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*Corresponding author: Bianca Maria Piraccini, V. Massarenti 1, 40138 Bologna, Italy
E-mail: biancamaria.piraccini@unibo.it

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Udo Schumacher, University Medical Center Hamburg-Eppendorf, Germany

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DERMATOLOGY | RESEARCH ARTICLE

Efficacious and safe management of thick scales, redness and flaky scalp condition using a specific shampoo containing urea, glycolic acid, salicylic acid, ichthyol pale and laureth 9

Bianca Maria Piraccini^{1*}, Nicolò Brandi¹, Aurora Alessandrini¹, Francesca Bruni¹ and Michela Starace¹

Abstract: Dandruff is a common condition, generally due to seborrheic dermatitis (SD) and occasionally to scalp psoriasis (SP), which is characterized by accumulation of scales, oily, red and flaky scalp, often accompanied by itch. The aim of our study was to evaluate the cleansing efficacy and tolerability of a new shampoo (Psorisdin Shampoo®) containing urea, glycolic acid, salicylic acid, ichthyol pale and laureth 9 compared to a nonspecific shampoo. A total of 10 subjects (4 males and 6 females, 18–60 years) with mild–moderate scalp inflammation with redness, itching and flaking, due to SP and/or SD, were included in this open clinical study. The treatment efficacy was assessed by comparison of global photography and trichoscopy pictures, evaluating the presence of scales and erythema on the scalp, the number and morphology of capillaries and verifying disease evolution, severity of symptoms and presence of scalp irritation/itch. The use of this medicated shampoo resulted in an important improvement of patient's scalp and hair clinical appearance and was well tolerated, with disappearance of scalp irritation and itching in almost all patients,

ABOUT THE AUTHOR

Prof. BM Piraccini is an associate professor in Dermatology at the University of Bologna. She is Head of the Outpatient consultation for Hair and Nail Disorders, Outpatient consultation of Allergology and the Laboratory of Mycology and Parasitology.

Her major research activities include clinical, diagnostic, therapeutic and basic aspects of hair science, nail science and mycology.

She is member of European Hair Research Society (EHRS) (President), European Nail Society (ENS) (President), Società Italiana di Dermatologia e Malattie Sessualmente Trasmesse (SIDeMaST), Council for Nail Disorders (CND) (Board member), American Academy of Dermatology (AAD), European Academy of Dermatology and Venereology (EADV) and North American Hair Research Society (NAHRS). She is also part of numerous editorial boards and reviewer for several Scientific Journals. Dr. Piraccini is author of 180 papers published on International and Italian Journals and of 12 monographies on diseases of the cutaneous appendages.

PUBLIC INTEREST STATEMENT

Dandruff is a common condition which is characterized by accumulation of scales, oily, red and flaky scalp, often accompanied by itch. The aim of our study was to evaluate the cleansing efficacy and tolerability of a new shampoo (Psorisdin Shampoo®) containing urea, glycolic acid, salicylic acid, ichthyol pale and laureth 9 compared to a nonspecific shampoo. The use of Psorisdin Shampoo® resulted in an important improvement of patient's scalp and hair clinical appearance and was well tolerated, showing higher cleansing and soothing property than a nonspecific shampoo; moreover, its effect was maintained over time, even after 5 days since the last wash.

showing higher cleansing and soothing property than a nonspecific shampoo. The effect of the tested shampoo was maintained over time, even after 5 days since the last wash.

Subjects: Dermatology; Dermatology; Cosmetic Dermatology

Keywords: scalp dermatitis; dandruff; seborrheic dermatitis; scalp psoriasis; shampoo

1. Introduction

Dandruff is a common condition in the general population and it is generally characterized by more or less thick accumulation of scales, oily, red and flaky scalp, often accompanied by itch. Seborrheic dermatitis (SD) and scalp psoriasis (SP) are the most frequent causes of dandruff and in their early stages, they are often hardly recognizable from each other.

SD is chronic inflammatory condition characterized by the presence of flakes on the scalp and in the hair (dandruff) often accompanied by itch, but patients with severe forms also commonly complain an increased hair loss. The more common affected areas of the scalp seem to be the forehead and the back of the ears beyond the hairline, but SD can also extend to other parts of the face, such as eyebrows and nasolabial folds (Lodén & Wessman, 2000). Dandruff affects approximately half of the adult population worldwide, while SD is described in 1–5% of the general population, a percentage that rises to 30–33% in immunocompromised patients (Paulino, 2017). SD had a higher prevalence and severity in men than in women, due to hormonal factors (5 α -dihydrotestosterone is a potent trigger to sebum production) and among young people than older people, probably due to the increased sebum production that occurs during adolescence and early adulthood (Misery, Rahhali, Duhamel, & Taieb, 2013). Heredity seems to play a small role in developing a predisposition for the conditions and climate changes, physical trauma (such as scratching), seasonal variations and emotional stress seem to aggravate clinical presentation (Seité et al., 2009). Despite their pathogenesis remains to be completely elucidated, most authors agree that the yeast organism *Malassezia* plays a key factor in triggering inflammatory process and hyperproliferative epidermal reaction that characterized SD. Indeed, *Malassezia* scalp quantity is elevated in affected patients and antifungals are usually efficient for symptom management (Turner et al., 2013). In particular, recent studies suggest that *Malassezia*, by digesting sebaceous triglycerides, is responsible for production of free fatty acids which promote inflammation in susceptible individuals (Dall'Oglio, Lacarrubba, Verzi, & Micali, 2016). Subsequently, the disruption of proliferation and differentiation processes of the epidermis secondary to inflammation in turn lead to a decreased barrier integrity and a further susceptibility to the yeast action (Schwartz et al., 2013). Impaired function of the stratum corneum of the scalp may also be a predisposing for the development of SD and some authors suggest that the intrinsic quality of this epidermal layer may drive individual susceptibility to SD because structural lipids are depleted and disorganized and transepidermal water loss is increased in affected patients (Turner, Hoptroff, & Harding, 2012).

In psoriasis, the scalp is the most common, and frequently the first site of disease involvement and an isolated SP affects about 2% of the general population (Van De Kerkhof & Franssen, 2001). The lesions are typically located behind the ear and neck but may appear anywhere on the scalp. The extent varies from fine scaling to thick erythematous scaly plaques diffuse on the entire scalp, typically crossing the hair line and affecting a small area of the adjacent facial skin. Itching and hair loss due to SP are common, but alopecia is almost always non-cicatricial and complete regrowth is observed after inflammation ceases.

Diagnosis of SD and SP are clinical and are based on the characteristic morphology and distribution of lesions. However, mild forms producing flaking, itching and moderate scalp erythema make differential diagnosis impossible only on a clinical basis. Trichoscopy can be useful for differentiating SD from SP: beside the difference in color and thickness of scales, which tend to

Figure 1. Tricoscopy (70× magnification) of SD: SD shows a multiform pattern of vessel dilation, with mildly tortuous capillary loops and isolated dilated (SD pattern).



be yellow in SD and white silvery in SP, observation of the scalp vessels, allowed by 70× magnifications, shows different patterns of the morphological changes of scalp capillaries allowing differential diagnosis in most of the cases. SD shows a multiform pattern of vessel dilation, with mildly tortuous capillary loops, isolated dilated capillaries and a substantial preservation of local micro-angio-architecture (SD pattern) (Figure 1), while SP shows a homogeneous pattern in all scalp areas with tortuous and dilated capillaries (with bushy appearance) and a completely disarranged microangio-architecture (SP pattern) (Figure 2) (Runne & Kroneisen-Wiersma, 1992).

Although both these flaky conditions are not life threatening, they have a significant negative impact on patient's quality of life, leading to social distress. In fact, the presence of skin scales on hair and clothing, as scalp redness along the hairline, is esthetically undesirable and scalp scratching in public is often socially embarrassing (Seité et al., 2009).

In general, cosmetic and pharmaceutical products for treating SD include keratolytics (such as sulfur or salicylic acid), regulators of sebum production (such as zinc or tar), antifungal drugs (such as selenium sulfide or azole drugs) and/or antimicrobial natural products (such as tea tree oil or

Figure 2. Tricoscopy (70× magnification) of SP: homogeneously distributed dilated tortuous capillaries with bushy appearance and small hemorrhages (SP pattern).



honey) (Rosina, Zamperetti, Giovannini, & Girolomoni, 2007). Because SD is also considered as an inflammatory disease, topical low- and mild-potency corticosteroids are popular treatments due to their anti-inflammation properties; nonetheless, the usage of these drugs is limited due to their potential side effects (e.g. skin atrophy, folliculitis and tachyphylaxis) and risk of rebound after treatment cessation (Dos Santos & Dias-Souza, 2017).

Treatment of SP includes corticosteroids or corticosteroids–vitamin D combination as first choice agents, but mild forms, presenting with erythema, dandruff and itching, may benefit from frequent use of shampoo designed to remove scales and have an anti-inflammatory action.

A specific shampoo (Psoridin Shampoo®) designed for scalp hygiene in patients suffering from thick scales, redness and flaky scalp has been recently developed. This new formulation contains urea, glycolic acid, salicylic acid, ichthyol pale and laureth 9.

The aim of our study was to evaluate the cleansing efficacy and tolerability of topical therapy with this medicated shampoo compared to a nonspecific shampoo.

2. Materials and methods

A total of 10 subjects (4 males and 6 females aged 18–60 years) with mild–moderate dandruff were included in this open clinical study. For all patients, the diagnosis of the condition causing scalp erythema, scaling and itching was established on clinical grounds and trichoscopy.

At the first visit (T0), after giving their written consent to participate, the patients were included in the study and throughout the study were evaluated with global photography and trichoscopy.

The study was divided in two parts:

- In the first part, the patients were evaluated after the use of a nonspecific shampoo. This evaluation was performed after 5 days of not washing the hair (T5), after which patients were asked to wash their hair with a nonspecific shampoo and come the day after (T6) to allow monitoring the cleansing efficacy of their personal shampoo.
- In the second part, the patients were asked to come to be reevaluated after not washing their hair for 5 days (T11); subsequently, they were asked to wash their hair with the tested shampoo and come back the day after (T12) to allow monitoring of the cleansing efficacy of this shampoo. Finally, after 5 more days without shampooing, the patients came back to the hospital to allow evaluation of maintenance of the tested shampoo's effects (T17).

The efficacy of the treatment was assessed by comparison of global photography and trichoscopy pictures at 20 and 70× magnifications, the former evaluating the overall appearance of the hair (greasy, opaque, in locks, with dandruff), the latter looking at presence of scales, erythema and/or sebum on the scalp (at 20× magnifications), the number of capillaries and their morphology (normal, dilated or glomerular) at 70× magnifications. At the end of each visit, both the volunteers and the researcher filled out a brief questionnaire on safety and efficacy of the tested shampoo, verifying disease evolution (worsening, stability, mild improvement, moderate improvement or major improvement), severity of symptoms (decreased, stable or increased) and presence of irritation/pain on the scalp (disappeared, decreased, stable or increased).

None of the patients was using other cosmetic or pharmaceutical anti-dandruff treatment or presented a known allergy to any component of the product under investigation.

3. Results

Each of the enrolled patients concluded the study. At the first visit (T0), eight patients (80%) presented the clinical evidence of greasy opaque hair associated with the trichoscopy features of

greasy scales, sebum in the follicular ostia and redness of the scalp at 20× magnifications, while two patients (20%) had white dry scales on hair and scalp with evident erythema. Trichoscopy at 70× magnifications showed an increased number of dilated scalp vessels in all subjects (100%), with eight patients showing dilated arborized or tortuous vessels distributed patchy on the scalp (due to SD) and two patients presenting with homogeneously tortuous and dilated capillaries in a bushy pattern all over the scalp (due to SP). These two patients were diagnosed as having SP, one suffered from mild plaque psoriasis.

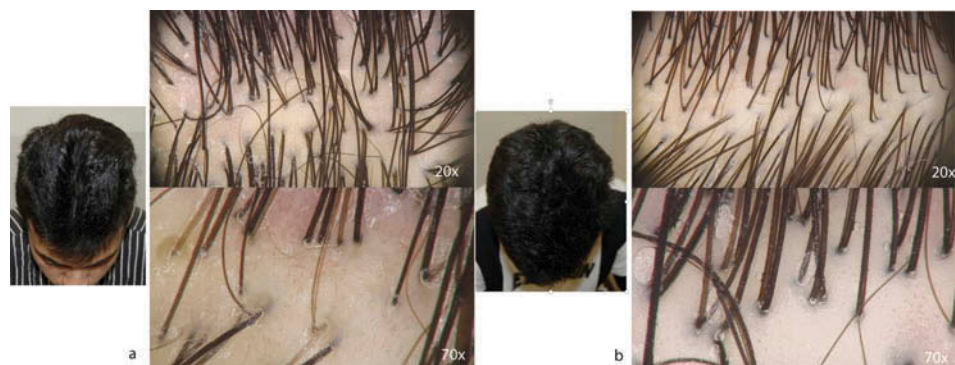
At T5, 5 days after not washing their hair, the trichoscopy features were not changed: eight patients (80%) presented the same amount of yellow scales on an oily scalp, two patients (20%) had white scales with local erythema. 70× magnifications showed an increased number of scalp vessels in all subjects (100%), with eight patients characterized by the SD pattern and two by the SP pattern.

The day after shampooing with a nonspecific product (T6), the clinical presentation remained almost unchanged, with the hair still oily and opaque, and at scalp trichoscopy, seven patients (70%) presenting yellow scales, two patients (20%) white scales and local erythema and nine patients (90%) an excess amount of sebum. Even 70× trichoscopy showed no particular changes, with a stable number of evident scalp vessels in nine patients and an increased number in one patient, capillaries morphology remaining constant. The efficiency of generic shampoos evaluated by the researcher showed a stability of the clinical presentation in nine patients and a worsening in one patient; similar rates were also reported by patients, seven of whom claimed to have noticed a stability of the disease and three worsening of it. Subjective signs described as irritation/itching of the scalp resulted stable in nine patients while one patient complained about an increase of itching after shampooing.

After 5 days without washing their hair from the last generic shampoo (T11), the patients returned to be reevaluated and the clinical presentation was identical to the second visit (T5), with 8 patients (80%) presenting yellow scales, 2 patients (20%) having white scales and local erythema on the scalp and 10 patients (100%) presenting an excess amount of sebum on hair/scalp. Trichoscopy showed an increased number of scalp vessels in eight subjects (80%) and a stable number in two subjects (20%), with seven patients characterized by the SD pattern and two patients by the SP pattern. All 10 patients reported a worsening of the subjective and objective symptoms, even if the clinical presentation was the same.

The day after washing the hair with the tested shampoo (T12) (Figures 1–3), the clinical presentation radically improved in six patients (60%), who had a marked improvement of the hair appearance, which was shiny and with no flakes. Scalp trichoscopy showed absent redness, greasiness and scales in six patients (60%), and presence of a small amount of yellow scales and sebum on the scalp in four patients (40%). These results were also confirmed by 70× trichoscopy that showed a reduced number of visible scalp vessels in all 10 patients; capillaries morphology had returned to normal in 7 patients, while 3

Figure 3. Flaky and red scalp with dilated capillaries 5 days after hair washing (a) and the day after using Psoridin Shampoo® (b), which induced disappearance of scales and sebum, reduction of redness and decrease in the number of dilated capillaries.



subjects still had a small amount of dilated vessels (1 SD pattern and 2 SP pattern). A significant improvement of all the clinical scores after the use of the tested shampoo was noted both by the researcher and the patients, with almost complete resolution of the scales (moderate improvement) in two subjects and even with a complete resolution of the condition in eight subjects (major improvement). Reduction of symptoms was documented in all patients; irritation/itching of the scalp disappeared in nine patients and was reduced in one.

After 5 more days without washing their hair (T17) (Figures 4 and 5), the patients returned to be reevaluated and at trichoscopy, the excellent therapeutic results obtained with the use of the tested shampoo were totally maintained over time in 60% of the patients and partially maintained in 40% of them, with one patients (10%) presenting yellow scales on the scalp and three patients (30%) having an excess amount of sebum on hair/scalp. Trichoscopy at 70× magnification showed no changes compared to T12 in nine subjects (90%) and a moderate increased number of dilated capillaries only in one subject. Clinical improvement after the use of the tested shampoo was also sustained over time, with no patient with flakes or scales on hair and scalp (Figure 6) and only two subjects complaining of greasy hair. Reduction of symptoms continued to be documented in all the patients, with irritation/itching remaining absent in nine patients and reduced in one.

No treatment-related side effects were recorded in any patient. All patients judged the tested shampoo effective and easy to apply and appreciated its cosmetic benefits. After the end of the study, all patients declared satisfaction with the results and their willingness to continue the use the tested shampoo over time.

Table 1 summarizes all the trichoscopic features observed at T5, T6, T11, T12 and T17.

Figure 4. Flaky and red scalp in a patient with seborrheic dermatitis 5 days after hair washing (a) and the day after using Psoridin Shampoo® (b), which induced reduction of sebum and inflammatory signs.

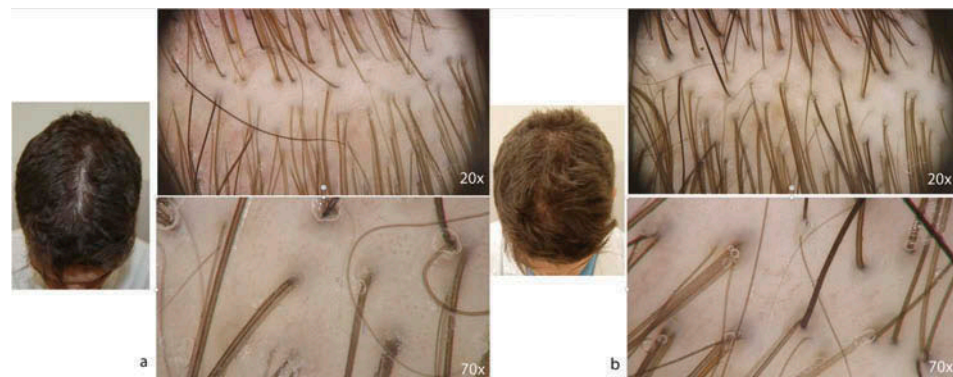


Figure 5. Greasy hair and flaky, oily and red scalp with dilated capillaries 5 days after hair washing (a) and the day after using Psoridin Shampoo® (b), which induced evident cosmetic improvement of the hair appearance, with shiny and non-greasy hair, and, at trichoscopy, disappearance of scales and sebum, reduction of redness and, at 70× magnification, decrease in the number of glomerular-shaped dilated capillaries.



Figure 6. Same patient of Figure 3 photographed 5 days after using Psorisdin Shampoo®: maintenance of the cosmetic, cleansing and anti-inflammatory effects.

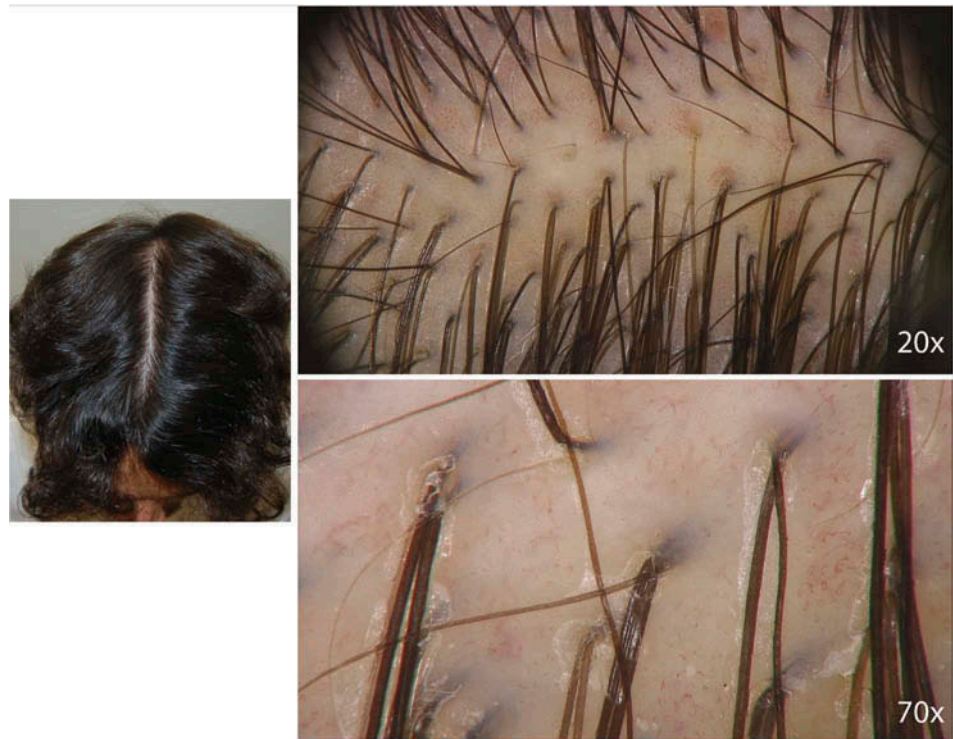


Table 1. Trichoscopic features observed at T5, T6, T11, T12 and T17

Trichoscopic features	No. of patients (%) at T5 (5 days after last hair washing)	No. of patients (%) at T6 (1 day after hair washing with a nonspecific shampoo)	No. of patients (%) at T11 (5 days after hair washing with a nonspecific shampoo)	No. of patients (%) at T12 (1 day after hair washing with Psorisdin Shampoo®)	No. of patients (%) at T17 (5 days after hair washing with Psorisdin Shampoo®)
Yellow scales on hair	8 (80%)	7 (70%)	8 (80%)	1 (10%)	1 (10%)
White dry scales on hair and scalp erythema	2 (20%)	2 (20%)	2 (20%)	0 (0%)	0 (0%)
Excess amount of sebum	10 (100%)	9 (90%)	10 (100%)	3 (30%)	3 (30%)
Number of scalp capillaries	Increased 10 (100%) Stable 0 (0%) Reduced 0 (0%)	Increased 1 (10%) Stable 9 (90%) Reduced 0 (0%)	Increased 8 (80%) Stable 2 (20%) Reduced 0 (0%)	Increased 0 (0%) Stable 0 (0%) Reduced 0 (100%)	Increased 1 (10%) Stable 9 (90%) Reduced 0 (0%)
Morphology of scalp capillaries	Dilated 8 (80%) Glomerular 2 (20%) Normal 0 (0%)	Dilated 8 (80%) Glomerular 2 (20%) Normal 0 (0%)	Dilated 7 (70%) Glomerular 3 (30%) Normal 0 (0%)	Dilated 3 (30%) Glomerular 0 (0%) Normal 7 (70%)	Dilated 1 (10%) Glomerular 2 (20%) Normal 7 (70%)

4. Discussion

Scalp itching, erythema and scaling, generally defined as “dandruff”, are very common symptoms among the general adult population and may be due either to SD or mild SP. Regardless of

etiology, in most of the cases, patients just want to find a proper and efficient treatment for their scalp problem, with no interest of knowing what is the main cause of their scalp problem.

It is generally recognized that dandruff is associated with the colonization of the scalp by *Malassezia* yeasts; this is true for dandruff due to SD but also for SP, where the role of this microorganism in exacerbation of the disease has been shown by several authors (Ortonne et al., 2011). *Malassezia* yeasts require an exogenous source of fatty acids in which to propagate and therefore areas of the head that have greater sebum production are particularly favored.

The most common treatment for thick scales, redness and flaky scalp due to SD or to SP is the use of shampoo formulations that most often contain antifungal agents (Gomez-Moyano et al., 2014). Despite these products are effective in improving dandruff, antifungal shampoos can often reduce cosmetic appearance of the hair and, consequently, lead to a tendency to revert to a nonspecific shampoo, with an inevitable return of dandruff symptoms (Turner et al., 2013). Over recent years, other therapeutic strategies have been developed, such as the inclusion of low concentration of salicylic acid in shampoo preparations. Salicylic acid shampoo has no antifungal activity but it works by loosening the attachments between the corneocytes and allowing them to get washed off, causing cornified epithelium to swell, soften, macerate and desquamate (Kobayashi et al., 2016). In addition to its exfoliating action useful in removing scalp hyperkeratotic skin, recent studies support that salicylic acid even shows some protection against yeasts and dermatophytes (Ranganathan & Mukhopadhyay, 2010).

Psoridin Shampoo® is specifically designed for scalp hygiene in patients suffering from thick scales, redness and flaky scalp. Its formulation contains urea, glycolic acid, salicylic acid, ichthyol pale and laureth 9 that contribute all together to an immediate and long-lasting anti-inflammatory, anti-itching, anti-sebum, keratolytic and antimicrobial effects on the scalp, simultaneously taking care of the hair and scalp health and beauty. Urea ingredient has antifungal, antimicrobial qualities and a high ability to act as a moisturizer for dry and flaky scalp. Salicylic acid provides to the shampoo a keratolytic effect, as it loosens and softens scalps scales, making them easier to remove. Ichthyol pale, the sodium salt of a pale sulfonated shale oil in aqueous solution, possesses different action principles, including anti-inflammatory, anti-itching, antimicrobial (including effects against *Malassezia* sp.), sebaceous gland regulating (anti-seborrheic) properties and also a keratostatic action. Laureth 9 (polidocanol) is a local anesthetic and antipruritic agent, contributing to the soothing and calming effect of the shampoo. Finally, the presence of glycolic acid contributes to the cosmetic effects of the medicated shampoo on the hair, as it helps it to maintain its moisture, provides hair conditioning, moisturizing, strengthening also preventing breakage and increasing the hair ability to stay stronger at high temperatures like heat styling.

The results obtained in our clinical study prove the good quality of the tested shampoo formulation showing that it is an effective and well-tolerated option for topical therapy of thick scales, redness and flaky scalp condition due to SD or SP. Moreover, our study showed that this emollient keratolytic, soothing shampoo is not only able to obtain better therapeutic results compared to a nonspecific shampoo but is also capable of maintaining such results over time.

First of all, by comparing the data of T5 and T6, i.e. the therapeutic results obtained after washing hair with generic shampoo, it emerges that clinical improvement was really minimal, with at trichoscopy a reduction of the amount of yellow scales in 12.5% of patients and an improvement of the excess amount of sebum in 10% of patients; moreover, there were no significant changes in the number and the morphology of the capillaries of the scalp seen at 70× magnification. Even if no significant differences were observed between the patient and the physician in terms of clinical evaluation, some subjects seemed to have perceived worse therapeutic outcomes than those reported by the researcher.

On the contrary, analyzing the data of T11 and T12, it is evident that the tested shampoo has an immediate effect on reducing scales on the scalp, with an improvement on yellow scales in 87.5% of patients, a complete disappearance of white scales and local erythema in 100% of patients with SP and a reduction of sebum excess in 70% of patients. In addition, since the first wash, the tested shampoo has a rapid action in reducing the number of capillaries and the grade of inflammation, an observation confirmed by the high rate of capillaries with normal morphology at the trichoscopy. We also observed that patients with the SP pattern maintained the same capillary morphology but presented a lower number of capillaries after the tested shampoo, indicating that SP was still present but in remission phase. The use of the tested shampoo resulted in an important improvement of patient's clinical appearance and was well tolerated, with disappearance of scalp irritation and itching in almost all patients. Finally, our study also highlighted that the effect of the tested shampoo is maintained over time, even after 5 days since the last wash. In fact, after 5 days (T17) from shampooing, a major improvement in clinical appearance was preserved in 80%. Further trials on SP are necessary to confirm efficacy of the tested shampoo on flaky and red scalp due to this condition on a higher number of patients; however, due to the similar clinical signs presented by patient affected by SD and SP, we can consider that the results in SD could be extrapolated for the benefit of patients with SP.

In conclusion, the global efficacy of Psoridin Shampoo® was significantly better than that of nonspecific shampoo, showing higher cleansing and soothing property: this medicated shampoo was efficient in reducing yellow scales in 87.5% of the cases compared to 12.5% for the generic shampoo, was able to reduce white scales and local erythema in 100% of the cases compared to the inefficiency of the nonspecific product and, finally, was capable to decrease the amount of sebum on scalp/hair in 70% of patients compared to 10% for the nonspecific product. These results confirmed previous literature reports (Seité et al., 2009) and demonstrated the high efficacy of this well-tolerated and cosmetically acceptable product. Moreover, the improvement of subject's scalp condition is directly related to an improvement of her/his quality of life, potentially contributing in a better compliance adherence to long-term therapy.

In accordance with Taylor & Francis policy and my ethical obligation as a researcher, we are reporting that Prof. Bianca Maria Piraccini received funding from a company that may be affected by the research reported in the enclosed paper. We have disclosed those interests fully to Taylor & Francis, and we have in place an approved plan for managing any potential conflicts arising from that involvement.

Disclosure statement

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Competing Interests

The authors declare no competing interests.

Author details

Bianca Maria Piraccini¹
E-mail: biancamaria.piraccini@unibo.it
Nicolò Brandi¹
E-mail: nicolo.brandi@studio.unibo.it
Aurora Alessandrini¹
E-mail: aurora.alessandrini@alice.it
Francesca Bruni¹
E-mail: francesca.bruni3@studio.unibo.it
ORCID ID: <http://orcid.org/0000-0001-7248-425X>
Michela Starace¹
E-mail: michela.starace2@unibo.it

¹ Dermatology, Department of Experimental, Diagnostic and Specialty Medicine, University of Bologna, Bologna, Italy.

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