Original Research Article

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Indulekha Bringha hair oil significantly improves hair density and reduces hair fall from roots in comparison to coconut oil in a randomized, single blinded, placebo-controlled clinical trial

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ABSTRACT

Background: This clinical evaluation was conducted with an objective of determining the safety and efficacy of medicated Ayurvedic hair oil (Indulekha Bringha oil) on healthy Indian adults (men and women) suffering from hair loss, by randomized, single-blinded controlled study.

Methods: The subjects were screened on the parameter of specified hair density and hair thinning, having no underlying disorder that may have caused the hair loss. The study included a washout period, following which subjects were randomized in one of the treatment groups. The treatment period was for four months during which the subjects visited the study center every month for their follow-up measurements.

Results: Indulekha Bringha oil showed efficacy from the first month of regular use. It was significant in improving hair density measure versus coconut oil and untreated control group by the end of the treatment phase. The follicular density was found to increase about 20% by the end of the treatment phase. There was above 40% reduction in hair fall (from the root) count by four months of regular oil use.

Conclusions: Indulekha Bringha oil was highly effective in promoting hair growth and controlling excessive hair fall from the roots and can be considered as a reliable option to provide hair growth benefits.

Keywords: Hair treatment, Bringha oil, Hair fall, Hair density, Safety testing

INTRODUCTION

Hair fall, and hair loss are one of the most common concerns and beauty-related issues among women and men.¹ Hair loss and hair fall have been experienced since years in all age groups irrespective of ethnicity, gender, and status.² As per the American Academy of Dermatology Association, the normal range of shedding hair every day ranges from 50-100 hair, however when the rate of new hair growth and hair loss becomes unequal due to whatever reason, then this turns into a condition known as hair thinning, hair loss or alopecia.^{3,4} It is a quite common condition among men and women, and it

imposes substantial mental and psychological burden on individuals. There are several different types of hair loss, include androgenic alopecia, alopecia areata and telogen effluvium; of them, androgenetic alopecia is the most common condition. Hair loss is a multifactorial phenomenon and may happen due to various intrinsic and extrinsic factors such as genetics, medical condition, lifestyles, stress, and nutritional inadequacies. Oxidative stress and deficiency of essential nutrients to hair follicles are mainly responsible for hair thinning. Hair loss and impact adversely on overall hair health. Major key causes for hair loss and hair thinning are intrinsic factors (e.g., hormonal change, genetics, and age), lifestyle, stress (internal and external), environmental, lack of proper

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nutrition to the hair follicles due to impaired vascularization, and external factors such as, unhealthy scalp, infections, heat and chemical treatments, exposure to pollution, and medication. While deficiencies and other underlying factors may be corrected with proper medicine, improper blood circulation in the scalp leading to hair fall needs local intervention in the form of massage for stimulation.

Hair oiling has been an ancient part of Indian culture for thousands of years. ¹⁴ Ayurvedic literatures have given profound information on benefits of oiling in hair fall control. ¹⁵ The traditional systems of medicine like Ayurveda advocate regular application of hair oil to keep the scalp and hair healthy, shiny and prevent premature greying and hair fall. Oiling has benefits by means of enhanced blood circulation and good conditioning medium to the hair shaft. ¹⁶ There are various Ayurvedic ingredients documented over the years, which aid in hair fall control. ¹⁷

This study focused on the hair fall and hair loss concerns in men and women. Indian human volunteers who do not have a severe medical condition yet have a self-perception of hair loss and hair fall and confirmed documented lesser hair density were recruited in this study. A blood test of volunteers was conducted to rule out any medical condition.

METHODS

Evaluate the effect of Indulekha Bringha oil in hair fall reduction and hair growth promotion; a single blinded, randomized, comparative, controlled study was conducted at MS Clinical Research Pvt. Ltd., Bangalore, India, between July 2016 to November 2016. This study was approved by an Independent Ethics Review Board, conducted in accordance with existing standards for Good Clinical Practices and in accordance with the declaration of Helsinki. Each subject provided a written informed consent prior to participating in any study-related activities.

Study design

This was a single-blind, randomized study consisting of three test groups: group A (Indulekha Bringha hair oil), group B (coconut hair oil) and group C (untreated/no oil) (Figure 1).

Indulekha Bringha hair oil is an Ayurvedic proprietary oil formulated with herbal ingredients used for treating hair and scalp-related problems such as hair thinning, hair fall and hair loss. The ingredients of the hair oil are: Bhringaraj, Svetakutaja, Nimba, Amalaki, Brahmi, Kumari, Draksha, Giloy, Yashtimadhu, Curry leaves, Vatadha, Camphor, Dugdha and Nalikera. Each 100 ml of Indulekha Bringha oil is prepared out of *Wrightia tinctoria* (12.12 g), *Aloe barbadensis* (1.816 g), *Vitis vinifera* (1.816 g), *Eclipta alba* (1.816 g), *Phyllanthus emblica* (1.816 g),

Tinospora cordifolia (1.816 g), Murraya koenigii (4.73 g), Prunus amygdalus (1.18 g), Bacopa monnieri (1.18 g), Glycyrrhiza glabra (0.187 g), Azadirachta indica (0.75 g), Cinnamomum camphora (camphor) (0.75 g), cow's milk (3.0 ml), coconut oil (25 ml) and coconut milk oil (75 ml). The oil is made following the Tailapakavidhi (procedure prescribed in Ayurvedic texts).

Commercially available marketed benchmark 'coconut oil' was used as a placebo and as one of the comparators in the study.

On the screening visit, 160 male and female subjects in nearly 1:2 ratio were enrolled based on the inclusion and exclusion criteria. Subjects between 20-45 years of age (both the ages inclusive) and having hair density of >100 and <200 hair follicle in per square cm as per Trichoscan® measurement were enrolled in the study, while subjects who had undergone hair growth treatment within 3 months before enrolment, with active scalp disease, hair transplants, chronic systemic diseases and hypersensitivity to cosmetic or pharmaceutical products were excluded from the study.

Subjects were randomized into three groups. Subjects were instructed to apply the oils thrice a week (3-8 ml in quantity), depending on need and requirement, which was to be followed by a gentle scalp massage. The test oil was allowed to stay on scalp for at least 30 minutes and then it was advised to wash thoroughly with a neutral shampoo provided. The subjects who were randomized to untreated control used only shampoo at least twice in a week throughout the study.

Subjects underwent two weeks of wash out period during which they were provided with neutral shampoo to use at home and were instructed not to use it more than thrice a week. After two weeks of washout period, baseline assessments were performed, and subjects were given their respective test products after randomization.

Assessment parameters

The assessment parameters used for evaluation of efficacy were as follows.

Hair fall evaluation by comb test

When the hair is detangled with comb as a usual practice, it results in hair fall due to combing force. Total number of hair fall including hair fall from the roots and hair fall due to breakage from the hair shaft were assessed by % reduction calculation and to find out statistical significance.

Assessment for hair follicular density

A phototrichogram assessment was performed using cutiscope camera attachment with digital zoom and Trichoscan® software. About 1 cm² area on the vertex of the scalp was shaved by trimmer and captured using digital

camera with optical zoom. Number of hairs in the area was counted by the software as hair density measure.

Statistical analysis

Demographic characteristics and results of the study summarized with statistics, including average and standard deviation (SD). The paired t-test applied to find out the significant difference in the mean values of scales from baseline to follow-up visit. Student t-test of unequal variance was performed to evaluate the level of difference between a pair of test groups.

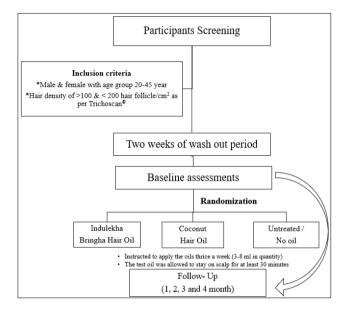


Figure 1: Study flow design.

RESULTS

A total of 117 subjects aged between 20 and 45 completed the study, with each of the three groups comprising 39 participants. The Indulekha Bringha oil test group included 28 females and 11 males, the coconut oil group had 26 females and 13 males, and the untreated group was made up of 28 females and 11 males (Table 1).

Table 1: Demographic characteristics.

Characteris -tics	Indulekha Bringha oil test group	Coconut oil group	Untreated group
Age (mean)	35.51	36.46	35.18
Male, n (%)	11 (31.4)	13 (37.14)	11 (31.4)
Female, n (%)	28 (34.14)	26 (31.70)	28 (34.14)

Hair density

The Indulekha Bringha oil showed significant improvement in hair density measure after one month and it was progressive during the treatment phase. The Indulekha Bringha oil was found to be significantly better

in hair density improvement than control (no oil) and coconut oil group at the end of the treatment phase (Table 2 and Figures 2 and 3). The hair follicular density was found to increase by ~20% by the end of treatment phase. At the end of treatment phase, the Indulekha Bringha oil was able to provide 3 times more benefit (change from baseline: delta between pre and post treatment) in terms of increase in the hair density than untreated control. The benefit (change from baseline: delta between pre and post treatment) with Indulekha Bringha oil was 2 times more than the coconut oil by the end of treatment phase. Coconut oil also showed significant improvement versus baseline after 3 months of product use, however the hair density remained almost constant from month 3 till the end of treatment phase. Therefore, the statistical significance attained over baseline at month 3 was found to be maintained till the end of the study. The untreated control i.e. "no oil" group showed improvement in hair density however was not found to be progressive with time and remain almost constant from 2nd month onward till end of the study.

The efficacy in Indulekha Bringha oil group was significantly higher at all time points in the treatment phase. The Indulekha Bringha oil performed significantly better to coconut oil with four months post treatment. The Indulekha Bringha oil was also significantly better than untreated control (no oil) from month 2 till the end of the study. Coconut oil was found to be significantly better than untreated control (no oil) from month 3 till end of the study.

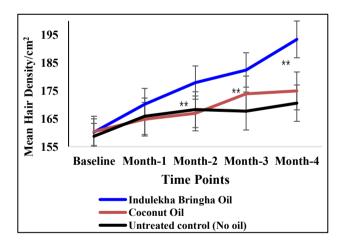


Figure 2: Graphical representation of improvement in the hair density.

Hair fall from the roots by comb test

Comb test is a representation of hair fall. A count of hair fall with bulb represents hair shedding. The hair in the telogen phase falls easily. The other reason of hair fall from the root can be associated with hair strength. The Indulekha Bringha oil showed significant improvement from hair fall after 2 months of product application. During the treatment phase the improvement was progressive. Compared to the baseline the hair fall count was found to

be significantly lesser at the end of the study. At the end of the treatment phase, the hair falls (from root) was significantly reduced by over 40%.



Figure 3: Photographical representation of improvement in the hair density at month 4.

Coconut oil also showed comparatively delayed responses, where statistical significance was achieved after 3 months when compared to the baseline. The untreated control

group showed no statistical change in the hair fall with bulb during the study (Table 3 and Figure 4).

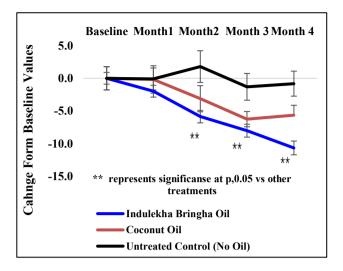


Figure 4: Graphical representation of reduction in hair fall from roots.

Table 2: Hair density assessment.

Test groups and time points	Baseline	Month-1	Month-2	Month-3	Month-4		
Indulekha Bringha oil							
N	39	39	39	39	39		
Mean±SD	160.2 ± 29.81	170.21±35.31**	177.94±37.14**	182.46±38.41**	193.39±41.1**		
Median	153.10	167.13	169.17	176.80	190.23		
Min/max	105.23/228.57	111.13/258.87	94.77/251.17	99.5/256.63	126.3/285.77		
LCL/UCL	150.54/169.86	158.76/181.65	165.91/189.98	170.01/194.91	180.07/206.71		
CFB	-	10.01	17.74	22.26	33.19		
Standard error	4.77	5.65	5.95	6.15	6.58		
P value versus baseline	-	0.0070	< 0.0001	< 0.0001	< 0.0001		
Coconut oil							
N	39	39	39	39	39		
Mean±SD	160.41±34.31	164.86±37.65	166.91±38.92*	173.9±39.71**	174.96±42.28**		
Median	157.63	161.20	172.17	174.63	164.97		
Min/max	100.73/273.8	91.33/267.53	100.1/263.17	102.6/262.87	106.17/269.57		
LCL/UCL	149.29/171.53	152.65/177.06	154.3/179.53	161.03/186.77	161.26/188.67		
CFB	-	4.44	6.50	13.49	14.55		
Standard error	5.49	6.03	6.23	6.36	6.77		
P value versus baseline	-	0.2493	0.0705	0.0006	0.0029		
Untreated control (no oil treatment)							
N	39	39	39	39	39		
Mean±SD	158.74±28.81	165.89±40.79*	168.25±40.07**	167.76±42.38**	170.59±40.65**		
Median	160.77	170.57	170.90	158.87	175.40		
Min/max	104.47/213.6	94/244.2	89.77/242	89.77/250.23	105.33/246.37		
LCL/UCL	149.39/168.08	152.67/179.11	155.26/181.24	154.02/181.5	157.41/183.76		
CFB	-	7.15	9.52	9.03	11.85		
Standard error	4.61	6.53	6.42	6.79	6.51		
					0.0072		

^{**}P\le 0.05 and *p\le 0.1

Table 3: Hair fall reduction (comb test).

Test groups and time points	Baseline	Month-1	Month-2	Month-3	Month-4			
Indulekha Bringha oil								
N	39	39	39	39	39			
Mean±SD	24.54±16.88	22.56±15.66	18.67±12.97**	16.51±12.08**	13.87±9.28**			
Median	21.00	17.00	15.00	13.00	13.00			
Min/max	7/89	5/60	0/50	0/52	1/47			
LCL/UCL	19.07/30.01	17.49/27.64	14.46/22.87	12.6/20.43	10.86/16.88			
CFB	-	-1.97	-5.87	-8.03	-10.67			
Standard error	2.70	2.51	2.08	1.93	1.49			
P value versus baseline	-	0.3468	0.0099	0.0003	< 0.0001			
Coconut oil								
N	39	39	39	39	39			
Mean±SD	20.38±11.04	20.21±13.12	17.26±12.5*	14.13±7.31**	14.74±9.42**			
Median	19.00	18.00	17.00	15.00	15.00			
Min/max	3/50	4/60	3/75	3/29	0/39			
LCL/UCL	16.81/23.96	15.95/24.46	13.2/21.31	11.76/16.5	11.69/17.8			
CFB	-	-0.18	-3.13	-6.26	-5.64			
Standard error	1.77	2.10	2.00	1.17	1.51			
P value versus baseline	-	0.8936	0.0517	< 0.0001	0.0003			
Untreated control (no oil treatment)								
N	39	39	39	39	39			
Mean±SD	18.31±11.16	18.21±10.55	20.1±15.15	17±12.81	17.49±11.96			
Median	17.00	19.00	17.00	13.00	14.00			
Min/max	3/50	2/60	3/60	3/70	3/55			
LCL/UCL	14.69/21.93	14.78/21.63	15.19/25.01	12.85/21.15	13.61/21.36			
CFB	-	-0.10	1.79	-1.31	-0.82			
Standard error	1.79	1.69	2.43	2.05	1.92			
P value versus baseline	-	0.9371	0.4112	0.4909	0.6245			

^{*}P≤0.1 and **p≤0.05

DISCUSSION

Bringharaj, amla, curry leaves, camphor are known to have several health benefits, including supporting hair growth, premature greying and alopecia. ^{18,19} Herbal-based hair oils offer a natural, safe, and effective solution for maintaining optimal scalp and hair conditions, thereby enhancing both the health and aesthetic appeal of hair. ²⁰

The improvement in hair density can be attributed to two main factors: reduced hair fall, likely due to the extension of the Anagen and Telogen phases, and follicular regeneration. Regular oiling is known to enhance blood circulation, and when the oil contains active ingredients, it can further promote hair growth by both regenerating follicles and reducing hair fall. The key ingredients of Indulekha Bringha oil, namely Bhringaraj, Svetakutaja, Nimba, Amalaki, Brahmi, Kumari, Draksha, Giloy, Yashtimadhu, Curry leaves, Vatadha, Camphor, Dugdha and Nalikera, have hair growth stimulating properties. Studies conducted using poly herbal oils with similar ingredients also showed hair growth which are in line with the present study. ^{21,22}

The results indicate that the application of Indulekha Bringha oil led to a notable increase in hair follicular density, as evidenced by the Phototrichogram assessment, while the comb test confirmed a significant reduction in hair fall. Notably, the Ayurvedic Indulekha Bringha oil demonstrated added benefits, with significant efficacy perceived earlier and significantly higher compared to coconut oil and the untreated control. These results clearly show that the Ayurvedic oil has a statistically significant impact on reducing hair loss and improving hair growth, making it suitable for regular use as a primary product for hair fall control and hair growth. Additionally, the Ayurvedic oil's effectiveness suggests it could be considered as adjuvant therapy in hair loss treatments, particularly in the Indian context, where oil application is culturally accepted.

Limitations

The current study is limited to the Indian population, therefore there may be a lack of generalizability to other populations and ethnicities. Additionally, underlying systemic conditions such as hormonal influences, genetic and lifestyle factors contributing to increased stress can

influence hair growth which were not evaluated in the current study. Despite these limitations, the study showed significant improvement in hair growth as evaluated by dermatological, instrumental and subject self-assessment.

CONCLUSION

The treatment regimen, involving oil application three times per week, reflects a widely practiced consumer habit in India. Indulekha Bringha oil (the test oil) has shown clinically proven efficacy in enhancing hair density and significantly reducing hair fall from the roots. This Ayurvedic oil not only demonstrated these benefits but also outperformed coconut oil and the untreated control groups, with its significant efficacy being observed both earlier and to a greater extent. These findings emphasize that Ayurvedic Indulekha Bringha oil is highly effective in promoting hair growth and controlling excessive hair fall from the roots. Given its proven benefits, it stands out as a reliable option for those seeking hair growth benefits.

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Conflict of interest: None declared

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Institutional Ethics Committee

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