



Role of a Caffeine Shampoo in Cosmetic Management of Telogen Effluvium

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Summary

Telogen effluvium (TE) is the most common hair-loss condition, that presents with a complaint of increased shedding over normal levels and associated diffuse alopecia. No specific medical treatment exists for TE. Recently, caffeine have shown to have beneficial effects in patients suffering from hair loss. We studied, in 30 women with TE induced by stress, the skin compatibility of a shampoo containing caffeine and assessed its anti hair loss efficacy and its cosmetic qualities.

The product in study has been shown to have a very good skin compatibility and a good cosmetic efficacy in the treatment of female TE. However, further studies need to be done to confirm and establish the role of caffeine in management of TE.

Riassunto

Il telogen effluvium (TE) è la più comune condizione di perdita dei capelli, che si manifesta con un aumento del diradamento rispetto ai livelli normali ed alopecia diffusa. Non esiste alcun trattamento medico specifico per il TE. Di recente, la caffeina ha mostrato effetti benefici nei pazienti con caduta di capelli. Abbiamo studiato, in 30 donne con TE indotta da stress, la compatibilità cutanea di uno shampoo che contiene caffeina e valutato la sua efficacia contro la caduta dei capelli e le sue qualità cosmetiche. Il prodotto studiato ha dimostrato di avere una tollerabilità cutanea molto buona e una buona efficacia nel trattamento cosmetico del TE femminile. Tuttavia, sono auspicabili ulteriori studi per confermare e stabilire il ruolo della caffeina nella gestione del TE.



INTRODUCTION

Telogen effluvium (TE) is the most common hair-loss condition that presents to the dermatologist and it is seen in all races and ethnic groups. Patients present with a complaint of increased shedding over normal levels and associated diffuse alopecia. The excessive shedding is the result of alterations of the hair-growth cycle with premature conversion of anagen follicles to telogen follicles, which represents a shift of 7–25% of anagen follicles to telogen. Clinically TE has been described as having at least three different clinical scenarios. It presents as acute (<4 months), chronic (>4 months), and chronic-repetitive. In chronic TE, the anagen cycle gradually shortens and the hair fibers become thinner and shorter. In acute and repetitive TE, follicular regeneration is common. Since TE is a medical sign rather than ultimate diagnosis, it is important to explore the possible triggers. An important trigger is the TE seen with the onset of androgenetic alopecia (AGA). Other triggers include hormonal fluctuations or abnormalities, endocrine disorders, postpartum, physiological, and metabolic stress, drugs, weight loss, nutritional deficiencies, systemic acute and chronic illnesses, surgeries, and scalp inflammation.

The diagnosis of TE is based on the clinical presentation and the confirmation of excess of shedding of telogen hair. The specific time of onset is important to establish. TE can begin 2 weeks after a trigger but peaks between 6–8 weeks and then tapers off in about 6–8 weeks if the trigger is removed or treated. Regrowth is not appreciated for several months, usually 4–6 months. Frequently, patients have multiple triggers that occur concomitantly, sequentially, chronic-repetitive, or chronic. Repetitive, multiple concomitant or sequential triggers, can prolong the TE and be mistaken for chronic TE. Prolonged or repetitive TE can also lead to diminished

regrowth and a chronic diffuse alopecia. The differential diagnosis of diffuse alopecia includes AGA, diffuse alopecia areata, and an inflammatory alopecia such as central centrifugal cicatricial alopecia and lichen planopilaris, especially when the primary loss involves the central scalp. Since the diagnosis of TE is dependent on demonstrating increased telogen hair loss (greater than 7%), the pull-test allows to roughly evaluate the intensity of the hair loss. On hair unwashed since 2 days, neither brushed nor combed within the 2 hours before examination, 3 areas of the scalp (fronto-temporal, parietal and occipital) are chosen. A clump of about 50 hair per area is taken between the thumb and the fore finger and slightly pulled. A loss equal or higher than 15 on the 3 areas is considered as abnormal.

To determine the true trigger of telogen hair loss, the relationship between the trigger and the hair loss must be reproducible, with improvement of the hair shedding following correction of or removal of the trigger, and deterioration on rechallenge (1).

No specific medical treatment exists for TE, but use of antiseborrheic and antiandrogen shampoos, such as ketoconazole or pyrithione zinc; topical corticosteroids, minoxidil; nutrient/hormonal support and antiandrogens have been invoked. Caffeine is a methylxanthine, a well-known substance, but its effect on human hair follicle growth is not yet defined. Recently, certain newer advances have shown caffeine to have beneficial effects in patients suffering from AGA (2,3,4,5). We studied, in a panel of healthy women with TE induced by stress, the skin compatibility of a shampoo containing caffeine¹ and assessed its anti hair loss efficacy and its cosmetic qualities, after application under the normal conditions of use.

MATERIALS AND METHODS

The study has been performed in 30 female sub-

¹ TRADEMARK: PLANTUR21 NUTRI CAFFEINE SHAMPOO.

jects. The mean age was 31. The informed consent form was personal and previous to the start of the study.

Inclusion criteria were: age from 18 to 40, female, phototype (Fitzpatrick) from I to IV, copious hair loss started in the past 2 months, presence of TE induced by stress, absence of clinical signs of AGA or other forms of alopecia, no significant skin disease located on scalp, able to compromise the evaluation of skin tolerance of the investigational product or being possibly aggravated by the application of the investigational product (dermographism, recurrent herpes, pityriasis versicolor, psoriasis, important pigmentary disorders), UV light induced dermatitis, urticaria, no history of organ removal (kidney, lung, spleen, axillary lymph node) or organ transplant, no current treatment able to interfere with the interpretation of the study results (immunosuppressive drugs, anti-inflammatory products, antihistamine products, antibiotics).

Exclusion criteria were: different causes of alopecia [AGA, alopecia areata, trichotillomania, hair loss due to medication (immunologics, chemo-therapy, etc.)], unhealthy condition of the scalp (highly expressed eczema, high grade of dandruff), regular use of hair dye, bleaching products or products for permanent wave, present or past history of hypo/hyperthyroidism or iron deficiency (at the present or in the past), known allergies to the same type of products as the investigational products (cosmetic hygiene and care products) or other products (drugs, food), personal history of atopy, treatment, prior to the study, able to interfere with the interpretation of the study results (topical or systemic medication with anti-inflammatory or antihistamine products within the 6 months, antibiotics within the 4 weeks, medication for malignancy).

Investigational products was a hair hygiene product containing caffeine.

The constraints for the test subjects during the study were no application of any other hair pro-

ducts than the tested one, no intensive sun or UVA exposure (UV lamps), no colouring, hair bleaching, permanent wave during the study, no additional vitamin supply (vitamins B or H) or products which could have an effect on hair, no hair loss treatment by oral route, no medical treatments likely to induce an alopecia (antimitotics, anticoagulants, antithyroid, antidepressive agents, anticonvulsants, beta-blockers, hypocholesterolemic drugs, retinoids), no application of hair lacquer or gel, no violent brushing and repeated massage of the scalp, no change of diet. The shampoo has been applied at home by the test subjects, once day for 6 months, on wet hair. The product has been left in contact with the scalp for 2 minutes, massaged with the fingers into the scalp and rinsed off accurately.

Checking of the skin compatibility (local tolerance) based on: skin examination of the scalp, at baseline, after 3 and 6 consecutive months of treatment, by the investigator; the analysis of the sensations of discomfort reported directly by the test subjects to the investigator, during the study or in the daily logs.

Assessment of the cosmetic qualities and efficacy based on: pull-test performed at baseline, after 3 and 6 consecutive months of treatment, to evaluate the resistance of the hairs to traction; proband and dermatological questionnaire after 3 and 6 consecutive months of treatment.

Statistics

For the data of the pull test and the questionnaire information, descriptive statistical indicators (mean, standard deviation, 25%, 50% [median] and 75% percentiles as well as frequencies and percentages (where applicable) have been calculated.

In order to check whether the number of the hairs pulled (Pull test) changed after application of the investigational product, the exact, non-parametric Wilcoxon signed-ranks test has been conducted.



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The questionnaire data have been also evaluated using the Wilcoxon test. One-tailed and two-tailed p-values has been reported, and the exact, two-tailed p-values have been used in each case.

RESULTS

After 3 and 6 consecutive months of product use at home, no intolerance reaction has been noted by the investigator and no sensation of discomfort has been described by the volunteers.

After 6 months of application of the shampoo, the number of hairs pulled was slightly, but significantly lower compared to the baseline [19.2 ± 3.9 vs. 21.2 ± 3.3 ; $p=0.003$, two-sided, exact Wilcoxon test], while after 3 months of application, the number of hairs pulled was only marginally lower (20.3 ± 3.6 vs. 21.2 ± 3.3 ; $p=0.095$, two-sided, exact Wilcoxon test).

In 17 (56.7%) subjects a decrease of hairs pulled has been observed after 3 months as well as after 6 months of application of the shampoo, whereas in 11 (36.6%) subjects and 8 (26.6%) the number of hairs pulled increased after 3 months and 6 months, respectively (Tables I, II).

The results of the pull tests are shown in Figure 1.

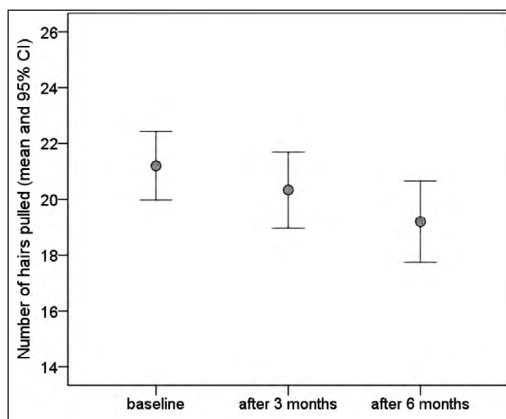


Fig. 1 Number of hairs pulled (pull test) at baseline, after 3 and after 6 months of application of Plantur21 Nutri Caffeine Shampoo (means and their 95% confidence intervals are shown).

The efficacy of investigational product has been assessed by the test subjects using the proband questionnaire at baseline, after 3 and 6 months of product application.

The following efficacy variables have been evaluated: intensity of hair loss, decrease or normalization of hair loss, number of hairs during daily combing, strength and thickness of hair.

After 6 months, as well as after 3 months, the intensity of hair loss significantly improved, compared to the baseline ($p<0.001$). Furthermore after 6 months, the majority of the test subjects agreed that their hair loss decreased or normalized.

After 3 months and 6 months of product application, the number of hairs during daily combing significantly decreased, compared to the baseline ($p<0.001$) and the strength of the hair significantly improved compared to the baseline ($p=0.031$ and $p<0.001$). Especially after 6 months of application, the contentment of the test subjects with the investigational product was high. The majority of the test subjects would like to continue with the shampoo and recommended it.

The scalp conditions have been assessed by the test subjects, evaluating itching and tension/dryness at baseline, after 3 and 6 months of product application.

After 3 and 6 months itching was slightly, but did not significantly improved, compared to the baseline ($p=0.312$ and $p=0.188$), while after 6 months tension/dryness improved compared to the baseline; this was not the case after 3 months ($p=0.016$ and $p=0.250$).

The efficacy of the investigational product has been assessed by the investigator using the dermatological questionnaire at baseline, after 3 and 6 months of product application. The following efficacy variables have been evaluated: strength of the hair, extent of the out falling hairs, progression of the thinning hair.

After 6 months, the strength of the hair significantly improved, compared to the baseline; this



was not the case after 3 months of application ($p=0.002$ and $p=0.50$). Similar results have been documented as regards the extent of out falling hairs ($p<0.001$ and $p=0.125$) and the progression of balding ($p=0.001$ and $p=0.100$), significantly decreased after 6 months, but not after 3 months of application.

After 6 months of product application, a reduction of balding/premature hair loss, an improved structure of hair or improved scalp conditions have been observed in the majority of the test subjects.

For the majority of the test subjects the shampoo has been recommended as a daily treatment of

hereditary hair loss to reduce the number of out falling hairs.

The scalp conditions have been assessed by the investigator, evaluating redness and scaling/dandruff at baseline, after 3 and 6 months of product application. Redness was absent in the vast majority of the test subjects. Therefore, after 3 and 6 months of product application, redness did not significantly improved compared to the baseline ($p=1.00$ and $p=0.50$). Instead, after 6 months of product application, scaling / dandruff significantly improved, compared to the baseline; this was not the same after 3 months ($p=0.016$ and $p=0.250$).

TABLE I*Number of hairs pulled - Descriptive statistics*

Number of hairs pulled (pull test)	N	Mean	Standard deviation	Min.	Max.	Percentiles		
						25th	50th (Median)	75th
at baseline	30	21,20	3,295	15	28	18,75	21,00	23,25
after 3 months of treatment	30	20,33	3,642	13	29	17,00	20,00	22,25
after 6 months of treatment	30	19,20	3,890	12	29	16,75	18,50	22,00

TABLE II*Number of hairs pulled - Results of exact Wilcoxon test*

Test Statistics ^b		
	3 months vs. baseline	6 months vs. baseline
Z	-1,674 ^a	-2,863 ^a
Asymp. Sig. (2-tailed)	,094	,004
Exact Sig. (2-tailed)	,095	,003
Exact Sig. (1-tailed)	,048	,002



DISCUSSION

The most common type of diffuse shedding is TE, in which anagen-phase hair follicles prematurely transition to the telogen phase, resulting in a noticeable increase in hair shedding at the end of the telogen phase 2 to 3 months later.

TE mainly affects women. Primary or idiopathic chronic TE almost exclusively involves women between 30 and 50 years of age (6). Hair loss, as it occurs with TE, provokes anxieties and distress more profound than its objective severity would appear to justify. This reflects the profound symbolic and psychosocial importance of hair. Stress has long been implicated as one of the causal factors involved in hair loss (7).

No specific pharmacological intervention is currently available to manage stress-induced hair loss.

The beneficial effects of topical application of caffeine in hair loss can be attributed to inhibition of phosphodiesterase, improvement in barrier function, follicular penetration, stimulation and promotion of hair growth (8). Thus it appears to be a useful adjuvant in the management of TE.

According to the experimental conditions adopted in this study, the shampoo in study has been shown to have a very good skin compatibility, after application under normal conditions of use. Moreover, the product has been shown to have a good cosmetic efficacy in the treatment of female TE. Precisely, the pull-test results documented an increase of the resistance to the traction strain of the hair and a decrease of hair loss in 56,7% of the volunteers after 3 as well as after 6 months of treatment.

Also the Investigator confirmed the good cosmetic efficacy of the product, noting a significantly improvement in the strength of the hair, a significantly decrease in the extent of the out falling hairs and in the progression of the balding.

After 6 months of treatment 66,7% of the volun-

teers have been satisfied with the product. Particularly, they referred a significantly improvement in the intensity of the hair loss, a significantly decrease in the number of hairs during daily combing and a significantly improvement of the strength of the hair.

Moreover, 66,7% of the volunteers agreed that their hair loss decreased or normalized with the treatment.

In other respects, the product was also well appreciated for its cosmetic qualities.

However, further studies need to be done to confirm and establish the role of caffeine in management of TE.



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