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Effectiveness of Dhathri Hair Care and herbal oil against alopecia and seborrheic dermatitis – a clinical study

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A – Research concept and design, B – Collection and/or assembly of data, C – Data analysis and interpretation, D – Writing the article, E – Critical revision of the article, F – Final approval of the article

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Abstract

Introduction. Treating alopecia with ayurvedic medicated oils have gained importance due to the safety and efficacy of their use. Dhathri Hair Care Plus herbal oil is an ayurvedic proprietary medicine formulated as oil with herbal extracts aimed at reducing alopecia (hair loss), premature greying of the hair and seborrheic dermatitis of the scalp (dandruff). It stimulates the growth of hair, provides a cooling effect to mind and body. The herbal oil contains herbal extracts prepared and concocted using the traditional healing effect of ayurveda.

Objective. The aim of this clinical study was to evaluate the effectiveness, safety and tolerability of Dhathri Hair Care Plus herbal oil in comparison with coconut oil in the management of alopecia, premature greying of hair and seborrheic dermatitis of the scalp in adults.

Materials and method. 36 healthy respondents were enrolled and completed the period of study positively. The 60 Second Hair Comb Test, Adherent Scalp Flaking Score, Gray Hair Shade Card Assessment, Objective Hair Assessment Questionnaire, Subjective Hair Assessment Questionnaire and Subject IP Feedback Questionnaire were used in the study.

Conclusions. Dhathri Hair Care plus herbal oil was effective in reducing hair loss, treating Seborrheic dermatitis and mildly delaying the premature greying of hair, compared with coconut oil as the standard.

Key words

alopecia, dandruff, Hair Comb Test, Adherent Scalp Flaking Score, hair loss

INTRODUCTION

Hair loss, dandruff and the greying of hair have become common problems today, and finding a suitable treatment has led to an increase in the use of herbal remedies which can cure these ailments since hair plays an important role in the general appearance and concern for social connections. Alopecia is the medical term for hair loss, a health condition in which hair is lost from the scalp or other areas of the body. Hair loss can be due to different reasons, such as environmental triggers, genetic tendencies, extreme stress or long illness, exposure to chemicals, medicines, nutritional deficiency, etc. Alopecia has been classified into many forms based on the hair loss pattern and causes such as Androgenetic alopecia and *Alopecia areata* [1].

Androgenetic alopecia (AGA) is the most common form of hair loss affecting women, characterized by genetic and microbiological conditions [2]. AGA commonly affects about 2% of the population, and lifestyle modifications play a prominent role in its higher prevalence in males (50%) over forty years of age than in females [3]. *Alopecia areata* is a type of autoimmune skin disease resulting in the loss of hair from the scalp and elsewhere on the body. It usually

starts with one or more small, round, smooth patches on the scalp and can progress to total scalp hair loss (*alopecia totalis*) or complete body hair loss (*alopecia universalis*). Alopecia universalis is the rarest form of *Alopecia areata* [1]. The Food and Drug Administration (FDA) has approved some synthetic drugs, but their side-effects reasonably restrict their usage. Seborrheic dermatitis and dandruff are very common infections of the scalp caused by yeasts i.e. *Malassezia furfur*, which cause erythema leading to scaling which causes itching. Presently, antifungal agents are used to treat this condition of the scalp, but very few studies have investigated herbal-based oil for the treatment of dandruff [4]. Hence, the scientific community is searching among plant-based formulations with negligible side-effects to replace synthetic formulas [5]. India is the source of a variety of medicinal plants which traditionally are used for healthcare and in cosmetic preparations.

OBJECTIVE

The aim of this randomized, open-label, two arm prospective and parallel-group study was to evaluate the effectiveness, safety and tolerability of Dhathri Hair Care Plus herbal oil in comparison with coconut oil in the management of alopecia, premature greying of hair, and seborrheic dermatitis of the scalp in adults.

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Dhathri Hair Care plus herbal oil is an Ayurvedic proprietary medicine formulated with 21 ingredients as oil with herbal extracts used for hair growth and treating hair-related problems. The ingredients of the hair oil are: *Indigofera tinctoria*, *Eclipta alba*, *Aloe barbadensis*, *Bacopa monnieri*, *Hibiscus rosa-sinensis*, *Bergera koenigii*, *Saccharum officinarum*, *Datura metel*, *Cardiospermum halicacabum*, *Hemidesmus indicus*, *Emblica officinalis*, *Terminalia bellerica*, *Terminalia chebula*, *Rubia cordifolia*, *Cyperus rotundus*, *Nardostachys jatamansi*, *Glycyrrhiza glabra*, *Cinnamomum camphora*, *Cocos nucifera*, milk and Puranakittam [6]. Some of the plants are listed in Table 1. Commercially available coconut oil was used as a control in the study.

Table 1. Properties of some ingredients of Dhathri Hair Care plus herbal oil

S. No.	Common name	Botanical name	Major properties
1	Aloe vera	<i>Aloe barbadensis</i>	Hair growth stimulator and anti-dandruff action
2	Amla	<i>Emblica officinalis</i>	Darkens hair, anti-dandruff activity, and hair growth stimulator
3	Coconut oil	<i>Cocos nucifera</i>	Hair growth stimulator
4	Brahmi	<i>Bacopa monnieri</i>	Treats scalp problems

Inclusion criteria:

- 1) respondents aged between 21 – 45 years;
- 2) respondents who willing to give written informed consent and ready to comply with the protocol;
- 3) respondents with active alopecia, premature greying of hair (grey hair shade card assessment $\geq 50\%$), and seborrheic dermatitis of the scalp (total ASFS score ≥ 16);
- 4) respondents with a minimum hair length of 2 inches and willing to maintain the same minimum length and hairstyle until the end of the study.

Exclusion criteria:

- 1) respondents on topical treatment for alopecia, premature greying of the hair, and seborrheic dermatitis for 8 weeks prior to the enrollment;
- 2) respondents with other dermatological disorders of the scalp that might interfere with evaluation of the study;
- 3) respondents with significant scalp scarring;
- 4) respondents with anaemia (iron deficiency);
- 5) respondents who have previously undergone hair transplantation procedures;
- 6) history of systemic and cutaneous malignancy or evidence of an immunocompromised state;
- 7) respondents with a history of skin allergy;
- 8) respondents on systemic steroids for more than 14 days, within 2 months prior to enrollment;
- 9) female respondents who are pregnant/planning a pregnancy or lactating;
- 10) respondents enrolled in an active investigational study for 30 days prior to enrollment;
- 11) respondents who in the opinion of the investigator or the expert dermatologist are not eligible for enrollment in the study

MATERIALS AND METHOD

The clinical trial was planned, initiated, and conducted in compliance with Good Clinical Practice (GCP). Prior to conduction, the study was reviewed and approved by the Universal Ethics Committee and registered with the Clinical Trial Registry of India (CTRI) (CTRI No. /2013/04/003593). The clinical study was conducted at Raam Polyclinic, Chennai, Tamilnadu in India. A total of 36 participants were screened by a dermatologist for the presence of active hair loss, premature greying, and dandruff levels, and enrolled in the study. Table 2 and Figure 1 outline the demographic characteristics of the participants. The participants were randomized in a 2:1 ratio into 2 arms: treatment arm – Dhathri Hair Care Plus Herbal and comparator arm – coconut oil.

Table 1. Demographic characteristics of participants

Characteristic	Value
Men (n, %)	19 (52.78%)
Women (n, %)	17 (47.22%)
Age range (years)	21–45

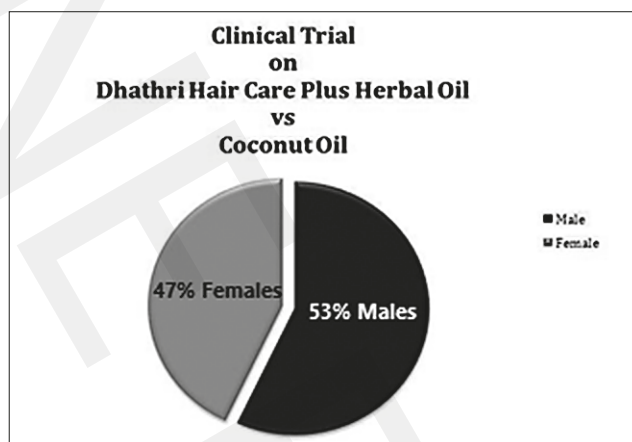


Figure 1. Demographic characteristics of respondents

60-Second Hair Comb Test. To assess the level of hair loss in the participants, the 60 Second Hair Comb Test was adopted from Bhat and Sheikh [7]. The respondents were asked to comb their hair for 60 seconds over a white paper before and after applying the oil. The direction of combing was starting with the comb at the rear of the scalp and moving the comb forward to the front of the scalp. The procedure was repeated 3 times, the hair counted, and the average recorded. The experiment was performed every other day for up to 6 weeks under the supervision of the dermatologist.

Adherent Scalp Flaking Score (ASFS). A validated and published assessment was performed to check for adherent dandruff levels on the scalp of each participant. The adherent scalp flaking score (ASFS) was evaluated by adopting an earlier method [7, 8]. The subject's scalp was divided into 8 zones which were assessed for dandruff flakes (Tab. 3) on a score of 0–10 (0 = no flakes, 10 = heavy flaking). The sum of 8 zones represents the final values. Loose flakes in the hair were not considered in the grading (0–80). For representation purposes, the subject score was categorized as 1 = Mild (16–24), 2 = Moderate (25–34), and 3 = Severe (35–80).

Table 2. Scoring system for Adherent Scalp Flaking Score

Grade	Standard Established
0	No scales
1	Thin scales
2	Diffused thin scales
3	Thick, heaped-up scales, but not forming plaques
4	Diffused, thick heaped-up scales, but not forming plaques
5	Very thick heaped-up scales forming plaques

The parameters mentioned below were assessed for daily application of 7 ml of Dhathri Hair Care Plus herbal oil and 7 ml of coconut oil for 6 weeks.

Grey Hair Shade Card Assessment. An assessment used by the medical expert dermatologist to check for differences in the premature greying of the participants' hair.

Objective Hair Assessment Questionnaire. An assessment performed by the medical expert dermatologist to assess hair loss, dandruff levels, roughness, and general appearance of the participant's hair, and compile the scores.

Subjective Hair Assessment Questionnaire. Each participant was asked to assess his/her own hair for hair loss and dandruff levels. This was a structured and scientific version of customer feedback on the effect of the product.

Subject IP Feedback Questionnaire. Each participant was asked their opinion about the investigated product as a below scientific version of a consumer survey on the satisfaction with the product and usage compliance.

Data analysis. Data were analyzed statistically. Student's T-test was performed for the difference between the 2 groups. The Quality of Hair Questionnaire was performed using the ANOVA Kruskal Wallis test. The data of hair loss monitoring, 60-second Hair Comb Test, Adherent Scalp Flaking Score, Grey Hair Shade Card Assessment, Dermatologist Assessment, and Participant Assessment, was analyzed using Chi square test as they represent variables.

RESULTS AND DISCUSSION

Results show that Dhathri Hair Care plus herbal oil reduced hair loss in the treatment of seborrheic dermatitis, and mildly delayed the premature greying of hair in the participants when compared with coconut oil as the standard. A total of 36 respondents were enrolled who completed the period of study positively. Results showed that the respondents obtained benefits from the treatment. The effect of Dhathri Hair Care plus herbal oil on the vital signs of the respondents was checked during every visit. There were no significant differences in their body temperature, blood pressure, pulse rate, and breathing rate. The results confirmed the safety of using this test.

Results of the clinical trial conducted on 36 participants (24 who used Dhathri Hair Care Plus herbal oil and 12 who used coconut oil for comparison) showed that the dandruff levels were reduced from 'Severe' to 'Minimal' and 'Nil' for all respondents who used Dhathri Hair Care plus herbal oil daily

for 6 weeks. All participants who used Dhathri Hair Care plus herbal oil reported that they were extremely satisfied with the product after daily usage for 6 weeks.

60-Second Hair Comb Test. The clinical trial was designed to expect a 50% reduction in shedding range (hair loss) in participants using Dhathri Hair Care Plus herbal oil, compared to coconut oil. The results of the clinical trial showed that 45.45% of participants had 50% less hair loss in just 3 weeks. 100% of the participants showed 50% less hair loss when they used Dhathri Hair Care plus herbal oil daily for a period of 6 weeks. None of the coconut oil group showed a reduction in hair loss. Dhathri Hair Care plus herbal oil helped in the reduction of hair loss after daily use for 6 weeks (Chi-square = 32; $p < 0.0001$). The obtained results were in line with reports of Anjum et al. (2013), who studies the effect of formulated herbal oil.

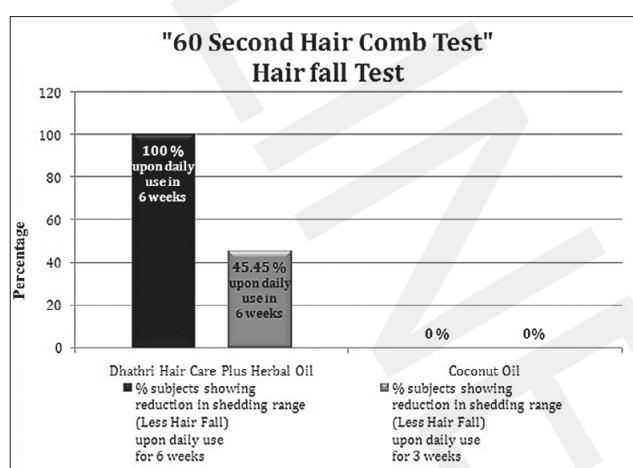


Figure 2. Result showing the 60 Second Hair Comb Test used in the study

Adherent Scalp Flaking Score (ASFS). The ASFS is a scale that shows dandruff levels from 0–80 (Fig. 5). For the purposes of the study the scalp is divided into 8 sections and the dandruff for each section graded separately. An efficacy showing a reduction of 10 scores from the first visit or a total score of 0 was anticipated. Within 3 weeks of using Dhathri Hair Care plus herbal oil daily, 86.36% of participants showed a reduction of 10 scores in ASFS. In 6 weeks of daily usage of Dhathri Hair Care plus herbal oil (Fig. 6), 100% of participants showed significantly less severity in flaking-dandruff of the scalp (Chi-square = 32; $p < 0.0001$). There was an 'Excellent Improvement' in the reduction of flaking severity and less dandruff in participants who used Dhathri Hair Care plus herbal oil daily for 6 weeks, as assessed by the dermatologist according to the Adherent Scalp Flaking Score method.

Grey Hair Shade Card Assessment. The shade card was used to assess the percentage of premature greying of the participant's hair (Fig. 7). 42.86% of participants who used Dhathri Hair Care plus herbal oil every day showed a 20% decrease in premature greying of their hair in 6 weeks. The same was observed by 4.76% of participants in just 3 weeks. None of the participants who used coconut oil showed this effect (Fig. 8). There was a 'Moderate Improvement' in the reduction of premature greying of hair in participants who used Dhathri Hair Care plus herbal oil.

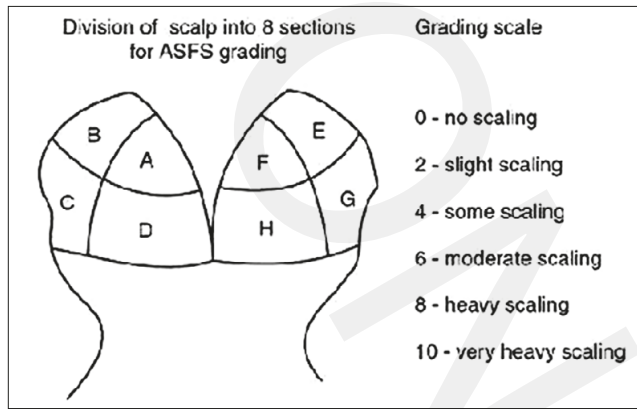


Figure 3. ASFS Scoring criteria used in the study

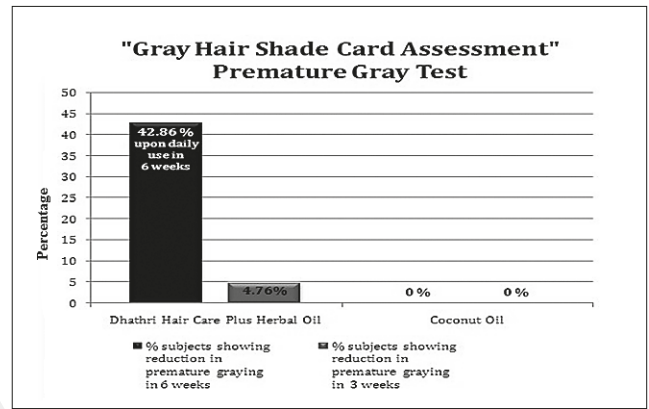


Figure 6. Dermatologist assessment of Grey Hair Shade Card Assessment of participants using Dhathri Herbal Hair care plus herbal oil and coconut oil

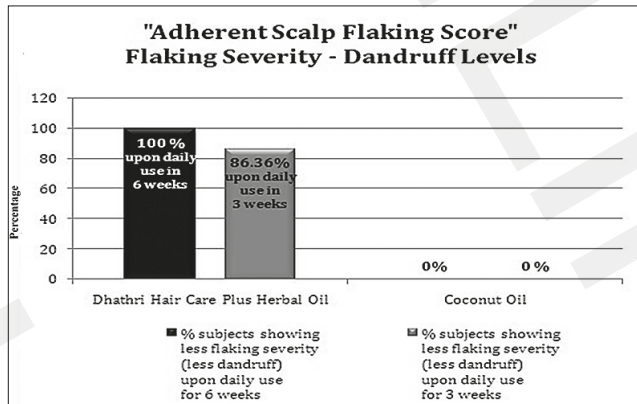


Figure 4. Effect of Dhathri Herbal Hair Care plus herbal oil and coconut oil on ASFS scoring function on anti-dandruff activity

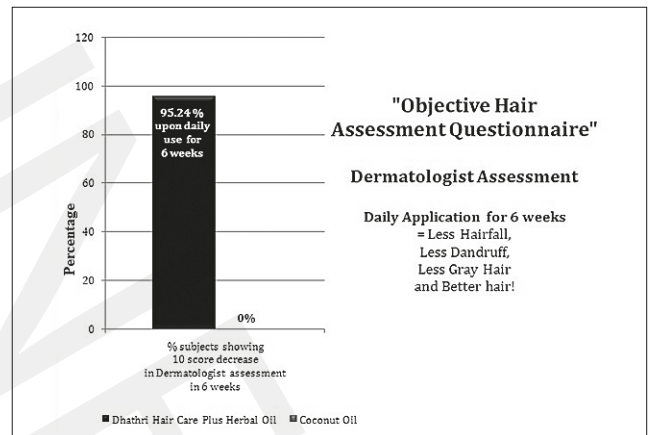


Figure 7. Dermatologist's Assessment of hair loss, premature greying, dandruff, hair texture, and overall appearance of the hair

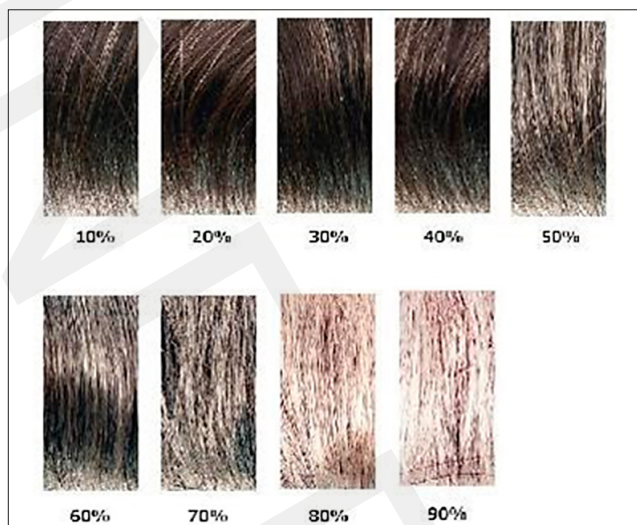


Figure 5. Grey Hair Shade Card Assessment chart used in the study

A medical expert dermatologist assessed and compiled the scores. A decrease in the 10 scores was expected. According to the dermatologist, 95.24% of the participants who used Dhathri Hair Care plus herbal oil showed a 'Remarkable Improvement' in the reduction of hair loss, better dandruff levels, darkening of premature greying, and improved overall appearance of the hair after daily use for 6 weeks. None of participants using coconut oil showed the same result (Chi-square = 27.9365; $p < 0.00001$).

Participant Assessment: hair loss, premature greying, dandruff, hair texture, and overall appearance of the hair.
 In the participant's assessment of their hair loss, premature greying, dandruff, and texture of their hair, a decrease of 5 scores was expected. 62.50% of the participants who used Dhathri Hair Care plus herbal oil felt a 'Remarkable Improvement' – their hair was better in texture and appearance, with reduced hair loss, premature greying and dandruff levels after using for 6 weeks. Participants were also more satisfied with Dhathri Hair Care plus herbal oil than with coconut oil (Chi-square = 23.7483; $p < 0.0001$).

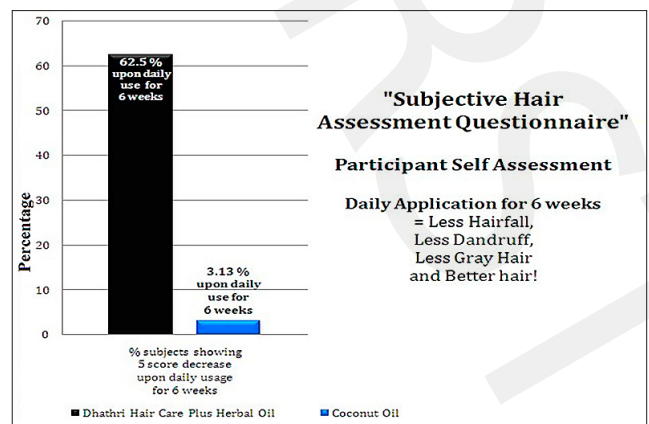


Figure 8. Participant's assessment of hair loss, premature greying, dandruff, hair texture, and overall appearance of the hair

Participant Assessment: opinion and satisfaction with investigated products. A score of 12 was decided as the cut-off for this assessment. Statistical analysis shows that there was a significant difference in the scores between the 2 treatment groups. Participants were much more satisfied with Dhathri Hair Care plus herbal oil than coconut oil (Chi-square = 32; $p < 0.0001$).

CONCLUSION

It is authenticated that as an Ayurvedic Proprietary Medicine, Dhathri Hair Care plus herbal oil contains herbal extracts which are deemed to be effective in the management of alopecia (hair loss) and seborrheic dermatitis, reducing the level of dandruff on the scalp, moderately effective against premature greying of the hair and stimulates new hair growth. This was assessed clinically and verified statistically. Dhathri Hair Care plus herbal oil is clinically safe for every day use. The overall appearance of the hair improved from 'Poor' and 'Fair' to 'Very Good' and 'Excellent' after daily application for 6 weeks. All participants who used Dhathri Hair Care plus herbal oil reported they were 'Extremely Satisfied' with the product after daily usage for 6 weeks.

Conflict of Interest. The authors declare that there is no conflict of interest

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