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Original Research Article

Anti-dandruff efficacy of ayurvedic scalp leave-on treatment: a double-blinded, randomized placebo-controlled clinical study

Machavolu Soubhagya Lakshmi Madhavi, Ravi Kant Shukla*, Susmita Gudulkar, Saurabh Mathur, Supriya Punyani

Research and Development, Hindustan Unilever Ltd., Mumbai, Maharashtra, India

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***Correspondence:**
Ravi Kant Shukla,
E-mail: Ravikant.shukla@unilever.com

ABSTRACT

Background: This study aimed to evaluate the efficacy and safety of ayurvedic leave on treatment product in the management of dandruff through a randomized, double-blind, placebo-controlled study.
Methods: A total of 112 subjects with clinically diagnosed moderate dandruff were randomly assigned to group A (ayurvedic leave-on treatment group) and group B (placebo group), where 110 subjects completed the study. The treatment phase was for 4 weeks, followed by a regression phase of 1 week. Subjects applied the allotted product on their scalp and massaged. It's a leave on product so the subjects were asked not to wash off.
Results: After 4 weeks of treatment, test product group A demonstrated a significantly greater reduction in dandruff severity compared to group B ($p<0.05$). The adherent dandruff scores in group A showed a significant reduction of 17.56 units/41% while in group B, it was noted to be 29.4%/12.4 units. Additionally, 100% of subjects in group A reported a subjective perception improvement in symptoms of dandruff within 2 weeks when compared to group B which is only by 81%.
Conclusions: Indulekha Svetakutaja scalp leave-on treatment is a safe and highly effective solution designed to combat dandruff while simultaneously enhancing the overall health of the scalp and hair.

Keywords: Anti-dandruff, Ayurvedic, Indulekha Svetakutaja

INTRODUCTION

Dandruff is a scalp condition with excessive scaling that affects up to 50% of the population irrespective of the gender.[1,2] Often dandruff presents with itch and scalp dryness, culminating into scalp irritation and redness compromising scalp health.[2] Role of *Malassezia* species on scalp is proven to play a key etiological role in development of the dandruff and implicated in inflammatory/ hyper proliferative response and impairs the scalp barrier function.[3] Lipolytic activities of *Malassezia* species release fatty acids by cleaving the sebaceous secretions, penetrate scalp inducing persistent microinflammation and hyperproliferation, which leads to incomplete corneocyte differentiation, a widely accepted mechanism in the etiopathology of dandruff.[4,5] High levels oxidative by products of lipids like hydroxy octadecadienoic acid (HODE) were isolated from dandruff scalps compared to healthy scalps, indicating the role of redox imbalance in development of dandruff.[6,7] Supporting the aforementioned mechanism, oxidative byproducts of sebum secretions like squalene peroxides were proven to trigger hyper-proliferation of keratinocytes with upregulated inflammatory mediators like PGE2 confirms the role of multiple factors in dandruff development.[8]

Hence, multi-dimensional approach is taken in the present clinical study to target dandruff and associated symptoms to restore scalp health.

One of the known strategies to target dandruff is reducing the *Malassezia* load from scalps and prevent them from coming back to the pre-treatment levels. In the cosmetic industry it is generally achieved using synthetic anti-fungal ingredients like zinc pyrithione, climbazole, and piroctone olamine, which works by inhibiting the *Malassezia furfur* growth, however, may not address other factors contributing to the susceptibility of dandruff. [9-11] Ayurveda, Indian system of medicine identifies the cause of dandruff as imbalance of vata and kapha dosha and recommends the combination of some potent herbs processed with coconut oil to apply on scalp as siroabhyanga as a treatment to improve scalp health.[12]

METHODS

Study design

The study was a full head, randomized, double-blind and monocentric, with two test products (placebo and leave-on treatment) run in parallel. Subjects were recruited as per inclusion and exclusion criteria. Both male and female in the age group of 18-36 years suffering from dandruff were included in the study. Pregnant and lactating women were excluded from the study. Volunteers with severe hair fall or any scalp related problems or allergies that can potentially interfere the study results were also excluded from the study as per the dermatologist's discretion. Subjects with moderate to severe dandruff were recruited and have undergone wash-out period of 2 weeks with a neutral shampoo. Post wash out, only those subjects meeting the inclusion and exclusion criteria and with total dandruff score >40 were proceeded into treatment phase. Total of 112 subjects qualified for treatment phase and 110 subjects completed the study.

On the baseline visit (day 0), subjects were acclimatized, followed by dermatologist visual assessment for adherent scalp flaking score and loose flakes, instrumental assessments to measure scalp sebum (using Sebumeter), transepidermal water loss (using Tewameter) and hair fall count (using combing test). Ayurvedic doctor also monitored the subjects throughout the study. Blinded test products were randomized between the two test groups (placebo and leave on treatment group) using computer generated randomization chart and product usage instructions were provided. Study volunteers were restricted to use any hair care product or treatments except the products provided throughout the study period.

Test products were used by volunteers at home as per the instructions provided thrice a week as leave-in on scalp. Subjects were instructed not to wash their hair 48 hours before assessment visit. The following were assessment visits: baseline, week 1, week 2, week 4 and regression-1 week.

Test products were withdrawn on week 4 assessment, followed by 1 week of regression period during which subjects were given a neutral shampoo to use and final assessment was done on week 5 which is a regression assessment (regression-1 week). Consumer assessment on product efficacy and sensory was taken during assessment visits. The attributes included overall satisfaction on product efficacy and sensorial like smell, texture, and consistency.

Demographics of the study volunteers

110 subjects completed the study and one subject from each group failed to follow up to complete the study due to personal reasons. Efficacy of the test products in reducing dandruff was assessed by dermatological visual assessment of both adherent scalp flaking score (ASFS) and loose flakes. Additionally, improvement in barrier function and sebum were measured by instruments, whereas hair fall was assessed by combing test. Demographic characteristics of the subjects are depicted in Table 1.

Table 1: Demographics and volunteers' characteristics at baseline.

Characteristics	Values
Age range	18-36 (inclusive both the ages)
Gender category	Both male and female
N (male: female)	110 (1: 3)
Dandruff level at baseline, >40 (ASFS+ loose flakes)	Dermatological assessment

Statistical analysis

All statistical tests were performed at two-sided 5% level of significance and 95% confidence interval and statistical software PAST 4.03 and SigmaStat 3.5 were used for the analysis of the data. Paired t-test was used to evaluate the efficacy of the product, and two sample t-test was used for evaluating significance between the groups.

Ethics and informed consent

Present clinical study was carried out as per GLP and ICH guidelines in compliance with the local government regulations. The study was reviewed and approved by independent ethics committee in India and an informed consent was obtained from all study subjects. The study was registered on Clinical Trial Registry of India, under ayurvedic study (CTRI/2023/09/057704) prospectively. Study was executed at Mascot Spincontrol India Pvt Ltd, Mumbai, India between September 2023 to December 2023.

RESULTS

Efficacy in reducing adherent scalp flakes

Dandruff scales were assessed based on the adherent scalp flaking score (ASFS). The scalp area was divided into 8

parts, and each partition was assessed individually on a 1-10 scale and added to get the total ASFS core. Both placebo and scalp leave-on treatment groups showed significant reduction in ASFS from week 1 onwards compared to their respective baselines. The scalp leave-on treatment group showed significantly higher performance compared to the placebo in reducing ASFS by 17.5 units by the end of 4 weeks (Figure 1).

Efficacy in reducing loose flakes

Subjects' scalp was evaluated for the presence of non-adherent loose dandruff flakes by partitioning scalp into 6 parts, using a scale from 0 to 10 for each partition. Both the groups showed a significant reduction in the severity of loose flakes from week 1 onwards compared to their respective baselines. Leave-on treatment group showed a significant reduction in loose flakes by 12.6 units by the end of 4 weeks and was significantly superior to placebo group at all assessment time points (Figure 2).

Efficacy in reducing scalp sebum levels

Scalp sebum levels were measured to quantify the sebum on scalp to assess the effect of treatment. Both groups showed a reduction in total scalp sebum levels from week 1 onwards with sustained reduction till week 4 and regression. The leave-on treatment group demonstrated significant sebum reduction compared to placebo group (Figure 3).

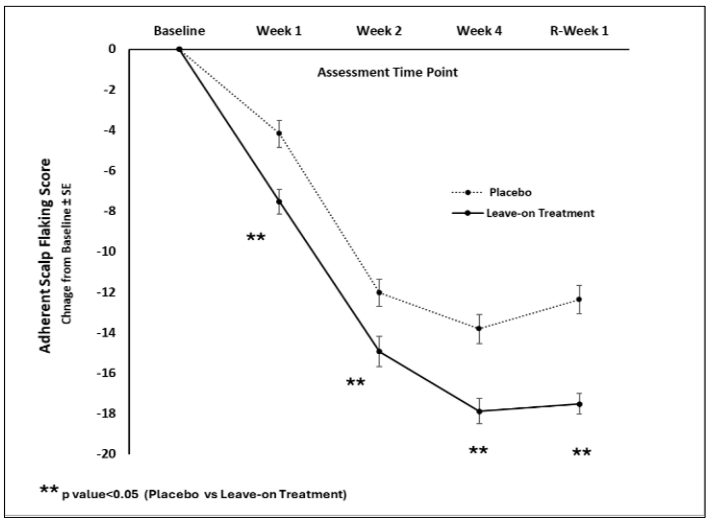

Figure 1: Dermatological assessment for ASFS, placebo versus leave-on treatment and values expressed as change from baseline±SE.

**p value <0.05.

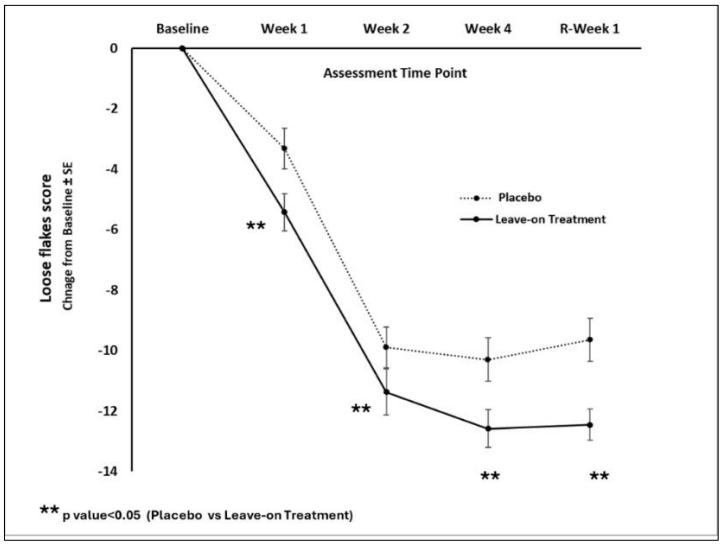

Figure 2: Dermatological assessment for loose flakes, placebo versus leave-on treatment (p value <0.05) and values expressed as change from baseline±SE.**

**p value <0.05.

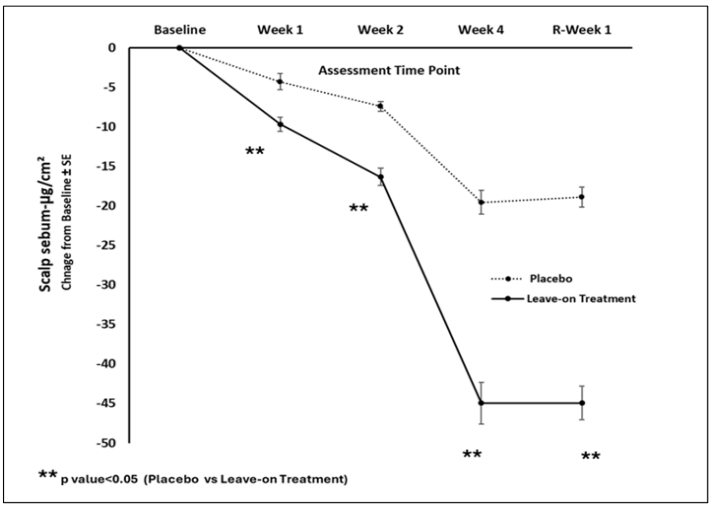

Figure 3: Sebumeter assessment for scalp sebum, placebo versus leave-on treatment and values expressed as change from baseline±SE.

**p value <0.05.

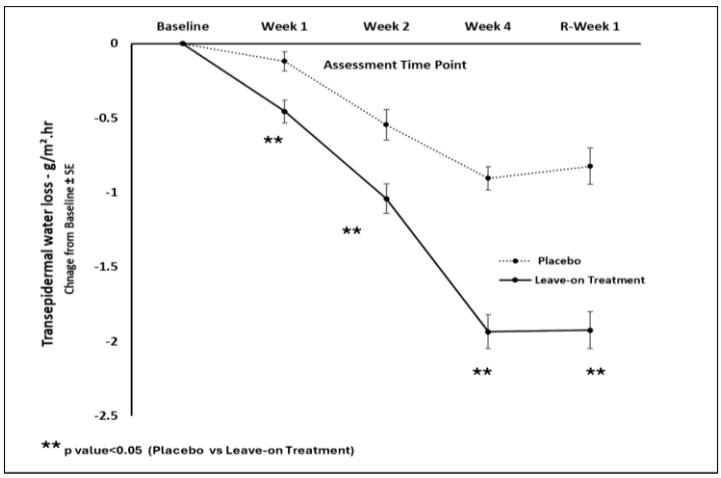

Figure 4: Instrumental assessment for barrier strength using Tewameter, placebo versus leave-on treatment and values expressed as change from baseline±SE.

**p value <0.05.

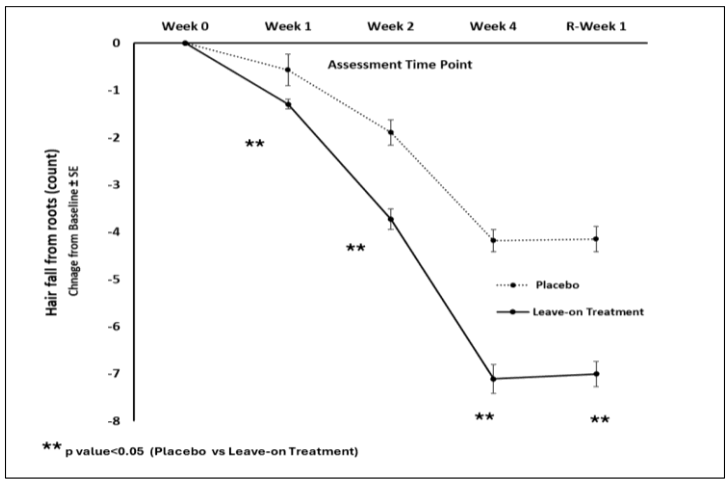

Figure 5: Technical assessment for hair fall count, placebo versus leave-on treatment and values expressed as change from baseline±SE.

**p value <0.05.

Efficacy in improving scalp barrier properties

Dandruff scalps are often associated with impaired scalp barrier with dryness and irritation. Hence to assess the improvement of barrier properties, transepidermal water loss (TEWL) was measured at all visits to assess the improvement of same. Scalp leave-on treatment group showed significant improvement in the TEWL vs their respective baseline from week 1 to regression, where are placebo showed improvement from week 2. Leave-on treatment is significantly superior in improving the scalp barrier properties compared to placebo (Figure 4) at all assessment time points.

Efficacy in reducing hair fall

Hair fall is also one the problems associated with dandruff. Hair fall is assessed using combing test from baseline to regression week. Scalp leave-on treatment group showed significant reduction in hair fall from week 1 to regression, where are placebo showed reduction from week 2 onwards. Leave-on treatment is significantly superior in reducing hair fall from roots compared to placebo (Figure 5).

DISCUSSION

Dandruff is a recurring problem due to the inherent susceptibility, excess of sebum secretion and the *Malassezia* species that are implicated in etiology of dandruff being commensals which cannot be completely eradicated from scalp.[13] Usually, dandruff starts around puberty and can extend to middle age which is a very long period deal with and there is no proven cure for dandruff. Persistent and severe dandruff impairs scalp health with high levels of histamines leading to itching, accompanied dryness, irritation and oxidative stress culminating into hair fall and hair thinning if left unattended.[14-16] Carbonylation of skin proteins, the oxidatively damaged proteins were reported to be one of the causes of barrier dysfunction and reduced hydration was also reported in dandruff scalps.[17,18]

Anti-dandruff shampoos are commonly used to tackle this condition using anti-fungal actives like Piroctone Olamine, Ketoconazole, Climbazole, and Zinc Pyrithione. Multiple strategies have been adopted by formulation scientists to deliver superior antidandruff benefit through wash off treatments, of which modifying the formulation with deposition aids had been proven to be effective and incorporation of salicylic acid to the formulations was also proven to enhance anti-dandruff efficacy.[19,20] These products cleanse sebum, wash off flakes or reduce the load of *Malassezia*, provides only short time relief and may not address all the symptoms of the dandruff. To treat this recurring dandruff from the roots and restore the scalp health multipronged approach and leave-on treatment is needed to counter every step in the pathogenesis of dandruff. Ayurveda recommends a multi herb approach to such conditions and the present clinical study demonstrates the approach in improving the scalp health in all the dandruff subjects participated in the study, which is worth noting.

The present anti-dandruff scalp leave-on treatment brings the knowledge of ancient ayurvedic texts into modern format, enabling the consumers to use the product any time of the day, as a wear and go treatment. The product is crafted using the ayurvedic ingredients like Amla, Svetakutaja, Neem and Rosemary which are highly concentrated using Kashaya process/arka vidhi and is clinically proven to not just reducing dandruff but also checks the sebum secretion and improves barrier strength.

Svetakutaja (*Wrightia tinctoria* Roxb) is one of the ingredients used in the leave-on treatment at active levels. Historically Svetakutaja has been used in Siddha and Ayurveda for various inflammatory skin conditions like psoriasis on skin and scalp.[21] Studies on exploring the phytochemical composition of the plant revealed the presence of amino acids, alkaloids, sterols, glycosides, phenolics, tannins, flavonoids along with indigo and indirubin.[22] Hydro alcoholic extracts of the leaves were proven to have anti-psoriatic activities. There is compelling scientific evidence of antioxidant, anti-microbial effects against pathogenic dermatophyte fungi and dandruff causing *Malassezia furfur,* making it a suitable candidate to be incorporated into ayurvedic formulations to treat dandruff effectively.[23,24]

Amla (*Phyllanthus emblica*), known as Amalaki as per ayurvedic texts, most referred ingredients in classical ayurvedic formulations for hair and scalp health and is rejuvenating in nature.[25,26] As per ayurveda Amla is a tridosha samaka/ pacifier and is recommended for multiple health conditions from digestion to hair fall.[27] Amla fruits are rich in tannins, alkaloids, flavonoids, vitamin C, amino acids like lysine, aspartic acid, cystine, glutamic acid and alanine making it a potent active to justify its use in treating scalp problems.[28] Various anti-dandruff research articles support the antifungal effect of Amla extracts against *Malassezia furfur* and known for exfoliation benefit supporting the age old ayurvedic knowledge recommendation of using this ingredient in dandruff treatment.[29,30] Several clinical studies with herbal/ayurvedic formulations with Amla as an active in formulations demonstrated anti-dandruff and scalp benefits in subjects suffering from dandruff, which provides a scientific and logical justification of using Amla in anti-dandruff formulations.[31,32]

Nimba (*Azadirachta indica*), the Neem is a classic herb widely used in Indian folklore and Traditional system of medicine like Siddha and Ayurveda for various skin and scalp ailments. In Ayurveda, Neem is known to balance Pitta and Kapha doshas and used in ayurvedic proprietary formulations like Nimbadi tailam along with other potent herbs.[33,34] Neem oil and extracts of Neem were proven to have anti-fungal benefits, especially against dandruff causing yeast. Neem is widely used in various herbal and

ayurvedic products to treat skin and scalp diseases due to its anti-microbial properties.[35] Clinical studies conducted on dandruff subjects with Neem leaf paste was proven to be effective in reducing dandruff within 2 weeks.[36] Scalp leave-on treatment developed for the present study uses Neem as a key ingredient to improve the efficacy in reducing dandruff flakes.

Rosemary (*Rosmarinus officinalis*) leaf/oil is known for its fragrance and flavor and widely used in culinary delights to elevate taste of food, however commonly used in scalp care formulations. Rosemary is proven to exhibit strong anti-fungal effect against *Malassezia furfur* allowing its usage as an active in anti-dandruff formulations.[37,38] Multiple scientific evidence-based studies support the efficacy of this oil for anti-inflammatory and antioxidant properties.[39,40] Considering the above benefits, it is logical to use this oil as an active in the present leave-on treatment to enhance the performance of anti-dandruff benefit.

The study was conducted on healthy individuals with dandruff concerns and did not include participants with underlying medical or genetically induced scalp conditions.

CONCLUSION

The present anti-dandruff leave-on treatment is made with multiple ayurvedic ingredients with multiple mechanisms of actions to deliver the end benefit of long-lasting anti-dandruff efficacy. Leave-on treatment was effective in reducing dandruff flakes, improved scalp barrier, reduced sebum in 100% of the study volunteers. All the study subjects participating in the study felt the product provides benefit of dandruff and scalp dryness reduction whereas 98% of the study participants experienced reduced hair fall. 100% of the users liked Ayurvedic sensory of the leave-on treatment. There were no adverse events reported throughout the study till regression, indicating that the leave-on treatment developed with multi-prong approach is not only efficacious but also safe to use. The present clinical study concludes the anti-dandruff, sebum reduction and barrier strengthening efficacy of the leave-on treatment and is safe to use in both men and women.

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Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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