



ISSN NO. 2320-5407

Journal homepage: <http://www.journalijar.com>

INTERNATIONAL JOURNAL
OF ADVANCED RESEARCH

RESEARCH ARTICLE

A Non comparative Open label Pilot study to see the Efficacy and Consumer Response of Vegetal Hair Well in preventing hair fall and promoting hair growth

Amit Madan¹, *Abhishek Arun², Sudeep Verma³

1. MBBS,DDVL,DNB Consultant Dermatologist Madan Skin Care Centre, Lucknow.
2. MBBS,MD Resident Department of Community Medicine, ELMC&H, Lucknow.
3. BAMS Consultant Ayurvedic Physician, Lucknow.

Manuscript Info

Manuscript History:

Received: 12 December 2013
Final Accepted: 15 January 2014
Published Online: February 2014

Key words:

Vegetal Hair Well; hair fall; hair growth

*Corresponding Author

Abhishek Arun

Abstract

Background: Hair loss and maintaining quality hair is major problem of society. It is a distressing condition for number of men & women. Now a days approach has been tried to develop herbal formulations for curing this conditions, to avoid harmful side effects of allopathic system. Vegetal hair well is a herbal formulation that contains Accacia concinna, Nadosstachys jatamansi, Aloe vera, Eclipta alba, Emblica officinalis, Lawsoniainermis etc. in adequate proportions and which have a proven results in preventing hair fall and promoting hair growth.

Aims and objectives: This study aimed to assess the effect of Vegetal hair well in preventing hair loss; promoting hair growth and its overall effect on scalp/hair.

Material and methods: 50 Healthy males or females aged >18 years and <65 with a clinical diagnosis of: mild to moderate hair loss; dandruff; frequent hair fall; willing to participate in this study were included. All the enrolled patients underwent a thorough clinical examination, and scalp skin examination. All the patients were advised to apply sufficient quantity of vegetal hair well to the affected area of scalp, twice weekly for a period of seven weeks, with gentle massage, and were advised to leave for 30 minutes then wash with normal water. The subjects were given a questionnaire to determine qualitatively the status of their hair loss and new hair growth, as well as the presence of side effects if any.

Results and discussion: The overall result of this study suggests that even a short-term treatment with herbal Vegetal Hair Well 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) and there was a significant improvement in the tensile strength of hair. After 7 weeks of treatment, majority of the subjects (>75%) reported near complete elimination of hair loss.

Conclusion: Vegetal Hair Well is safe and effective in prevention of hair loss. It helps in regeneration of new hair by seven weeks. It has got an excellent result on scalp/hair health.

Limitations and recommendation: This was a pilot study conducted only on 50 subjects with only single study centre furthermore comprehensive and detailed multi centric study can be done to evaluate the effectiveness of Vegetal Hair Well

Copy Right, IJAR, 2013., All rights reserved.

Introduction:

Hair loss and maintaining quality hair is major problem of society. It is a distressing condition for number of men & women. Alopecia is an inherited condition, most likely dominantly inherited with variable penetrance, which progressively appears as men age¹ (Hadshiew IM et al.2004).

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 (Drake LA et al.1996). In women, hair loss typically begins in their twenties to forties, and does continue to progress with increasing age.

There are number of allopathic medicines available for treating androgenic alopecia. Now a days approach has been tried to develop herbal formulations for curing this conditions, to avoid harmful side effects of allopathic system.

Vegetal hair well is a herbal formulation that contains *Accacia concinna*, *Nadosstachys jatamansi*, *Aloe vera*, *Eclipta alba*, *Embllica officinalis*, *Lawsonia inermis* etc. in adequate proportions and which have a proven results in preventing hair fall and promoting hair growth.

Key ingredients of Vegetal Hair Well and their respective roles:

Ingredient/content	Important documented role
<i>Accacia concinna</i> 'Shikakai'	Anti dermatophytic properties
<i>Nadosstachys jatamansi</i> 'Jathamansi'	hair growth promotion
<i>Aloe Barbadensis</i> 'Aloe vera'	anti-oxidants, good for hair and scalp
<i>Eclipta Prostrada</i> 'Bhangra'	potentiate hair growth promotion
<i>Embllica officinalis</i> 'Indian gooseberry-Amla'	nourish the hair and scalp and prevent premature grey hair
<i>Lawsonia inermis</i> 'Henna'	Cosmetic hair dye

Product details:

Vegetal Hair Well is an approved ayurvedic medicine, comprising of noble herbs like *Acacia concinna* (Shikakai), *Nardostachys Jathamansi* (Jathamansi), *Bacopa* (Brahmi), *Aloe Barbadensis* (Aloe Vera), *Lawsonia inermis* (Henna), *Eclipta Prostrada* (Bhangra), *Embalica Officinalia* (Amla), *Holarrhena antidiysenterica* (Indrajau), *Trigonella Foemun* (Methi). It is a complete natural supplement for the hair and scalp when used as topical application. It strengthens the hair shaft, controls hair fall and brings back the lost sheen and softness to your hair.

This preliminary study focuses on the effect of a topical application of herbal Vegetal Hair well, in the reduction of hair loss and promotion of new hair growth in men and women.

Aims and Objectives:

To study the effect of Vegetal hair Well in preventing hair fall.

To study the effect of Vegetal hair Well in promoting hair growth.

To study the effect of Vegetal hair Well on overall health and scalp.

Key inclusion and exclusion criteria:

Healthy males or females aged >18 years and <65 with a clinical diagnosis of: mild to moderate hair loss; dandruff; frequent hair fall; willing to give informed consent and comply with protocol were included in the study.

Un cooperative subjects; those having significant systemic diseases; pregnant and lactating females; those having overt bacterial and fungal conditions/allergic dermatosis were excluded from the study.

Materials and Methods

Fifty patients composed of 27 males and 23 females were enrolled in the study. The subjects ranged in age between 18 and 65 years.

Each patient's demographic medical history (esp. local fungal infection, dandruff, pediculosis, trichotillomania, stress, diet, past illness, and drugs), and treatment details will be recorded. All the enrolled patients will undergo a thorough clinical examination, and scalp skin examination (which includes the assessment of number of hairs lost in one-minute combing test, presence of alopecic patches, number of exclamation point hairs, hair pull test, epidermal changes and alopecia pattern Viz. "reticular patches" (with extensive hair loss), or "coalescent patches/ophiasis" (with localized hair loss), or "sisaipho" (with hair loss sparing the sides and back of the head).

All the patients were advised to apply sufficient quantity of vegetal hair well to the affected area of scalp, daily for a period of seven weeks, with gentle massage, and were advised to leave for 30 minutes then wash with normal water.

The subjects were given a questionnaire to determine qualitatively the status of their hair loss and new hair growth, as well as the presence of side effects.

Primary and Secondary Endpoints:

Primary end points :

35% improvement in hair loss assessed by the 1 min combing test

Secondary End points :

Elimination of dandruff

Improvement in hair shine and luster as per patient feedback form

Improvement in over all hair quality and scalp assessed by Patient feed back form .

Statistical Analysis

Statistical analysis was done according to intent-to-treat principles. Changes in various parameters from baseline values and values after 1, 3 and 7 week were analyzed by the “*Repeated Measures ANOVA test*”. A *p* value of <0.05 was considered as significant.

Results:

The overall result of this pilot study suggests that even a short-term treatment with herbal Vegetal Hair Well is effective in significantly reducing hair loss and may stimulate new hair growth in a portion of the subjects.

Table 1: Demographic data of patient's on entry

Age in years	Total number
18-35 years	13
36-50 years	25
51-65 years	12
Total	50
Gender	
Male	27
Female	23

Fig 1: Total number of patients according to age distribution

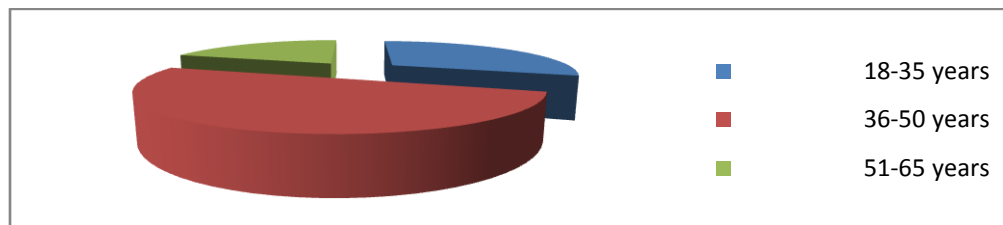
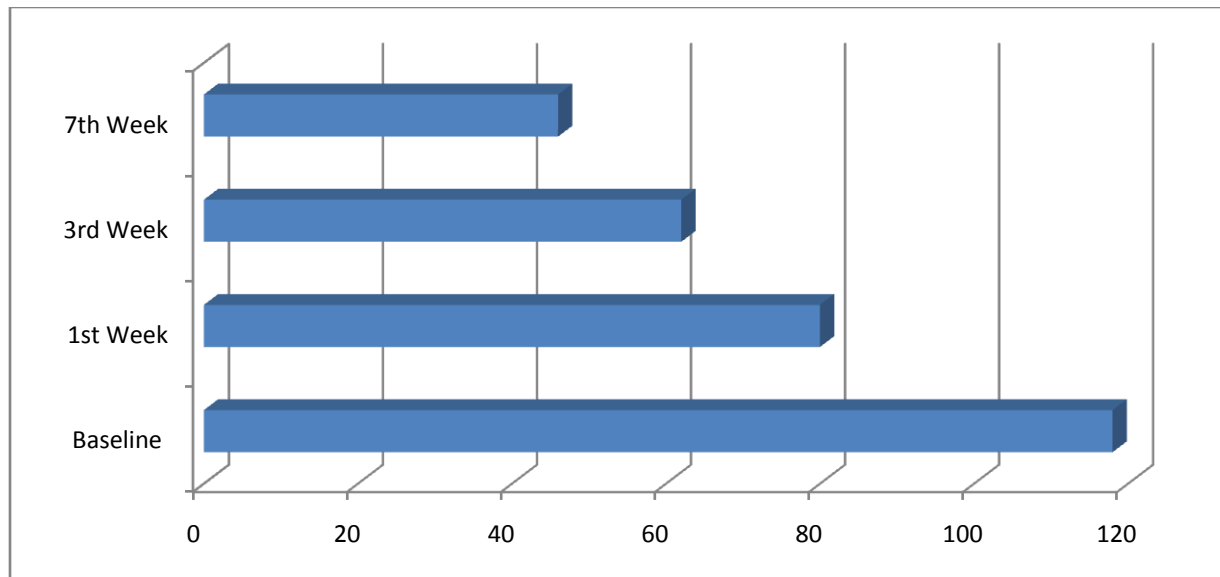
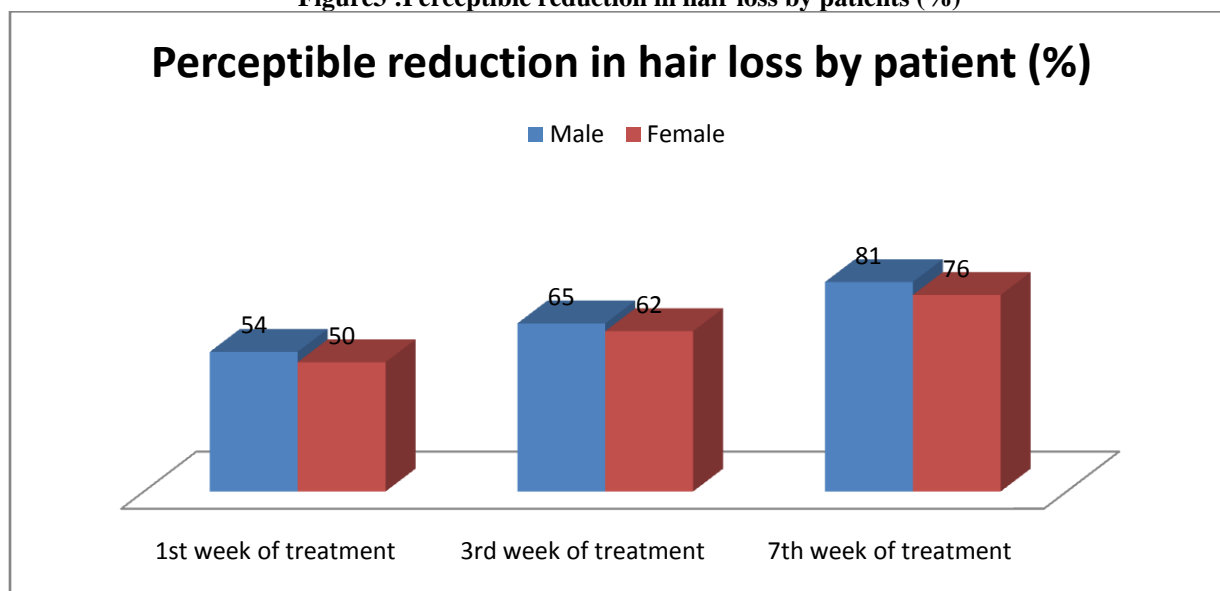


Table 2: Number of patients based on severity of hair loss			
Hair loss problem (number of patients)	Grade	Male	Female
	Severe	8	1
	Medium	15	14
	Mild	4	8

Although most of the subjects have not exhibited severe alopecia, all reported hair loss with varying degrees of severity, as shown in Table 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 day. The subjects were given the topical vegetal hair well for a total study period of 7 weeks.

Parameter	Baseline	1 st week after treatment	3 rd week after treatment	7 th week	
Mean hair loss (/combing)	120.2 ± 5.2	80.2 ± 10.4*	59.4 ± 9.4*	42.5 ± 2.4*	
Perceptible reduction in hair loss by patients (%)	Male	-	54%	65%	81%
	Female	-	50%	62%	76%

* $p < 0.01$ as compared to baseline parameter

Fig 2: Mean hair loss on combing test**Figure3 :Perceptible reduction in hair loss by patients (%)**

There was a significant reduction in the hair symptoms (itching, irritation and dryness of the scalp) within 1 week, and by the end of 7 weeks, 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 3)

Parameter	Baseline	1 st week	3 rd week	7 th week
Mean	1.27	2.00	2.31	2.89
Std deviation	0.46	0.00	0.54	0.32
Std error	0.089	0.00	0.104	0.061
Repeated measures of ANOVA summary	F= 204, R ² = 0.88, p<0.001, Highly significant			

There was a significant improvement in the overall subjective and objective evaluation score after each monthly interval from baseline to 1.27, 2.00, 2.31, and 2.88, (Table 4).

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 1 week of treatment, over 54% of the male and 50% of the female participants noted a perceptible reduction in shedding or hair loss. After 7 weeks of treatment, majority of the subjects reported near complete elimination of hair loss. Upon closer inspection, it is apparent that older men (i.e.50 years of age or older) showed a delayed reaction to herbal Vegetal Hair Well. This group is of particular interest, as alopecia in Asian men often starts to manifest after reaching middle age.

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 Vegetal Hair Well 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 Vegetal Hair Well treatment resulted in noticeable hair growth in both males and females, it should be noted that these generally occur in younger ones.

Criteria	Baseline	1 st week	3 rd week	7 th week
Score at time of Vegetal hair Well application	70/100	70/100	80/100	90/100
Score of wet hair assessment	30/100	45/100	60/100	85/100
Score of dry hair assessment	20/100	40/100	60/100	90/100
Score for scalp health	40/100	55/100	70/100	90/100
Hairgrowth evaluation	25/100	42/100	60/100	86/100
Overall Rating of the product(1-10)	4	6	7	9

Fig 4: Showing overall rating of Vegetal Hair well over different visits.

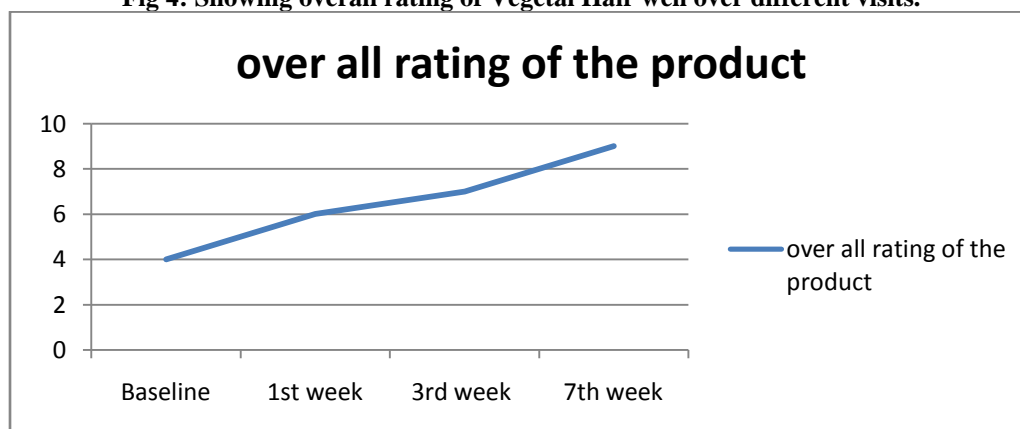


Table 5 shows significant improvement in the overall rating of the product – Vegetal hair well on application over a period of 7 weeks. It also highlighted a significant improvement in total hair texture score, hair growth score along with score for scalp health over the study period there by highlighting the quality of the product.

Treatment visit	Itch score	Significance
Baseline	1.23±0.55	NS
1 st week	0.61±0.42	p<0.01
3 rd week	0.47±0.51	p<0.01
7 th week	0.45±0.51	p<0.01

Itching at the baseline visit was 1.23 ± 0.55 . It reduced with treatment to 0.61 ± 0.42 at the end of 1st week, which again reduced to 0.47 ± 0.51 at the end of 3rd week, to 0.45 ± 0.51 ($p < 0.01$) at the end of 7th week, all the significance values are as compared to the first visit values (Table 6).

Discussion:

Various factors contribute to hair fall/loss. Genetic predisposition and hormonal factors predominantly contribute to the above. Disease states such as typhoid, malaria, jaundice, etc. and use of chemotherapeutic agents also cause hair fall. Hormone therapy, use of α -reductase inhibitors and vasodilators like minoxidil are widely used to reduce the hair fall/loss. The synthetic drug, minoxidil is a potent vasodilator appears safe for long-term treatment. Treatments available for the various forms of alopecia have limited success with unwanted adverse effects. New technologies in cosmetic transplant surgery and hair replacement systems are available that can be completely undetectable³ (Safavi KH et al.1995).

The present study shows that Vegetal hair Well is beneficial in the management hair fall and promotes hair growth with an over all improvement in scalp and hair texture. Vegetal hair well consists of potent herbs, namely Acacia concinna (Shikakai), Nardostachys Jathamansi (Jathamansi), Bacopa (Brahmi), Aloe Barbadensis (Aloe Vera), Lawsonia inermis (Henna), Eclipta Prostrada (Bhangra), Embalica Officinalia (Amla), Holarrhena antidysenterica (Indrajau), Trigonella Foemun (Methi).

Acacia concinna popularly know as 'Shikakai' has been widely used in washing hair by the people of India and Sri Lanka. Acacia concinna has significant anti dermatophytic properties. Ecliptaalba is traditionally known to potentiate hair growth promotion. Ethanolic extract of Nardostachys jatamansi (Valerianaceae) and Cyperusrotundus (Cyperaceae) was evaluated for hair growth on albino rats. The hair growth activity that was worked on Chemotherapy induced alopecia model were investigated by using various parameters like hair density, lymphocyte count and testosterone level along with histopathological study⁴ (Price VH 1999). Hair growth initiation time was markedly reduced to half on treatment with extract as compared to control animal the time required for complete hair growth was also significantly reduced. Aloe vera is rich in anti-oxidants, which neutralize free radicals. It is also good for the hair and scalp.

Lawsonia inermis, also known as Henna has been used since antiquity to dye skin, hair, and fingernails, as well as fabrics including silk, wool, and leather⁵ (Bergfeld WF et al.2001).

In earlier studies *Butea mono sperma* has potent anti inflammatory activity^{6,7} (Stenn KS et al.2001)(Bergfeld WF 1989), which could be responsible for decreasing local inflammation and hence help in hair growth. Its anti fungal activity too may contribute to its efficacy⁸ (Madani S et al.2000). The active ingredients of *Butea frondosa* are flavones and flavonoids (butrine, isobutrine and free amino acids), while the active ingredients of *Butea parvi flora* are glycosides, which may help in decreasing hair loss.

Serious side effects

Participants of this study were asked to evaluate the presence of adverse side effects of the herbal Vegetal Hair Well treatment. None of the patients exhibited any adverse effect to the Vegetal Hair Well.

Conclusion

Vegetal Herbal Hair Well is a safe and effective in prevention of hair loss. It helps in regeneration of new hair by seven weeks.

There was significant reduction in hair fall after 3rd week of treatment, which further continued to show reduction until the end of the study. Similarly, itching also reduced with treatment and there was significant relief from four months until the end of the study. Hair loss reduced in 39 out of 50 cases treated with Vegetal hair well. Further

safety of the product was also substantiated by clinical parameters. Therefore, it can be concluded that Vegetal hair well is safe and effective in treatment and management of hair loss and improves the overall hair and scalp health.

Limitations of study and future recommendations

This was only a pilot study conducted on 50 subjects and was done only at one centre with limited end points and shorter duration. Further more comprehensive and multi centric studies can be done with multiple parameters to evaluate the potential benefits of this product.

References

1. Hadshiew IM, Foitzik K, Arck PC and Paus R. Burden of hair loss: stress and the underestimated psychosocial impact of telogen effluvium and androgenetic alopecia. *J. Invest. Dermatol.* 2004;123(3):455-457.
2. Drake LA, Dinehart SM and Farmer ER. Guidelines of care for androgenetic alopecia. *J. Am. Acad. Dermatol.* 1996;35:465-469.
3. Safavi KH, Muller SA, Suman VJ, Moshell AN and Melton LJ. 3rd incidence of alopecia areata in Olmsted County, Minnesota, 1975 through 1989. *Mayo. Clin. Proc.* 1995;70:628-633.
4. Price VH. Treatment of hair loss. *N. Engl. J. Med.* 1999;341:964-973.
5. Bergfeld WF and Mulinari-Brenner F. Shedding: how to manage a common cause of hair loss. *Cleve. Clin. J. Med.* 2001;68:256-261.
6. Stenn KS and Paus R. Control of hair follicle cycling. *Physiol. Rev.* 2001;81:449-494.
7. Bergfeld WF. Alopecia: Histologic changes. *Adv. Dermatol.* 1989;4:301-320.
8. Madani S and Shapiro J. Alopecia areata update. *J. Am. Acad. Dermatol.* 2000;42:549-566.