

**Clinical evaluation of herbal Hair Loss Cream
in management of Alopecia aerata: An open study**

G. Ravichandran, M.D.,D.D., M.Derm., Consultant Dermatologist,
Avilochan Singh, Ayurvedic Consultant
Spectra, Clinical Research Wing of Apollo Hospitals,
Apollo Hospitals, Chennai, India.
Pralhad S. Patki*, M.D.,
Head - Medical Services and Clinical Trials
S.K. Mitra, M.D., Executive Director
R&D Center, The Himalaya Drug Company, Bangalore, India.

*Corresponding Author

ABSTRACT

This preliminary study focuses on the effect of a topical application of herbal Hair Loss Cream, in the reduction of hair loss and promotion of new hair growth in men and women. Twenty subjects (15 men and 5 women), with varying levels of hair loss, were enrolled in this six month study. This study indicates that herbal Hair Loss Cream is effective in reducing hair loss in both men and women: 54% of the male and 52% of the female participants reported a noticeable decrease in hair loss after one month of treatment. 67% of men and 63% of women reported significant fall in the hair loss by three months of treatment. By the end of the study majority of men and women reported new growth of hair.

This study also suggests that herbal Hair Loss Cream may be beneficial in stimulating new hair growth. This effect, however, seems to be more pronounced in men and women under the age of 40 years, who are expected to have normal hair growth cycles. Nevertheless, as most of the subjects of this study have been diagnosed with alopecia, this result suggests that a subsequent study should be performed to determine quantitatively the effect of herbal Hair Loss Cream in stimulating hair regeneration in patients with severe alopecia.

INTRODUCTION

Androgenetic alopecia or male pattern baldness is a common condition affecting approximately 50% to 80% of Caucasian men and is the most widespread form of baldness. Alopecia is an inherited condition, most likely dominantly inherited with variable penetrance, which progressively appears as men age¹. Typically, 30% of Caucasian men in their thirties have alopecia. This number increases to 40% for men in their forties, and so on, up to 80% of men in their eighties and older. This progressive rate of appearance of alopecia is also found in other ethnicities, although in total, baldness may appear at a lower rate than in Caucasian men. For example, it is estimated that only a total of 30% to 40% of Asian men are affected by androgenetic alopecia.

Although not often appreciated, alopecia is also present in a significant portion of women. It is estimated that 20% to 40% of women have this condition, although not with the same severity as men². In women, hair loss typically begins in their twenties to forties, and does continue to progress with increasing age.

It has been suggested that androgenetic alopecia is linked to the activity or concentration of enzymes, such as the 5-alpha-reductase which makes a potent form of testosterone called dihydrotestosterone (DHT), in the scalp and hair follicles, or to the sensitivity of hair follicle receptors to DHT³. Indeed, medications for Androgenetic alopecia concentrating on blocking the activity of 5-alpha-reductase have been developed, with varying degrees of success and sometimes with the presence of serious side effects⁴. As it has proven difficult to regenerate hair in alopecia patients, attention has also been focused on stopping the hair loss in the first place. In this preliminary study, we investigate the effectiveness of a topical herbal Hair Loss Cream application consisting of extracts of *Butea monosperma* and *Butea parviflora* in preventing hair loss and promoting new growth of hair in men and women.

Aim of the Study

This study was planned to evaluate the clinical efficacy and safety of Hair Loss Cream in the management of alopecia aerata.

Study Design

This study was an open, phase IV clinical trial, conducted at the Department of Dermatology of Apollo Hospitals, Chennai, India, from November 2004 to December 2005.

The study protocol, case report forms, product information, and informed consent forms were approved by the local ethics committee.

MATERIALS AND METHODS

Twenty alopecia patients composed of 15 males and 5 females were enrolled in the study. The subjects ranged in age between 21 and 71 years, with the mean age of 39.5 ± 6.9 years for the male subjects and 31.5 ± 2.9 years for the female subjects. Although most of the subjects have not exhibited severe alopecia, all reported

hair loss with varying degrees of severity, as shown in Table 1.

Number of patients		20	
Male, Female		Male: 15; Female: 5	
Diet		Vegetarian: 15; Mixed: 5	
Mean age		Male: 39.5 ± 6.9 years Female: 31.5 ± 2.9 years	
Mean serum creatinine (mg%)		0.67 ± 0.2	
Number with abnormal thyroid function tests		Nil	
Hair Loss Problems (No. of patients)	Grade	Male	Female
	Severe	4	1
	Medium	6	2
	Mild	5	2

Hair loss severity is defined as mild if the subject estimates that daily hair loss is less than 40 strands per day; medium if it is between 40 and 100 strands per day; and severe if it is more than 100 strands per day⁵. The subjects were given the topical herbal Hair Loss Cream for a total study period of 6 months. All the patients were advised to apply sufficient quantity of Hair Loss Cream to the affected area of scalp, daily, at night, for a period of six months, with gentle massage, and were advised to leave the cream overnight and left to dry naturally without blow drying or toweling. The subjects were given a weekly questionnaire to determine qualitatively the status of their hair loss and new hair growth, as well as the presence of side effects.

Exclusion Criteria:

1. History of systemic or cutaneous malignancy
2. Nevi or cutaneous lesions currently
3. Evidence of immunocompromised state
4. Advanced or poorly controlled diabetes
5. Unstable cardiovascular disease
6. Clinically significant medical or psychiatric disease
7. History of alcohol or drug abuse within two years of assessment for study enrollment
8. Serious local infection (e.g. cellulites, abscess) or systemic infection (e.g. pneumonia, septicemia) within three months prior to the first dose of investigational drug.

Primary and Secondary Endpoints

The predefined primary efficacy endpoints were improvements in the subjective and objective score. The subjective evaluation was done using global evaluation scores (0=poor, 1=fair, 2=good, and 3=excellent). The objective improvement evaluation included: (1) Mean number of hair lost during one minute combing test (>150 hairs lost=poor, 100-150 hairs lost=fair, 50- 100 hairs lost=good). The secondary end point was adverse effects reported by the patients.

Statistical Analysis

Statistical analysis was done according to intent-to-treat principles. Changes in various parameters from baseline values and values after 1, 2, 3, 4, 5, and 6 months were analyzed by the “*Repeated Measures ANOVA test*”, The minimum level of significance was fixed at 99% confidence limit and a 2-sided *p* value of <0.05 was considered as significant.

RESULTS AND DISCUSSION

The overall result of this preliminary study suggests that even a short-term treatment with herbal Hair Loss Cream is effective in significantly reducing hair loss and may stimulate new hair growth in a portion of the subjects. There was a significant reduction in the hair symptoms (itching, irritation and dryness of the scalp) within 2 weeks, and by the end of fortnight, all these symptoms disappeared. There was a significant improvement in the tensile strength of hair as judged by the pull test and combing test. (Table 2)

Parameter	Base line	1 month after treatment	3 months after treatment	At 6 months	
Mean hair loss (/combing)	118.2 ± 6.2	79.2 ± 12.4*	60.4 ± 19.4*	45.5 ± 12.4*	
Perceptible reduction in hair loss by patients (%)	Male	-	54%	67%	72%
	Female	-	52%	63%	70%

**p*<0.01 as compared to baseline parameter

Prevention of hair loss

A significant portion of the male and female subjects reported noticeable and significant reduction in hair loss even after only a short treatment period. After one month of treatment, over 54% of the male and 52% of the female participants noted a perceptible reduction in shedding or hair loss. After 6 months of treatment, majority of the subjects reported near complete elimination of hair loss. Upon closer inspection, it is apparent that older men (i.e. 40 years of age or older) showed a delayed reaction to herbal Hair Loss Cream. This group is

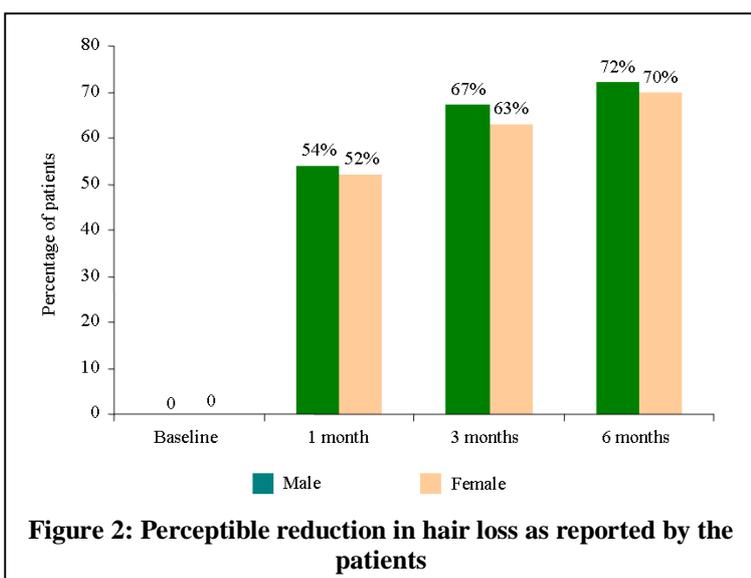
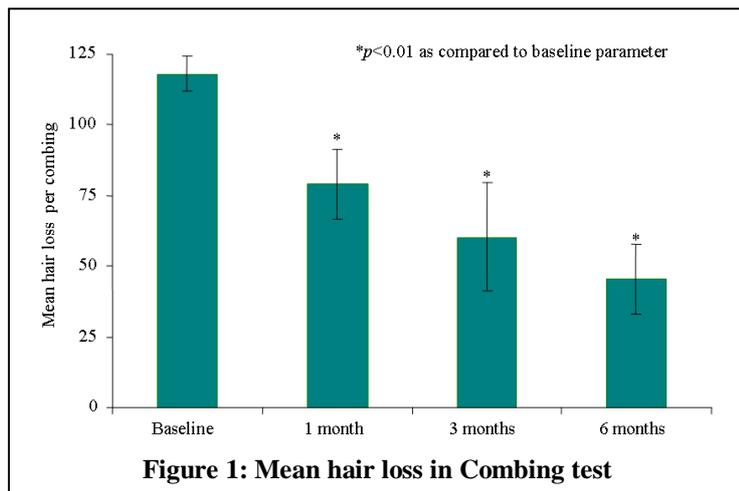
of particular interest, as alopecia in Asian men often starts to manifest after reaching middle age.

Stimulation of new hair growth

In addition to the weekly qualitative evaluation of their hair loss, the subjects were asked to assess whether there was noticeable new hair growth after herbal Hair Loss Cream treatment. None of the subjects reported any noticeable new hair growth in the first week. Majority of men reported new hair growth by the end of the study. Although it seems that herbal Hair Loss Cream treatment resulted in noticeable hair growth in both males and females, it should be noted that these generally occur in younger ones.

Serious side effects

Participants of this study were asked to evaluate the presence of adverse side effects of the herbal Hair Loss Cream treatment. None of the patients exhibited any adverse effect to the hair cream.



DISCUSSION

The results indicate beneficial effect of herbal Hair Loss Cream in minimizing hair loss and helps in generation of fresh crop of new hair if used for a period of six months. It is effective and safe. Its exact mechanism of action cannot be identified. *Butea monosperma* has potent anti inflammatory activity^{6,7}, which could be responsible for decreasing local inflammation and hence help in hair growth. Its anti fungal activity too may contribute to its efficacy⁸.

The active ingredients of *Butea frondosa* are flavones and flavonoids (butrine, isobutrine and free amino acids), while the active ingredients of *Butea parviflora* are glycosides⁹, which may help in decreasing hair loss. Its acetylcholine esterase inhibitor effect may also contribute in its beneficial effects¹⁰.

In an experimental study, the effect of “Hair Loss Cream (PCPB Hair Cream)” was evaluated in chemotherapy-induced alopecia in cell line model. Synchronized hair cycle were treated with cyclophosphamide, which resulted in complete alopecia followed by hair regrowth¹¹. It is possible that the clinical effect is a synergistic effect.

CONCLUSION

Herbal Hair Loss Cream is a safe and effective in prevention of hair loss. It helps in regeneration of new hair by six months.

ACKNOWLEDGEMENT

We are thankful to Dr. Rangesh Paramesh M.D(Ay) for the help and support for this project.

References

1. Ellis, J.A., Harrap, S.B. The genetics of androgenetic alopecia. *Clin. Dermatol.* 2001; 19: 149-154.
2. Birch, M.P., Lalla, S.C., Messenger, A.G. Female pattern hair loss. *Clin. Expt Dermatol.* 2002; 27: 393-398.
3. Takashima, I., Montagna, W. Studies of common baldness of the stump-tailed macaque (*Macaco speciosa*). VI. The effect of testosterone on common baldness. *Arch. Dermatol.* 1071; 103: 527-534.
4. Khandpur, S., Suman, M., Reddy, B.S. Comparative efficacy of various treatment regimens for androgenetic alopecia in men. *J. Dermatol.* 2002; 29(8): 489-98.
5. Van Neste. Natural scale hair repression in preclinical stages of male androgenetic alopecia. *Skin Pharmacology and Physiology* 2006; 19: 168-176.
6. Shahavi, V.M., Desai, S.K. Antiinflammatory activity of *Butea monosperma*. *Fitoterapia* 2008; 79: 82-85.
7. Yadava, R.N., Tiwari, L. New antifungal flavane from *Butea monosperma*. *J. Enzyme Inhib. Med. Chem.* 2007; 22: 497-500.
8. Kuntze, O., Yadava, R.N., Tiwari, L. A potential antiviral flavone glycoside from the seeds of *Butea monosperma*. *J. Asian Nat. Prod. Res.* 2005; 7: 185-188.
9. Shah, K.G., Baxi, A.J. Phytochemical studies and antioestrogenic activity of *Butea frondosa* flowers. *Indian J. Pharmaceu. Sci.* 1990; 52(6): 272-275.
10. Mukherjee, P.K., Venkatesan Kumar, Mainak, Houghten, P.J. Acetylcholine esterase inhibitors from plants. *Phytomedicine* 2007; 14: 289-300.
11. Evaluation of the efficacy of PCPB Hair Cream in chemotherapy induced alopecia in cell line model. Data on file.

- 0 -