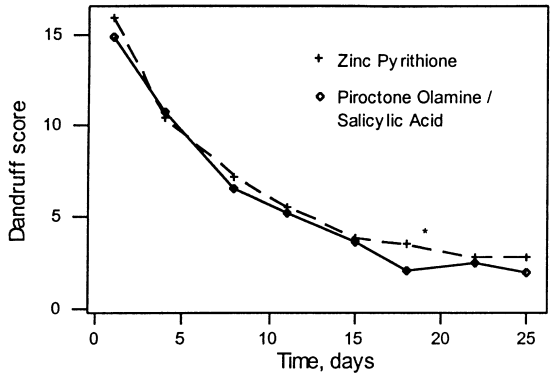

Fig. 1. The dandruff score (combined from severity and area involved) after shampoo treatment with zinc pyrithione and piroctone olamine/salicylic acid shampoo twice weekly. Maximum possible score = 40. * = significant difference, $n = 19$.

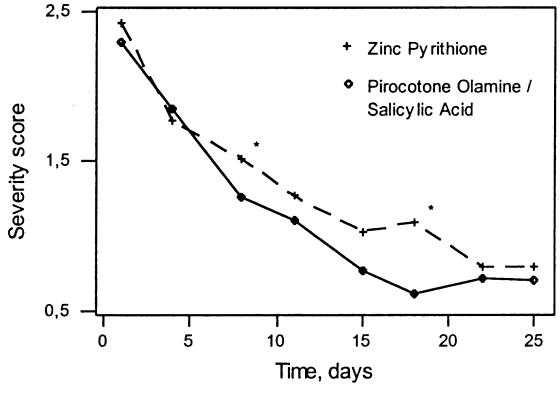

Fig. 2. The severity score after shampoo treatment with zinc pyrithione and piroctone olamine/salicylic acid shampoo twice weekly. Maximum possible score = 5. * = significant difference, $n = 19$.

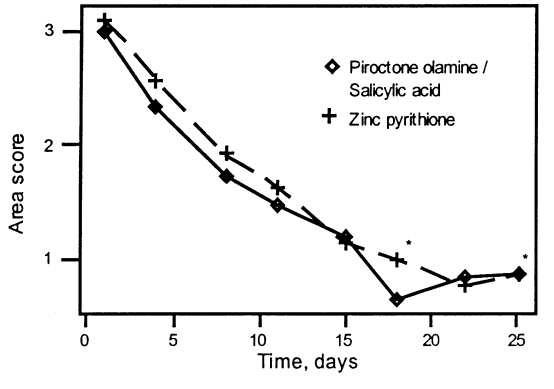

Fig. 3. The area score after shampoo treatment with zinc pyrithione and piroctone olamine/salicylic acid shampoo twice weekly. Maximum possible score = 4. * = significant difference, $n = 19$.

and peripherial neuritis with paraesthesia and muscle weakness has also been associated with the prolonged used of a shampoo containing 2% of the substance in one patient [4]. PO has been used in shampoos for the treatment of dandruff for several years [1,2] and in this formulation it has been combined with SA. Apart from being a keratolytic agent, SA also exhibits antifungal properties [2]. SA is considered to be a weak sensitizer, but very few reports of contact sensitization to salicylates have been recorded [5]. It is readily absorbed from the skin, but toxicity from percutaneous absorption is rare and has not been reported from rinse-off treatments [5].

In conclusion, the efficacy of two anti-dandruff shampoos was monitored using a randomised, double-blind and bilateral study. The results showed that a combination of PO and SA was slightly more effective than ZPT in reducing the severity and area affected of the scaling. This may suggest a higher therapeutic index for the former combination.

Acknowledgement

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