



**Research Article**

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## Effectiveness, safety and tolerability of dheedhi herbal shampoo against alopecia and seborrheic dermatitis - a clinical perspective

Sahadevan Sajikumar<sup>1</sup>, Appukkuttan Rajeshkumar<sup>1</sup>, Meenakshi Sundaram<sup>2</sup>, K MS Ramasamy\*<sup>2</sup>

<sup>1</sup> Dhathri Ayurveda Pvt. Ltd., Adappilly Road, Vennala, Ernakulam, Kerala, India

<sup>2</sup> Sanjeev Biomedical Research Centre, 1/15, Kumaran St, Keelkattalai, Chennai – 117, Tamil Nadu, India

### ABSTRACT

Dandruff affects more than half of the population irrespective of age and gender. The traditional based proprietary formulation, Dheedhi Hair Care herbal shampoo contained six plants that are used in Ayurveda for many years against the hair loss and its associated symptoms. Here, we investigated its hair growth potential on patients with Alopecia (hair fall) and Seborrheic Dermatitis (CTRI /2013/05/003622) for six week period. Totally 36 subjects (female, 52.78% and males, 42.22%) were enrolled and randomized in a 2: 1 ratio arm for test product and a positive control. The subjects were analyzed based on 60 Second Hair Comb Test, Adherent Scalp Flaking Score (ASFS) and questionnaires on hair fall, dandruff levels, roughness and general appearance of the participant's hair and scored the same with a IP feedback. Dheedhi Hair Care Herbal Shampoo herbal shampoo helped to maintain softness, coldness and glossy hair and reduced the hair fall. It showed 90.5% reduced hair fall against a regular shampoo (28.27%). Further, it eliminated the dandruff efficiently (90.48%) compared with positive control (52.38%). Dermatologist assessment score for Dheethi hair shampoo was 76.19 against regular shampoo. The results further showed that it had protected the skin from eruptions and itching. The product was rated positively by 100% of participants for texture, smell, and hair condition. Additionally, these results also no adverse events on Dheethi hair shampoo. These results had proved that Dheedhi Hair Care herbal shampoo is excellent natural source for anti-dandruff and anti-hair fall activity without any side effects.

**Keywords:** Alopecia, Seborrheic dermatitis, Herbal shampoo.

### INTRODUCTION

Hairs play a vital role in individual's general appearance and become as an essential criteria for social estimations. In contrast, Androgenetic alopecia (AGA) is the most common form of hair loss and creates psychological impacts on one's daily socio economic and cosmetically [1]. Physiologically, AGA is a dermatological disorder characterized by genetical and microbiological reasons. AGA commonly affects about 2% of the population and life style modifications play a prominent role on its higher prevalence in males (50%) over forty years than females [2]. AGA also could be the side effects of anticancer drugs, immunosuppressants and many other drug treatments. Enhancing the blood vessel formation and their circulation, providing the androgens antagonists, regulating potassium channels and inhibiting 5-alpha reductase are most popular methods for treating AGA [3]. FDA also approved few of the synthetic drugs but, their side effects reasonably restricting their usages. Hence, the scientific community search the plant based formulations to replace the synthetic ones with negligible side effects [4]. India has been deposited with a variety of medicinal plants and traditionally, many of them are used for healthcare and cosmetic preparations.

*Aloe barbadensis* is one of the plants used predominately for its cosmetic enhancement particularly, as hair growth supplement. Its gel is used traditionally against alopecia for hair growth improvement. Many compounds such as barbaloin (15-40%), hydroxaloin (3%), mucilage (Glucose, Galactose, Mannose, Galacturonic acid), aloe-emodin, aloesone, aloenin, alocutin A and B may enhance hair growth without scalp irritations [5-7]. Tulsi or Tulasi or Vaishnavi (*Ocimum sanctum*) or holy basil is a sacred plant of India. The plant is believed to be with divine potential and it has been proved to be a booster for human health in Indian systems of Alternative Medicines against ardiopathy, hemopathy, leukoderma, asthma, bronchitis, catarrhal fever, otalgia, hepatopathy, vomiting, lumbago, hiccups, ophthalmia, gastropathy, genitourinary, disorders, ringworm, verminosis and skin diseases [8]. Rathi *et al.* reported that the polyherbal preparation based on tulsi had showed hair growth properties *in vivo*. Their study revealed that the extracts showed complete hair growth in shaved mice skin on 19<sup>th</sup> day compared to minoxidil, showed on 20<sup>th</sup> day. They also added that *O.sanctum* did not produce any irritations on the studied animals during

\*Corresponding author:

**K MS Ramasamy**

Sanjeev Biomedical Research  
Centre, 1/15, Kumaran St,  
Keelkattalai, Chennai – 117, Tamil  
Nadu, India

Email: sanjeevbiomed02@gmail.com

the experimental tenure [9]. Herman *et al.* also reviewed the hair growth activity of the essential compounds present in *O. santum* extract [10]. *Emblica officinalis* is another well known herb with richer content of tannins, flavonoids, saponins, terpenoids, ascorbic acids and many other compounds with numerous pharmacological activities including antimicrobial, antioxidant, anti-inflammatory, radio-protective, hepatoprotective, antitissuive, immunomodulatory, hypolipidemic and many other [11]. It is used in ayurveda as a health booster. Many studies showed its hair growth properties along with anti-dandruff activity. *Bacopa monnieri* is used for scalp problems in ayurvedic medicines. It is also used for central neurological consequences [12]. The texture and healthier appearance of skin and hair are always maintained by *Acacia concinna* due to its medicinal valuable compounds. It is used in traditional hair shampoos by a number preparations [13]. Coconut oil, (*Coccus nucifera*) is used as hair growth supplement because of its enriched minerals and bioactive substances [14-17].

The aim of this open-label study was to evaluate the safety, tolerability and efficacy of the Dheedhi Hair Care Herbal Shampoo in Comparison with Regular Shampoo in the Management of Alopecia and Seborrheic Dermatitis of the Scalp in Adults in subjects during and following a treatment period of six weeks

## METHODOLOGY

Totally 36 subjects (female, 52.78% and males, 42.22%) between the ages of 21-45, were recruited for the study. They had been randomised in a 2: 1 ratio arm for test product and a positive control and all 36 subjects completed the study. Table 1 outlines the demographic characteristics of the participants. The clinical study was conducted at Raam Poly Clinic, Chennai, Tamilnadu. All subjects signed an informed consent form and a photographic release form. Institutional review board approval was obtained for this study (CTRI /2013/05/003622).

**Table 1:** Subject demographic characteristics

Characteristic	Value
Men (n, %)	19 (52.78)
Women (n, %)	15 (42.22%)
Age range (years)	21-45
Seborrheic dermatitis (n, %)	31 (86%)
Dandruff (n, %)	27 (75%)

The test product was Dheedhi Hair Care Herbal Shampoo (Table 2). It is an Ayurvedic Proprietary Medicine formulated as shampoo with herbal extracts aimed at reducing Alopecia (hair fall) and Seborrheic Dermatitis of the scalp (dandruff of the scalp). Commercially available regular hair oil was used as control against the test product.

## 60 Second Hair Comb Test

60 Second Hair Comb Test was adopted from Bhat and Sheikh [18]. The subjects were asked to comb their hair before and after shampooing over a white paper. The direction of combing was starting with the comb at the back top of the scalp and moving the comb forward to the front of the scalp. The procedure was repeated for three times and the hair was counted and average was recorded. The experiment was done on every other day up to 6 weeks by the supervision of the dermatologist.

**Table 2:** Plants used to prepare herbal extracts of the proprietary formulation

S. No.	Common name	Botanical Name	Ayurvedic Name	Major Properties
1	Aloe vera	<i>Aloe barbadensis</i>	Ghritkumari	Hair growth stimulator, Antidandruff
2	Thulasi	<i>Ocimum sanctum</i>	Tulsi	Anti fungal agent
3	Amla	<i>Emblica officinalis</i>	Amla	anti-oxidant, hair growth stimulator, darkens hair and Anti dandruff agent
4	Brahmi	<i>Bacopa monnieri</i>	bacopa	Remedy for scalp problems
5	Cheeyakayi	<i>Acacia concinna</i>	Shikakai	Good cleanser and a conditioner
6	Coconut Oil	<i>Coccus nucifera</i>	Nalikerā	Hair growth and adds shine

## Adherent Scalp Flaking Score (ASFS)

The adherent scalp flaking score (ASFS) was evaluated by adopting previous method [19-20]. The subject's scalp was divided in to eight zones and they were assessed for dandruff flakes (Table 3) by means of scoring 0-10 scale (0 means no flakes and 10 mean heavy flaking). The sum of eight 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 3:** 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

## Data processing and analysis

Data was analysed by both methods such as subjected to both per protocol (PP) analysis and intention to treat (ITT) and results were found to be comparable. Tests of significance for difference between the two groups were performed using Student's t-test. The quality of life questionnaire was performed using ANOVA Kruskal Wallis test. Further, the data for monitoring hair fall, antifungal activity and hair softness was analyzed using Chi square test as they represented categorical variables.

## RESULTS AND DISCUSSION

The present study aimed to evaluate the efficacy and tolerability of the dheethi hair oil compared with the commercially available regular hair oil in subjects with alopecia and dandruff. The results demonstrated that the dheethi hair oil showed that it has the ability to maintain soft and glossy hair, reduced hairfall with cooling effects and eliminated dandruff, skin from eruptions and itching compared with positive control in the studied subjects.

Totally, 36 subjects were enrolled in the study and completed the tenure without any fail. The study consisted of 52.78% females and 42.22% males (Figure 1) and the results showed most of the subjects were benefited out of the test treatment than the positive control (Figure. 2). Their vital signs were checked during every visits and the results showed that the dheethi hair oil maintain the vital signs and there is no much differences in blood pressure, body temperature, pulse rate and breathing rate in studied subjects and concordant with the previous report [21]. These results confirmed that the test product had no effects on the physiological signs compared with the positive control during the study period

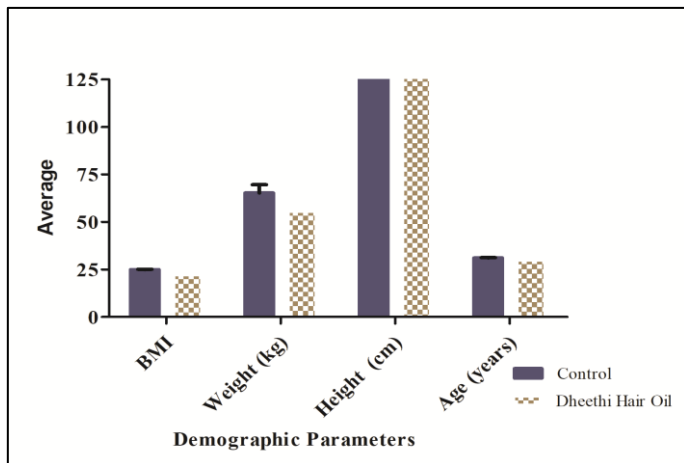


Figure 1: Demographic parameters of the study subjects that satisfy the inclusion criteria

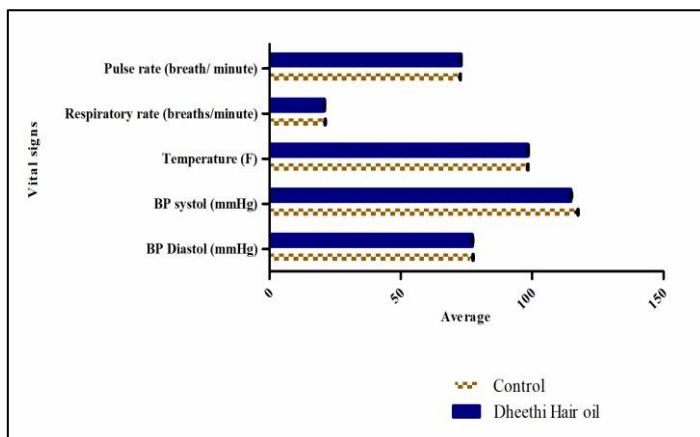


Figure 2: Vital signs in the subjects during study period

The clinical trial was designed to expect 50% reduction in shedding range (hairfall) in 6 weeks in subjects using Dheedhi Hair Care Herbal Shampoo vs Regular Shampoo in 60 Second Hair Comb Test. The results of the clinical trial showed that 28.57% of subjects had less hairfall in just 3 weeks. 90.5% of the subjects showed less hairfall (Figure.3) when they used Dheedhi Hair Care Herbal Shampoo daily for a period of 6 weeks. 0% of the Regular Shampoo group showed such reduction in hairfall (Chi-square = 25.5918, p < 0.0001). Previously, Anjum *et al* also reported anti dandruff activity of the plant based hair oil. Our results could be attributed with their results [21].

The ASFS is a scale that shows dandruff levels from 0 to 80 (Figure.3). The study was designed to expect an efficacy showing reduction of 10

scores from first visit or a total score of 0. Within 3 weeks of using Dheedhi Hair Care Herbal Shampoo daily, 52.38% of subjects showed reduction of 10 scores in ASFS (Figure 4.). In 6 weeks of daily usage of Dheedhi Hair Care Herbal Shampoo, 90.48% of subjects significantly less severity in flaking – less dandruff of the scalp (Chi-square = 25.5918, p < 0.0001).

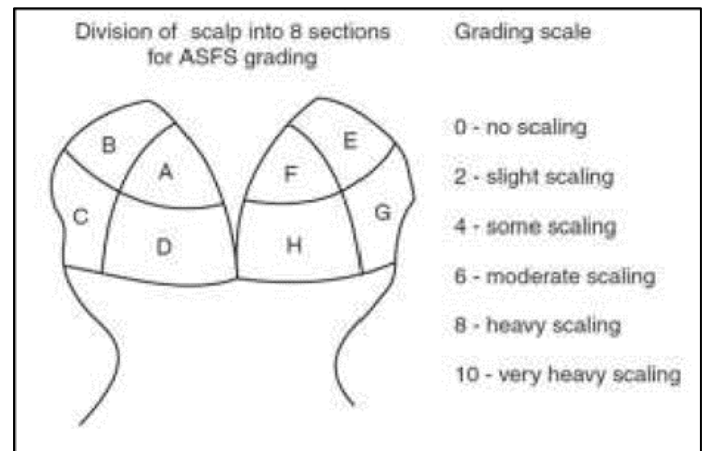


Figure 3: The ASFS scoring criteria used in the study

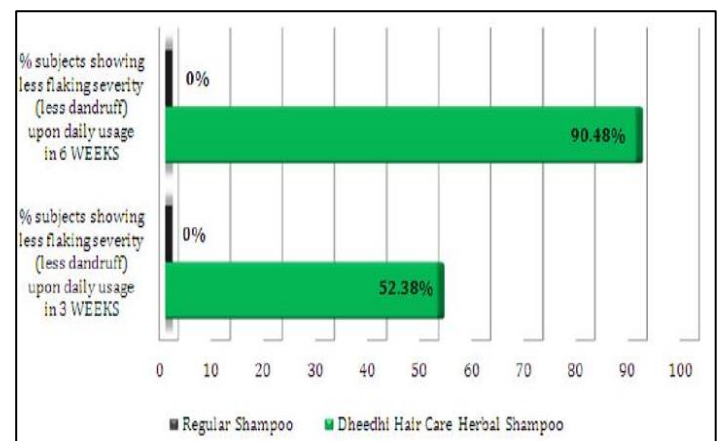
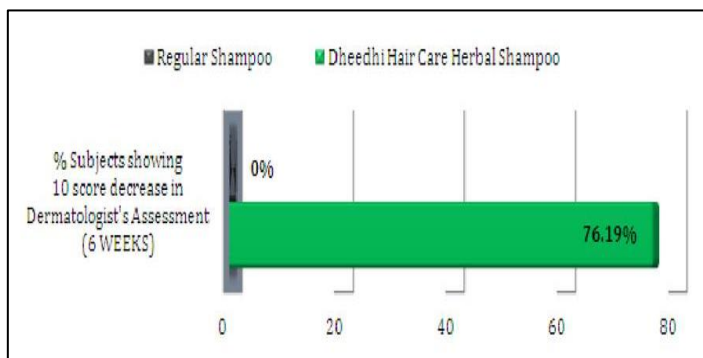


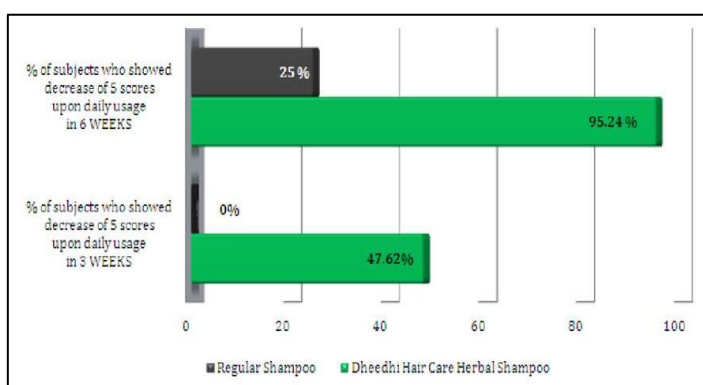
Figure 4: The Effectivity of Dheedhi hair oil compared to regular oil based on ASFS scoring function on Anti Dandruff activity

Dermatologist Assessment in the study showed that dheethi hair oil showed a decrease in 10 score as expected. According to the Dermatologist, 76.19% of the subjects using Dheedhi Hair Care Herbal Shampoo (Figure. 5) showed reduction in hairfall, had better dandruff levels, and improved overall appearance of the hair. Meanwhile, 0% of subjects using Regular Shampoo showed the same result (Chi-square = 17.7479, p < 0.0001).

In the subject's assessment of their hairfall, dandruff and texture of their hair, the results were satisfactory. A decrease of 5 scores was given for dheethi hair oil by the participants. 95.24% of the subjects who used Dheedhi Hair Care Herbal Shampoo (Figure.6) felt that their hair was better, with reduced hairfall and dandruff levels in a period of 6 weeks while only 25% of subjects who used Regular Shampoo felt the same. (Chi-square = 17.8374, p < 0.0001)



**Figure 5:** The Dermatologist assessment of Effectivity of Dheethi hair oil compared to regular oil based on questionnaire for Anti Dandruff activity in study subjects



**Figure 6:** The Participants assessment of Effectivity of Dheethi hair oil compared to regular oil based on questionnaire for Anti Dandruff activity in study subjects

## CONCLUSION

Ayurveda based dheethi herbal shampoo enhanced the hair growth in alopecia affected subjects between age 21- 45 years in six week tenure. It also showed excellent anti dandruff activity and promoted the hair growth comparatively higher than commercially available regular hair oil. The study participates and dermatologists were satisfied with its anti-hair falling activity. This study confirmed the hair regrowth on studied subjects and its antidandruff nature simultaneously.

## Conflict of interest

The authors declare that no conflict of interest.

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