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ORIGINAL ARTICLE

Clinical benefit and tolerance profile of a keratolytic and hydrating shampoo in subjects with mild to moderate psoriasis. Results from a double-blind, randomized, vehicle-controlled study

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Abstract

Introduction: Scalp psoriasis frequently goes with other disease location and may lead to a significant burden and impairment of quality of life (QoL). Adherence to local treatments is a frequent problem. A keratolytic and hydrating shampoo containing 2% salicylic acid, 5% urea, and 1% glycerin (active shampoo) has been developed for psoriasis-prone scalp.

Objective: To assess the efficacy and tolerability of an active shampoo in subjects with mild to moderate scalp psoriasis.

Materials and methods: A single-center, randomized, double-blind, vehicle-controlled study was conducted on 67 adults with mild to moderate psoriasis. The active shampoo or its vehicle were applied daily for 14 days and 3 times/week for another 14 days. Assessments included the Psoriasis Scalp Severity Index (PSSI), Investigator Global Assessment (IGA), calculated total surface affected hair, scalp greasiness, irritation, and assessed scalp dermatitis–specific quality-of-life issues using SCALPDEX and product acceptability.

Results: The active shampoo significantly ($p < 0.05$) reduced the PSSI by 39.0%, 37.2%, 63.0%, and 69.0% immediately after washing compared to a 22.8%, 5.5%, 19.6%, and 13.0% with the vehicle at Days 1, 8, 15, and 30, respectively. SCALPDEX items, IGA, and irritation significantly ($p < 0.05$) reduced with the active shampoo. Hair and scalp greasiness improved continuously with both products until Day 21. Subject-reported symptom scores paralleled the positive evolution of clinical signs. The active shampoo was well tolerated, subjects were highly satisfied and had an improved QoL.

Conclusion: The active shampoo significantly improved clinical signs, symptoms, and QoL of mild-to-moderate scalp psoriasis compared to the vehicle. It was very well tolerated and highly appreciated by the subjects.

KEYWORDS
dermocosmetic, scalp, psoriasis, salicylic acid, randomized double-blind study

1 | INTRODUCTION

Psoriasis is a chronic, inflammatory skin disease that affects 2% of the global population.[1] Scalp psoriasis is estimated to affect up to 80% of patients with psoriasis and can lead to a significant burden and reduced quality of life (QoL).[2–4] It requires special consideration due to the difficult-to-treat nature and disproportionate impact QoL.[3,5,6] Moreover, due to its chronicity, poor accessibility, and poor cosmetic effect of topical treatments, adherence to local treatments is a frequent problem.[7,8] Treatments mainly rely on topical steroid-based formulations that can lead to skin irritation (especially hydroalcoholic lotions) during the short term and to local adverse events during long term use. A keratolytic and hydrating shampoo (PSOlution, Laboratoires Vichy International, France, hereafter "active shampoo") containing 2% salicylic acid, 5% urea, and 1% glycerin, acting on psoriasis symptoms has been developed for psoriasis prone scalp.

The aim of this study was to assess in subjects with mild-to-moderate scalp psoriasis, the efficacy and local tolerance of an active shampoo.

2 | MATERIALS AND METHODS

A single-center, randomized, double-blind, vehicle-controlled study was conducted in adult subjects with mild-to-moderate psoriasis who applied the active shampoo or its vehicle daily for 2 minutes from Day 1 to Day 15 and then 3 times/week until Day 30 after having stopped their psoriasis treatment. The study received local ethics committee approval and all subjects provided written informed consent prior to inclusion.

Demographic data were collected on Day 1. Clinical examinations were conducted on Day 1 pre-wash, Day 1 post-wash, Day 8, Day 15, and Day 30. Efficacy was assessed using the Psoriasis Scalp Severity Index (PSSI), including erythema, scaling, and induration on a 5-point scale each, were summed and weighted by the percentage of the affected area in 4 defined areas on the scalp and the total surface affected was calculated, the (IGA) and the evolution of clinical signs and symptoms. Other evaluations at selected visits included hair and scalp greasiness, QoL using the scalp dermatitis–specific quality-of-life issues (SCALPDEX) questionnaire and product characteristics.

Sample size estimation was based on a previous unpublished study conducted in order to achieve at least a statistical power to obtain a 20% of difference for the assessed parameters.

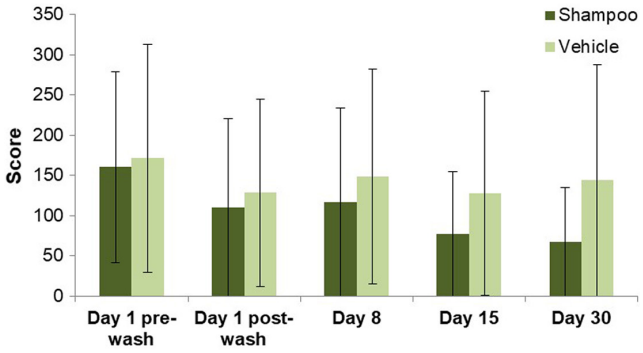

FIGURE 1 Evolution of the Psoriasis Scalp Severity Index over time. Between-group differences were statistically significant ($p < 0.05$) in favor of the active shampoo on all post-Day 1 visits.

All values obtained at Day 1 post-wash, Day 8, Day 15, and Day 30 were compared (Wilcoxon signed-rank test for all the continuous data comparisons) to Day 1 pre-wash values. Paired comparisons were processed through the Student's *t*-test, taking a $p < 0.05$ as threshold of significance, using the SPSS 23 package (IBM™). A 95% level of significance was adopted.

Subjective data were submitted to a binomial test.

3 | RESULTS

In total, 67 individuals were included, 65.7% were females. The mean age was 43.2 years, and 86.6% had Fitzpatrick skin Phototype III. All had sensitive scalps, 58.2% had mild, and 41.8% moderate. scalp psoriasis.

The active shampoo significantly ($p < 0.05$) reduced the PSSI by 39.0%, 37.2%, 63.0%, and 69.0% immediately after washing on Days 1, 8, 15, and 30, respectively, compared to a 22.8%, 5.5%, and 19.6% decrease and a 13.0% increase with the vehicle (Figure 1).

After 30 days of daily use, the IGA was significantly ($p < 0.001$) decreased with the active shampoo by 47.5% from Day 1 (1.4 ± 1.3 vs. 2.5 ± 0.5) compared to 6.9% with the vehicle (2.4 ± 0.9 vs. 2.5 ± 0.5).

Irritation scores were significantly ($p < 0.001$) decreased by 26.8%, 27.3%, 39.9%, and 33.8% immediately with the active shampoo at Day 1, 8, 15, and 30, respectively. Figure 2 shows the improvement of the scalp over time. Scores increased after an initial improvement with the vehicle (3.9%, and 0.5% decrease immediately after washing on Day 1 and Day 8 and by 1.5% and 4.4% at Day 15

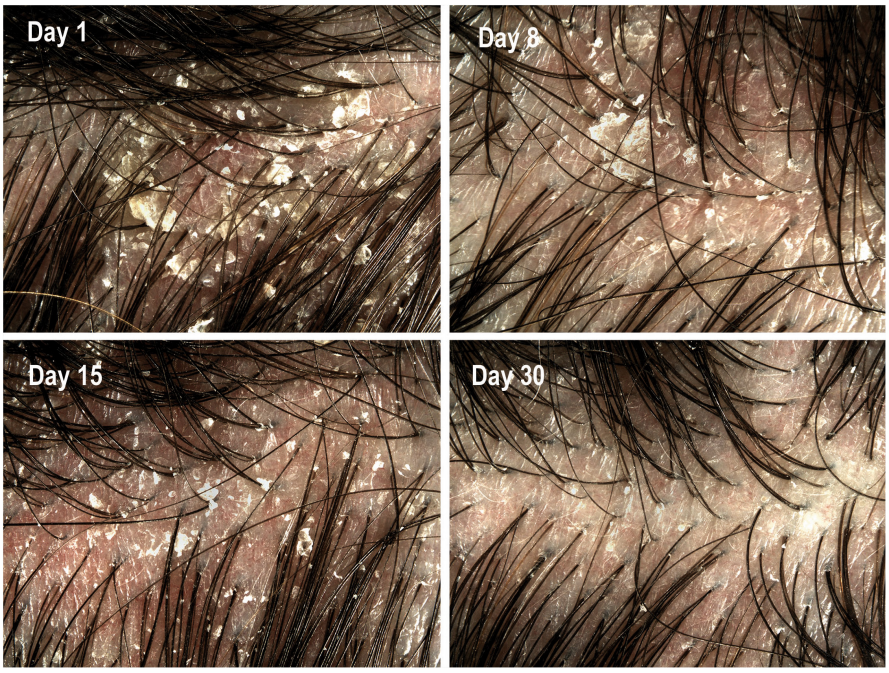

FIGURE 2 Improvement of the scalp over time with the active shampoo.

and Day 30, respectively); between-group differences were statistically significant ($p < 0.05$) at all post-Day 1 visits.

Hair and scalp greasiness improved continuously with both the active shampoo and vehicle until Day 21. Between-group differences were statistically not significant. QoL improved in both groups, however, with no statistically significant difference.

Overall, 90.9% of the participants were satisfied with the active shampoo compared to 82.3% with the vehicle. Moreover, all subjects who applied the active shampoo stated to wish to continue its use. The keratolytic shampoo was very well tolerated.

4 | DISCUSSION

Results from this double-blind, randomized study showed that a non-medicated shampoo containing keratolytic and hydrating agents significantly (all $p < 0.05$) improves the PSSI, IGA, and psoriasis-related symptoms of subjects with mild to moderate scalp psoriasis compared to its vehicle within 2 weeks of daily application followed by a 3 times/week use while studies showed that a shampoo containing LHA significantly improved scalp psoriasis or scalp dermatitis only after 4 weeks of treatment.[9,10] Similar were only obtained when using shampoos that contain corticosteroids or tar in moderate to severe scalp psoriasis over 4 weeks.[11] The present beneficial outcome with the tested shampoo is particularly important as the continuous use of pharmacologically active formulations to treat scalp psoriasis, especially corticosteroids is not recommended. Due to this restriction of use, regular treatment-free periods are mandatory in order to reduce or to prevent corticosteroids-related side effects.[12] As a consequence, treatment-free periods may result in the relapse of psoriasis, requiring another treatment period going along with a novel risk of treatment-related side effects. Thus, using a non-medicated shampoo to maintain the treatment success of pharmacologically treated mild-to-moderate scalp psoriasis during the treatment-free period may reduce treatment cycles or increase the delay between such courses. Moreover, the shampoo may be indicated in the management of milder forms of scalp psoriasis, without any restriction. The excellent local tolerance of the tested active shampoo may help to improve adherence to care, thus prolonging the treatment-free period even further.

Unfortunately, the study did not show any differences between the active shampoo and the vehicle concerning QoL which may be due to the highly appreciated vehicle formulation—that also serves as the basis for the active shampoo. This formulation contains glycerin which is known to improve skin hydration, improving skin dryness, signs, and symptoms going along with the latter. As a result of improved skin dryness, subjects may experience an improved quality of life through a decreased burden, as with any other emollient, moisturizer, or hydrating rinse-off formulation.

As for all clinical studies, the present investigation has its limits. In addition to the rather small number of participants which did not allow for adjusting for SCALPDEX assessments, the study design may not reflect real-life use of the active shampoo; subjects may not apply the product on the hair for 2 min thus reducing its benefit leading to a potentially earlier relapse. Despite these issues, the study provided evidence that subjects who were successfully treated for the scalp psoriasis followed be the use of the tested active shampoo maintain the initial treatment outcome.

In conclusion, the tested keratolytic and hydrating shampoo improves mild to moderate scalp psoriasis. It is an interesting option in the daily care of this chronic inflammatory disease, alone or combined with local reference medications.

AUTHOR CONTRIBUTIONS

PM, VR, DK, and SS developed the protocol. PCP, BMP, LR, DFM, SVG, and WYW participated in the study, PM, VR, DK, and SLM analyzed the data. All authors participated in the production and review of the manuscript.

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CONFLICT OF INTEREST STATEMENT

Philippe Massiot, Virginie Rasmont, Stéphanie Leclerc-Mercier, and Delphine Kerob are employees of L'Oréal Group. The other authors have no conflict of interest to disclose.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

ETHICAL APPROVAL

The study received local ethics committee approval of the Comissão de Ética para a Saúde Clínica Dr. Carlos Ramos, Lousado, Braga, Portugal on August 3, 2021 and is registered in the Clinical Studies National Register (RNEC) of Portugal under the number: 307937. All subjects provided written informed consent prior to inclusion and provided written consent for the use of their scalp photographs.

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