Research Article

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CLINICAL EVALUATION OF HAIRBAC TABLET AND OIL IN THE MANAGEMENT OF DIFFUSE HAIR LOSS: AN OPEN CLINICAL STUDY

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ABSTRACT

Hair is an important component of the body derived from ectoderm of skin. Keratin is the main component of hair fibers. Hair has great psycho-social significance for persons. The average growth rate in a normal scalp is 0.41 mm per day but lower growth rate is observed among aged persons and chronic disease persons. Hair loss is a most common problem among men and women of all age groups and it is a socially and psychologically distressing also. Its severity varies from a small bare patch to a more diffuse and obvious pattern. Diffuse hair loss may occur at any age and gender. It affects the whole scalp. Management of hair fall is extremely complex. Treatments for the various forms are available but alopecia has limited success. As a general rule, it is easier to maintain remaining hair than it is to re-grow; however, the success rate is very less with unwanted adverse effects. There are claims that poly herbal formulations are giving promising results. So, a poly herbal formulation 'Hairbac' tablet and oil, is evaluated for its safety and efficacy in diffuse hair loss. The subjective parameters used for assessment were Hair Texture, Hair Density/cm sq area and Hair Loss. The beneficial effects of Hairbac Tablets and Oil assessed in the context of hair texture, density /1cm² and hair loss among females suffering with diffuse hair fall showed highly significant improvement without any adverse effects assessed by the respondents.

Keywords: Diffuse hair loss, Hair Texture, Hair Density, Hairbac tablet, Hairbac oil.

INTRODUCTION

Hair is a primary characteristic of mammals. Hair is an important component of the body derived from ectoderm of skin. It is protective appendage on the body and considered necessary structure of the integument along with sebaceous glands, sweat glands and nails. Hair gives physical protection. It exerts a range of functions such as sensory activity and thermoregulation. It influences the social life and social interactions¹. Keratin is the main component of hair fibers. Hair has great psycho-social significance for persons. The average growth rate in a normal scalp is 0.41 mm per day² but lower growth rate is observed among aged persons and chronic disease persons. Each scalp hair grows in three cyclic phases viz. Anagen (growth), catagen (involution) and telogen (rest)³. The anagen phase may be short as 2-6 years and approximately 80 % of hair follicles are present in this phase. The remaining percentage of hair follicles is present in catagen and in telogen phase. The hair growth activities increases in catagen phase with span of 2-3 weeks and moves to telogen phase i.e. resting state phase, lasts for 2-3 months. It is reported that in general 100-150 hairs at random are shed every day⁴. Hair loss is a most common problem among men and women of all age groups and it is a socially and psychologically distressing also. Its severity varies from a small bare patch to a more diffuse and obvious pattern. Diffuse hair loss may occur at any age and gender. It affects the whole scalp. Benign hair loss have marked deleterious effects on body-image,

self esteem and psychology of human being. The most widespread form of hair loss is baldness affecting both the genders. Affected proportion of men by this morbidity is 50 % by the age of 50 years and it increases by 80 % as age increased up to 80 %.

Causes of Hair Fall

The causes of Hair loss is multiple faceted. The commonest are cornrows, Trichotillomania, traumas, severe stress, Child birth, use of fertility-stimulating drugs, fungus infections, Hypothyroidism, sebaceous cysts, certain hereditary disorders and short anagen syndrome etc. The diagnosis of hair disorders is complex. Diagnostic techniques include clinical examination such as scalp condition; hair loss pattern; length and diameter of hair fibers; one-minute combing test; clipping, plucking and microscopic examination of hair fibers; scrapings of scalp scales for microbial culture and scalp-punch biopsy. Other laboratory tests such as complete blood count, ferritin measurement and thyroid screening may be helpful. Management of hair fall is extremely complex. Treatments for the various forms are available for alopecia but have limited success. As a general rule, it is easier to maintain remaining hair than it is to re-grow; however, the success rate is very less with unwanted adverse effects. There are new technologies in cosmetic transplant surgery and hair replacement systems are available and that can be completely undetectable. There are claims that poly herbal formulations are giving

promising results. So, a poly herbal formulation 'Hairbac' tablet and oil, is evaluated for its safety and efficacy in diffuse hair loss.

Drug Review

Each Hairbac tablet contains: Amla (*Emblica officinalis*) - 250 mg, Giloy (*Tinospora cordifolia*) -100 mg, Bhringraj (*Eclipta alba*) -50 mg, Anant mool (*Hemidesmus indicus*) -50 mg, Mulethi (*Glycyrrhiza glabra*) -50 mg, triturated and Processed with the extracts of Bhumii Amla (*Phyllanthus niruri*), Safed Chandana (*Santalum album*) and Spirulina (Blue green algae). The given Dosage is 2 Tablets twice a day for 3 months. Each 100 ml Hairbac oil contains Sesame Oil - 50 ml, Groundnut oil - 40 ml, Olive Oil - 10 ml, Extracts derived from 10 g. each of Neela Patra (*Indigofera tinctoria*), Bhringaraja (*Eclipta alba*), Brahmi (*Bacopa monnieri*), Amla (*Emblica officinalis*), Jatamansi (*Nardostachys jatamansi*). It is advised to use Hairbac Oil by massaging the scalp hair.

MATERIAL AND METHODS

To evaluate the effect of Hairbac Oil and Hairbac Tablet in the management of diffuse hair loss; an open clinical study was planned and conducted at V.S. Hospital, Ahmedabad and Gujarat, India. The same is being approved by the Departmental Drug Research Committee vide letter No. VS/DERMA/DDRC/2012-13/002 Dated 05-01-2012 as an open clinical trial on phase IV post marketing surveillance study.

Plan of Study

Female patients who were suffering with diffuse hair loss visiting to the skin OPD of V.S. Hospital, Ahmedabad, Gujarat, India were registered in the study based on the following inclusive and exclusive criteria:

Inclusion Criteria

- Female patients, whose age is more than 18 years;
- Patients; who are willing to give written, signed and dated informed consent to participate in the study.
- Patients who are clinically diagnosed for diffuse hair loss were included in this study.

Exclusion Criteria

The excusing criteria includes

- Pregnant or breastfeeding or planning to become pregnant during the study period,
- Known case of Hypersensitivity to Investigational drug content,
- Patient using any other treatment for this indication at the same time
- Received any other investigational medicinal therapy within 30 days and topical therapy within 7 days prior to screening
- Patient suffering from any active general illness or have History of any general illness

Study Groups and Duration of study

A group of 40 female patients enrolled in this study and out of which 37 were completed the study. The total period of study was 3 months with 3 follow-ups at 1

month each as interval. The study was conducted from February 2012 to May 2012.

Clinical Study

The information related to demographic details, history of present illness, medical history and personal history was recorded in prepared case sheet for this purpose. The subjective parameters used for assessment are as follows.

Hair Examination

- Hair Texture: Examined by simple method of touching the patient's Hair.
- Hair Density/cm sq area: Examined at a fixed site of scalp with Trichoscope.
- Hair Loss: Counted after constant combing of patient's hair for one minute with the same comb.

The Grading of assessment is as follows:

The Grading of assessment – Hair Texture, Density and Loss (Table 1)

Laboratory parameters: Serum Hb. %g, serum ferritin, Evaluation of treatment

This is done by subjective and objective analogue scale which is given below.

Evaluation of treatment on symptoms Hair Texture, Density and Loss – The Analogue Scores (Table 2)

The adverse effect of infection was recorded for all eligible subjects.

Statistical Analysis

The quantitative and analogue scale variables were presented in the form of mean and standard deviation along with range. The paired t-test was applied to find out the significant difference in the mean values of analogue scale from base line to different follow- ups i.e. at one, two and three months intervals. The qualitative and categorical variables were presented in number and percentage. The 16 .0 version of SPSS (Statistical Package for Social Science) developed by IBM (International Business Machine), USA, was used for data analysis.

RESULTS

Baseline characteristics of the study subjects (N=37)

The mean age of patients was 38.76 years and the standard deviation was 13.06. The range was 18- 60. The mean of duration of illness in years was 2.29 and standard deviation was 1.27 while range was 0.5-6.0. The mean of hemoglobin was 11.97 and standard deviation was 1.22 while the range for this parameter was 9.12-14.40. The mean of serum ferretin was 27.82 and standard deviation was 41.36. The range of it was 1.87-226.26. The standard deviation of abnormal serum ferretin was 9 (24.30 %). The hair textures are grouped in three different group's viz. Good, moderate and rough. 5 patients have good hair texture (13.60 %). The moderate texture was present with 16 patients (43.20 %) while 16 (43.20 %) patients are having rough hair texture. The mean hair density was 4.22 and the standard deviation was 47.55. The range is 16-340. The mean hair loss (combing for one minute) was 108.47 and the standard deviation was 24.31. The range is 55-170. (Table 3)

Subjective improvement among hair examinations at different follow ups (N=37)

Table 1: Grading of assessment – Hair Texture, Density and Loss

Observation	Description	Score
Hair Texture:		
No improvement	Same Texture	0
Poor improvement	A little smoother	1
Fair improvement	Greatly smoother	2
Excellent improvement	Smooth and shiny	3
Hair Density/cm sq area:		
No improvement	Same	0
Poor improvement	10-15	1
Fair improvement	15-20	2
Excellent improvement	20-25	3
Hair Loss :		
No improvement	Same	0
Poor improvement	>150	1
Fair improvement	100-150	2
Excellent improvement	80-100	3

Table 2: Evaluation of treatment on symptoms Hair Texture, Density and Loss – The Analogue Scores

Analogue Scale Scores	Description	Improvement
0	No improvement	<25 % reduction
1	Poor improvement	25 to 49 % reduction
2	Fair improvement	50 to 74 % reduction
3	Excellent improvement	>75 % reduction

Table 3: Baseline characteristics of the study subjects (N=37)

Parameter	Mean	S.D.	Range
Age (in years)	38.76	13.06	18-60
Duration of illness (in years)	2.29	1.27	0.5-6.0
Hemoglobin	11.97	1.22	9.12-14.40
Serum Ferritin	27.82	41.36	1.87-226.26
Abnormal Serum Ferritin	9 (24.3 %)		
Hair Texture	Good 5(13.6 %)	Moderate 16 (43.2 %)	Rough 16 (43.2 %)
Hair Density /1 cm ²	4.22	47.55	16-340
Hair loss (combing for one minute)	108.47	24.31	55-170

Table 4: Subjective improvement among hair examinations at different follow ups (N=37)

Hair examination	1 Month	2 Months	3 Months
Hair Texture			
Poor improvement	30 (81.1)	12 (32.4)	1 (2.7)
Fair improvement	7 (18.9)	24 (64.9)	24 (64.9)
Excellent improvement		1 (2.7)	12 (32.4)
Mean	1.19	1.68	2.30
S.D.	0.40	0.58	0.52
t-value	18.22	17.58	26.88
p-value	<0.001	<0.001	<0.001
Density /1cm²			
No improvement	10 (27.1)		
Poor improvement	18 (48.5)	17 (45.9)	6 (16.2)
Fair improvement	9 (24.3)	18 (48.6)	15 (40.6)
Excellent improvement		2 (5.4)	16 (43.2)
Mean	0.97	1.60	2.27
S.D.	0.73	0.60	0.73
t-value	8.15	16.19	18.86
p-value	<0.001	<0.001	<0.001
Hair Loss			
No improvement	1 (2.7)		
Poor improvement	18 (48.6)	9 (24.3)	2 (5.4)
Fair improvement	18 (48.6)	25 (67.6)	22 (59.5)
Excellent improvement		3 (8.1)	13 (35.1)
Mean	1.46	1.84	2.27
S.D.	0.56	0.55	0.65
t-value	15.92	20.20	21.19
p-value	<0.001	<0.001	<0.001

Table 5: Objective improvement among hair examinations at different follow ups (N=37)

Hair examination	1 Month	2 Months	3 Months
Hair Texture			
Poor improvement	30 (81.1)	13 (35.1)	3 (8.1)
Fair improvement	7 (18.9)	23 (62.2)	21 (50.8)
Excellent improvement		1 (2.7)	13 (35.1)
Mean	1.19	1.68	2.27
S.D.	0.40	0.53	0.61
t-value	18.22	19.24	22.72
p-value	<0.001	<0.001	<0.001
Density /1cm²			
No improvement	9 (24.3)	1 (2.7)	
Poor improvement	18 (48.6)	13 (35.1)	7 (18.9)
Fair improvement	10 (27.0)	21 (56.8)	20 (54.1)
Excellent improvement		2 (5.4)	10 (27.0)
Mean	1.03	0.73	2.08
S.D.	1.65	0.63	0.68
t-value	8.61	15.84	18.55
p-value	<0.001	<0.001	<0.001
Hair Loss			
No improvement	1 (2.8)		
Poor improvement	18 (48.6)	8 (21.6)	3 (.1)
Fair improvement	18 (48.6)	25 (67.6)	19 (51.4)
Excellent improvement		4 (10.8)	15 (40.5)
Mean	1.46	1.89	2.32
S.D.	0.56	0.57	0.63
t-value	15.92	20.30	22.59
p-value	<0.001	<0.001	<0.001

Table 6: Final evaluation of Hairbac tablet and Hairbac oil after 3 Months among diffused hair loss female patients (N=37)

Improvement	Assessed by		χ^2 (p-value)
	Subjective	Objective	
Poor	6 (16.22)	7 (18.92)	0.284(0.87)
Fair	19 (51.35)	20 (54.05)	
Excellent	12 (32.43)	10 (27.03)	
Score Mean $\pm$ S.D.	15.65 $\pm$ 3.22	15.60 $\pm$ 3.03	
Range	9-22	10-23

Figure 1: Final Evaluation of Hairbac Tablet and Hairbac Oil after 3 Months treatment among diffused Hair Loss in female patients
 The above graph shows that Hairbac tablet and oil showed subjective improvement in 83.78 % of cases, whereas Hairbac tablet and oil have shown objective improvement in 81.08 % of cases. This includes fair and excellent results.

The poor improvements in the hair texture were observed in 30 (81.10 %) patients after one month, in 12 (32.40 %) patients after two months and in 1 (2.7 %) patient after three months. The fair improvements were observed in 7 (18.9 %), 24 (64.90 %) and 24 (64.90 %) patients after 1, 2 and 3 months respectively. The excellent improvement was observed in only 1 (2.7 %) and 12 (32.40 %) patients after 2 and 3 months respectively. The mean for improvements after 1, 2 and 3 months were 1.19, 1.68 and 2.30 respectively. The standard deviation for one month was 0.40, two months was 0.58 and 2.30 for three months. The t-value for one month, two months and three months are 18.22, 17.58 and 26.88 respectively. The improvement in density/ 1 cm square was as described. There were 10 (27.10 %) patients who observed no improvement in hair density after one month. There were 18 (48.50 %), 17 (45.90 %) and 6 (16.20) patients were shown poor improvement after 1, 2 and three months respectively. The fair improvement was shown in 9 (24.30 %), 18 (48.60 %) and 15 (40.60 %) patients after one, two and three months respectively. The excellent improvement was shown in 2 (5.4 %) and 16 (43.20 %) after two and three months respectively. The mean of density improvement was 0.97 for one month, 1.60 for two month and 2.27 for three months. The standard deviation for one month was 0.73, 0.60 for two months and 0.73 for three months. The t-value for this were 8.15, 16.19 and 18.86. In hair loss no improvement is shown in only one patient (2.7%). The poor improvement was shown in 18 (48.6 %), 9 (24.3 %) and 2 (5.4 %) patients after one, two and three months respectively while fair improvement was shown in 18 (48.6 %), 25 (67.6 %) and 22 (59.50 %) patients after one, two and three months respectively. The excellent improvement was shown only in 3 (8.1 %) and 13 (35.10 %) patients after two and three months respectively. The mean for improvement in hair loss after one month was 1.46, 1.84 and 2.27 after one, two and three months respectively. The standard deviation for one, two and three months are 0.56, 0.55 and 0.65. t- Value for one month, two months and three months are 15.92, 20.20 and 21.19 respectively. (Table 4)

Objective improvement among hair examinations at different follow ups (N=37)

The hair texture was improved in following manner. Poor improvement was observed in 30 (81.10 %) patients after one month, 13 (35.10 %) showed again poor improvement after two month and only 3 (8.10 %) patients showed poor improvement after three months. Fair improvement was observed in 7 (18.90 %), 23 (62.20 %) and 21 (50.80 %) patients after one, two and three months respectively while excellent improvement was observed in only 1 (2.7 %) and 13 (35.10 %) patients after two and three months respectively. The mean score was 1.9 for one month, 1.68 for two month and 2.27 for three months. Standard deviations were 0.40, 0.52 and 0.61 for one, two and three months respectively. Paired t-value for one month, two months and three months are 18.22, 19.24 and 22.72 which shows very highly significant improvement. The density of hair in per cm square was also observed. The values are mentioned here. No improvement was observed in 9(24.3 %), 1(2.7%) patients after one and two months respectively. Poor improvement was

observed in 18 (48.6 %), 13 (35.1 %) and 7 (18.9 %) after one, two and three months respectively. Fair improvement was observed in only 10 (27 %), 21 (56.8 %) and 20 (54.1 %) patients after one, two and three months while excellent improvement was observed in only 2 (5.4 %) and 10 (27 %) patients after two and three months respectively. The mean for one month, two month and three months are 1.03, 0.73 and 2.08 respectively. The standard deviations are 1.65, 0.63 and 0.68 after one, two and three months respectively. T-value for one month, two months and three months are 8.61, 15.84 and 18.55 respectively. The improvement in hair loss was also observed. Only 1 (2.8%) patient showed no improvement in hair loss after one month. Poor improvement was observed in 18 (48.6 %), 8 (21.6 %) and 3 (0.1 %) patients after one, two and three months respectively. Fair improvement was observed in 18 (48.6 %), 25 (67.6 %), 19 (51.4 %) patients after one, two and three months respectively while excellent improvement was observed in only 4 (10.8 %) and 15 (40.5 %) patients after two and three months respectively. The mean for one, two and three months are 1.46, 1.89 and 2.32 respectively. The standard deviations were 0.56, 0.57 and 0.63. T- Value for one, two and three months was 15.92, 20.30 and 22.59 respectively. (Table 5)

Final evaluation of Hairbac tablet and Hairbac oil after 3 Months among diffused hair loss female patients (N=37)

The final evaluation of the effect of Hairbac tablet and Hairbacoil after three months of treatment assessed by the study subjects and objective evaluation by the treatment physician as shown in Table 4. The mean subjective score was 15.65 with standard deviation 3.22 and objective score mean was 15.60 with standard deviation 3.03. There was no significant difference in the subjective and objective score evaluation. The excellent improvement was assessed by 32.43 % subject as compared to 27.13 % by the physician. No significant association was found between improvement level and assessed persons $\chi^2=0.284$, $p=0.87$. The comparative evaluation of subjective and objective assessment was also shown in Figure 1 through bar diagram. (Table 6)

DISCUSSION

The treatment and management of diffuse hair loss in both the sexes among all age group was extremely complex. Hormone therapy, Use of e-reductase inhibitions, synthetic drugs, minoxidil, new technologies in cosmetics transplant surgery and hair replacement systems are available for the treatment of hair loss/fall with some adverse effects. The result of present study with poly-herbal formulation - Hairbac tablet and Hairbacoil had shown that this combination is beneficial in the management of diffuse hair loss. In the context of hair texture 32.4 % respondents were found themselves as excellent improvement and 35.1 % respondents were assessed by the treating physicians as excellent improvement. In the density / 1 cm² 43.2 % respondents were assessed as subjective and 27.0 % as objective for excellent improvement. 35.1 % respondents were assessed as excellent improvement on subjective basis and 40.5 % as objective basis in context of hair loss. It is observed

that in overall one third subjects found an excellent improvement.

Probable Mode of action of trial drug Hairbac tablet and Hairbac oil

As mentioned earlier Each Hairbac tablet contains various herbs and Hairbac oil contains various oils and herbs at different concentration. The synergetic effect of combination of these ingredients is resulting in to different pharmacological actions. Various studies conducted on these herbs has proven that these herbs have immunosuppressive, antioxidant, immune-booster, anti-bacterial, anti-inflammatory and anti-allergic properties, rejuvenative, alterative, demulcent, diaphoretic, diuretic, blood purifier antiseptic, demulcent actions.⁵⁻¹⁰.

CONCLUSION

The present study concludes that Hairbac tablet and oil is a very effective and absolutely safe treatment in the management of diffused hair loss. The beneficial effects of Hairbac Tablets and Oil assessed in the context of hair texture, density / 1 cm² and hair loss among females suffering with diffuse hair fall showed highly significant improvement without any adverse effects assessed by the respondents. Therefore, it can be concluded that Hairbac Tablets and Oil is safe and cases effective treatment among diffuse hair loss.

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