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To Evaluate the Efficacy of "Rovaan Poshak Taila" in the Management of Khalitya (Diffuse Alopecia)

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ABSTRACT

Objectives: To Evaluate the Efficacy of "*Rovaan Poshak Taila*" in the Management of *Khalitya* (Diffuse Alopecia) **Methods:** A total of 55 subjects who were suffering from *Khalitya* (Diffuse Alopecia) were included in the study. Out of total 55 subjects, only 50 subjects completed the trial. The clinical assessment recorded for the *Rovaan Poshak Taila* in 50 subjects was evaluated based on improvement in *Kandu* (Itching on scalp), *Kesha Bhoomi Rukshata* (Dryness on scalp), *Darunaka* (Dandruff), *Keshchyuti* (Hair loss/day), hair texture status and hair pull test. Clinical parameters were assessed at Day 0, Day15 Day30 and on follow up day (Day 45). All subjects were given *Rovaan Poshaka Taila* for local application on the scalp for 10 minutes, keeping up overnight and rinsing the next morning, performing it thrice a week for 30 days. **Results:** Treatment with *Rovaan Poshak Taila* for 30 days resulted in a significant decrease in hair loss/day Score from 1.909± 0.5535 to 1.453±0.5740 & 0.9800±0.9145 & 0.9800±0.8687 (mean ± SD, P<0.0001; t=3.204; t=6.427; t = 6.427) on Day15, Day 30 & on Day 45. This result indicates that *Rovaan Poshak Taila* is able to control the *Keshchyuti* (Hair loss/day) on day 30 with hair loss on 51st to 100th / day from frequent hair loss of 101 to 120 hair loss from Day 0.**Conclusion:** The study revealed that *Rovaan Poshak Tail* is effective in the treatment of *Khalitya* (Diffuse Alopecia).

Key Words Rovaan Poshak Tail, Hair loss, Alopecia, Khalitya

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INTRODUCTION

Alopecia is a very common medical condition in which there is partial or complete, sudden or gradual loss of hair either from a single area and the multiple areas from head, face and any other part of the body. Diffuse alopecia is a condition which is characterised by a decrease in the hair density all over the scalp. Hair is an ectodermal structure with great cosmetic importance. It helps an individual to maintain self-image and carry on healthy and meaningful social interactions¹. Normal hair cycle results in replacement of every hair on the scalp by 3-5 years². Alopecia is

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significant source of patient distress and it is a matter of concern in any individual irrespective of age and gender, more so in females³.

The probable causes of diffuse alopecia were found to be psychological stress in 30%, fever in 33%, abortion and delivery in 21%, trauma and surgical operation in 13%, and hypothyroidism in 10%. In 57% patient's more than two factors, while in 6% no probable cause could be found on the basis of history⁴. Losing hair in strands or clumps on their cloths and pillow when they wake up in the morning, thinning of hair, easy breaking of hair are the sign and symptoms of alopecia. Sometimes itching or burning sensation, dandruff and redness on the scalp also present. Diffuse hair loss usually occurs without any inflammation or scarring.

Khalitya- Diffuse alopecia or diffuse hair fall can be clinically correlated with khalitya in Ayurveda text according to its sign and symptoms. Khalitya is mainly a Pitta dominant Tridoshaja Vyadhi⁵ where Tejas Mahabhoota combining with Vatadi Dosha reaches the Shira Kapala and cause hair fall by Dahana of Roma Koopa (hair follicles)⁶. "Ayurveda" the traditional Indian system of medicine reports number of herbs for treatment of hair loss without any adverse effect. The present study is intended to assess the efficacy of Rovaan Poshak Taila in the condition of Khalitya (Diffuse Hair fall).

REVIEW OF LITERATURE

- A. DISEASE REVIEW
- > KHALITYA

KESHOTPATTI (ORIGIN OF HAIR)

Ayurveda believes that the human body is consist of main seven body element as dhatus viz. Rasa, Rakta, Mamsa, Meda, Asthi, Majja and Shukra⁷. In spite of some controversies the major part of them believed that the production of the latter dhatus occur from the former by the function of their respective agni⁸. It has been further explained that, from the poshakansha of former dhatu there is not only production of latter dhatu but also consequently there is side by side production of its upadhatu and mala. There is no detailed description found in ayurvedic classics regarding the production of hair in particular, but it has been started in the process of dhatu nirmana that when paka of asthidhatu occurs by its own agni the majja dhatu emerges from the sara bhaga and the same time hair of scalp and body and nails emerges as *mala*⁹. According to ancient classics the hair is one of the pitruj bhava means the structure, color and quantity of hair of a progeny are dependent on paternal side. Achaaryas have considered the hair as parthiva dravya because of its qualities like roughness, steadiness, and heaviness¹⁰.

KESHOTPATTI KALA

According to *charak* the *keshotpatti kala* in foetus is at seventh month during gestational age. While according to *vagbhatta keshotpatti kala* in foetus is six months¹¹.

KESH POSHAN (NUTRITION OF HAIR)

According to *Acharya Charak*, *Aaharapacana* in the *Kostha* (corresponding to gastro-intestinal digestion), which leads to separation of *Sarabhaga* September 10th 2021 Volume 15, Issue 2 **Page 245**





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(Nutrient fraction) of the *Aahara* from the *Kittabhaga* (the indigestible or undigested residue of the food). The waste product is responsible for the production and nutrition of so many things like sweat, urine, hair, nails etc. and among them are the hair follicles the hair of the head and beard, hairs of the body¹². According to *Acharya Sushruta*, *Kesha* get nutrition from the end part of the *dhamanis* which are attached to the *romakoopa*¹³.

SAMPRAPTI OF HAIR FALL (KHALITYA)

As per *Acharya Sushruta*, Vitiated *pitta* along with *vata* reaches *romakoopa* and causes hair fall and thereafter *shleshma* along with *shonita* obstructs

the *romakoopa* which leads to the stoppage of regeneration of hair and this condition is known as *khalitya*¹⁴. *Acharya Charaka* describes that *tejas* combining with *vatadi doshas* reaches the *shira kapala* and causes hair fall by *dahana* of *romakoopa* (hair follicles)¹⁵.

Nidan sevana- Ushna, Tikshna, Ruksha, Atilavanasevana, Ksharaatisevana + Divaswapana, Prajagarana, Atapasevana, Ushar bhomi + Manahtapa \rightarrow Vata prakopa, Pitta prakopa, Kapha prakopa \rightarrow Rasarakta dushti & Asthidhatwagni dusti \rightarrow Kesha patana & Siramukha avarodha \rightarrow Khalitya.

B. DRUG REVIEW

Table 1 Composition of *Rovaan Poshak Taila*

S.	Ingredients	Latin name	Part used	Qty	Properties
No.					
1.	Keshraj	Eclipta alba	Whole plant	300 mg	Keshya ¹⁶
2.	Madhuyasthi	Glycyrrhiza glabra	Root/ stem	200mg	Keshya ¹⁷
3.	Vibhitaki	Terminalia bellirica	pericarp	150mg	The antibacterial and antifungal
					activities protect hair root from
					infection and degeneration ¹⁸
4.	Amla	Emblica officinalis	pericarp	100mg	Strengthens hair follicle ¹⁹
5.	Nimba	Azadirachta indica	Leaf/ seeds	100mg	Hair growth promoting activities ²⁰
6.	Brahmi	Bacopa monnieri	Whole plant	50mg	The net result in increased follicular
					size by large blood supply ²¹
7.	Neelinee	Indigofera tinctoria	Whole plant	25 mg	Usefull for promoting the growth of
	(Neelpushpa)				hairs ²²
8.	Indravaruni	Citrullus colocynthis	fruit	25 mg	Hair growth promoting ²³
9.	Go dugdha			1ml	Ksheera paka kalpana – a unique
					dosage form for special group of
					patients ²⁴
10.	Rosenary oil	Rosmarinus officinalis	leaf	.01 ml	Hair growth and anti-microbial and
					ant parasitic activities ²⁵
11.	Til Taila	Sesamum indicum	seed	9.88 ml	Hair restorer and useful in baldness
					and alopecia ²⁶

MATERIALS AND METHODS

The present study was planned to evaluate the efficacy of *Rovaan Poshak Taila*. Subjects aged between 18 to 45 years who has Diffuse alopecia and considered who do not have any acute medical condition or chronic medical/surgical condition

that requires both immediate or continuous medical monitoring and treatment were enrolled into the study. All subjects were given *Rovaan Poshaka Taila* for local application to the scalp for 10 minutes and keeping up overnight and rinse next morning thrice a week for 30 days.





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The efficacy of *Rovaan Poshak Taila* was evaluated based on clinical improvement in *Kandu* (Itching on scalp), *Kesha Bhoomi Rukshata* (Dryness on scalp), *Darunaka* (Dandruff), *Keshchyuti* (Hair loss/day), hair texture status and hair pull test and Clinical parameters were assessed at Day 0, Day15 Day30 and on follow up day (Day 45).

A total of 50 subjects who were suffering from the following symptoms were included in the study

- *Kandu* (Itching on scalp)
- Kesha Bhoomi Rukshata (Dryness on scalp)
- Darunaka (Dandruff)
- *Keshchyuti* (Hair loss/day)
- Hair Texture
- Hair pull test

Inclusion Criteria

- Age between 18-45 years
- Subjects having diffuse alopecia
- Subjects willing to participate in the study
- Subjects able to provide signed ICF prior to any study related procedure

Exclusion Criteria

- Subjects below 18 years and above 45 years of age
- Subjects on immunosuppressive drugs with evidence of skin infection
- Subjects who had used any topical therapy for diffuse hair loss in the 2 weeks prior to the initiation of study
- Individuals with immediate life threatening diseases such as pre-existing cardiovascular, liver or neoplastic diseases

- Individuals who received any immunosuppressant, sedative, hypnotic or tranquilizer within 14 days prior to enrolment.
- Individuals with any psychiatric illness which may impair the ability to provide written ICF.
- Individuals participating in any other clinical trial.
- Pregnant and lactating females.

STUDY PRODUCT

Rovaan Poshak Taila is a polyherbal formulation recommended for the treatment of hair problems which manufactured by Multani Pharmaceuticals Ltd., New Delhi on the basis of ancient Ayurveda processes known as Tail Pak Vidhi and Kshir Pak Vidhi. To utilize the properties of milk along with properties of herbs our ancestors invented the Kshirpaka Kalpana. In any preparation of milk, on gradual increase in temperature the solubility of fat and protein in the media also increased which may enhance the extraction of the medicinally important active constituents and retain them in the media. It would also be supportive in the absorption of the medicament (Table 1).

STUDY DESIGN AND PROCEDURE

This study was an open labeled single armed study of 50 subjects of *Khalitya* (Diffuse alopecia). Each patients complete medical history including personal data, a description of symptoms and details of past medical history (especially local fungal infection, dandruff, pediculosis, trichotillomania, stress, diet, past illness and





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drugs), family history of hair problems and history of possible exacerbating factors. All the enrolled patients underwent a through clinical examination and scalp skin examination.

All the patient were advised *shiro abhyang* with *Rovaan Poshak Tail* on scalp till it gets absorbed, thrice a week for a period of 30 days. Recruited patient were advised pathya/apathya as per the ayurvedic concept as: *Pathya: Sasthikashali, Kshira, Amra, Amalaki, Dadima, Matulunga, Taila, Takra, Kanjika, Narikela, Yusha, Haritaki, Puranaghrita, Seka, Lepa, Shirobasti, Musta, Kumari.*

Apathya: Virudhha anna, Divaswapana.

Table 2 Clinical parameters analysis

Parameter

CRITERIA FOR ASSESSMENT OF RESULTS

Assessment of Subjective parameters

The clinical parameters were assessed at pretreatment day-Day 0, Day 15, Day 30 and on follow up (Day 45). Out of a total of 55 subjects, only 50 subjects completed the trial. The clinical assessment is recorded for the 50 subjects (Table No. 2).

The clinical parameters are as follows:

- Kandu (Itching on scalp)
- Kesha Bhoomi Rukshata (Dryness on scalp)
- Darunaka (Dandruff)
- Keshchyuti (Hair loss/day)
- Hair Texture status
- Hair pull test

		11000111 (0)		
1.	Kandu (Itching on scalp)	Occasionally (1)		
		Frequently & moderate (2)		
		Constantly & severe (3)		
		Absent (0)		
2.	Kesha Bhoomi Rukshata (Dryness	Negligible (1)		
on sc	alp)	Without discomfort on scalp (2)		
		With discomfort on scalp (3)		
		Absent (0)		
3.	Darunaka (Dandruff)	Visible inside the hair (1)		
		Visible over the hair (2)		
		Spread over the shoulder (3)		
		Up to 50 per day (0)		
4.	Keshchyuti (Hair loss/day)	51 to 100 / day (1)		
		101 to 200 /day (2)		
		> 200/ day (3)		
		No improvement (Same texture) (0)		
5.	Hair Texture	Poor improvement (A little smoother) (1)		
		Fair improvement(Greatly smoother) (2)		

Response
Absent (0)

6. Hair pulling test	
Grade 0	No improvement
Grade 1	Poor response <25% reduction
Grade 2	Moderate response 25-49 % reduction
Grade 3	Good response 50-74% reduction
Grade 4	Excellent response >75% reduction
·	

Extremely improvement (Smooth and shining) (3)



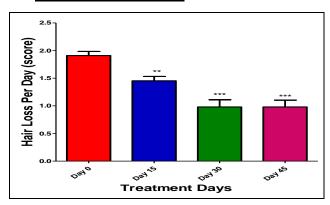


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OBSERVATION AND RESULT

Primary End-Point Assessment:

A. Keshchyuti (Hair loss/day)



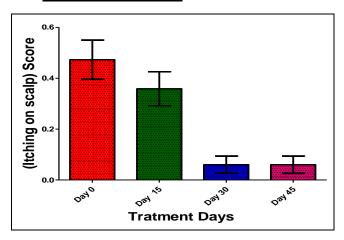
Graph 1 The changes Improvement in *Keshchyuti* (Hair loss/day) with Score

Treatment with *Rovaan Poshak Taila* for 30 days resulted in a significant decrease in Hair loss/day Score from 1.909± 0.5535 to 1.453±0.5740 & 0.9800±0.9145 & 0.9800±0.8687 (mean ± SD, P<0.0001; t=3.204; t=6.427; t = 6.427) on Day15, Day 30 & on Day 45 (Graph 1). By considering lower score, this result indicates that *Rovaan Poshak Taila* is able to control the *Keshchyuti* (Hair loss/day) on day 30 with hair loss 51 to 100 / day from frequent hair loss of 101 to 120 hair loss

from Day 0 (Table No.3). However, there is minimal improvement in *Keshchyuti* (Hair loss/day) Score on 15th day from Day 0 treatment.

Secondary End Points Assessments:

A. Kandu (Itching on scalp)



Graph 2 Kandu (Itching on scalp) with Score

Treatment with *Rovaan Poshak Taila* for 30 days resulted in a significant decrease in Itching on scalp Score from 0.4727 ± 0.07722 to 0.3585 ± 0.06650 & 0.0600 ± 0.03393 & 0.0600 ± 0.03393 (mean \pm SEM, P<0.0001; t=1.422; t=5.061; t=5.061) on Day15, Day 30 & on Day 45.

Table 3 Overall assessment of scalp health: Keshchyuti (Hair loss/day)

Parameter	Response	(Day 0)	Day 15	Day 30	Day 45
	Up to 50 per day (0)	0	0	19(38%)	17(34%)
	51 to 100 / day (1)	9(18%)	31(62%)	15(30%)	19(38%)
Keshchyuti (Hair	101 to 200 /day (2)	35(70%)	18(36%)	14(28%)	12(24%)
loss/day)	> 200/ day (3)	6(12%)	1(2%)	2(4%)	2(4%)

Table 4 Overall assessment of scalp health: *Kandu* (Itching on scalp)

Parameter	Response	(Day 0)	Day 15	Day 30	Day 45	
	Absent (0)	29 (58%)	32(64%)	47(94%)	47(94%)	
	Occasionally (1)	19 (38%)	18(36%)	3 (6%)	3(6%)	
Kandu (Itching	Frequently & moderate (2)	2 (4%)	0	0	0	
on scalp)						
<u>-</u> ·	Constantly & severe (3)	0	0	0	0	

By considering the lower score, this result indicates that *Rovaan Poshak Taila* was able to control *kandu* (Itching on scalp) Score on day 30 with absent in Itching from occasionally itching on

Day 0 (TableNo.4). However, there is minimal improvement in *Kandu* (Itching on scalp) Score on day15 from Day 0 treatment.

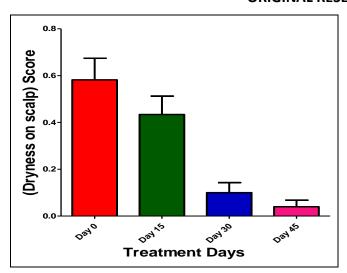
B. <u>Kesha Bhoomi Rukshata</u>

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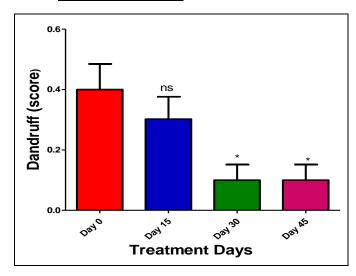
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Graph 3 Kesha Bhoomi Rukshata (Dryness on scalp) score Treatment with Rovaan Poshak Taila for 30 days resulted in a significant decrease Kesha Bhoomi Rukshata (Dryness on scalp) score from 0.5818 ± 0.09244 0.4340 to ± 0.07858 & 0.1000 ± 0.04286 & 0.0400 ± 0.02799 (mean \pm SEM, P<0.0001; t=1.570; t=5.040; t =5.668) on Day15, Day 30 & on Day 45. By considering lower score, this result indicates that Royaan Poshak Taila is able to Kesha Bhoomi Rukshata

(Dryness on scalp) Score on day 30 with Negligible Dryness on scalp & on day 45 with Absent in Dryness on scalp from without discomfort on scalp on Day 0 (Table No.5). However, there is minimal improvement in *Kesha Bhoomi Rukshata* (Dryness on scalp) score on day15 from Day 0 treatment.

C. <u>Darunaka</u> (Dandruff)



Graph 4 Darunaka (Dandruff) score

Table5 Overall assessment of scalp health: *Kesha Bhoomi Rukshata* (Dryness on scalp)

Parameter	Response	(Day 0)	Day 15	Day 30	Day 45
Kesha Bhoomi	Absent (0)	25 (50)	29 (58)	45 (90%)	48 (96%)
Rukshata	Negligible (1)	19 (38)	19 (38)	5(10)	2(4%)
(Dryness on	Without discomfort on scalp (2)	6 (12)	2(4%)	0	0
scalp)	With discomfort on scalp (3)	0	0	0	0

Table 6 Overall assessment of scalp health: *Darunaka* (Dandruff)

Parameter	Response	(Day 0)	Day 15	Day 30	Day 45
	Absent (0)	33 (66%)	36(72%)	46(92%)	46 (92%)
	Visible inside the hair (1)	15(30%)	12(24%)	3 (6%)	3 (6%)
Darunaka	Visible over the hair (2)	1(2%)	2 (4%)	1 (2%)	1 (2%)
(Dandruff)	Spread over the shoulder (3)	1(2%)	0	0	0

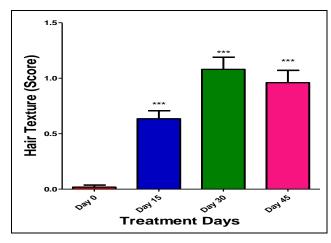
Treatment with *Rovaan Poshak Taila* for 30 days resulted in a decrease in dandruff score from 0.4000 ± 0.08449 to 0.1000 ± 0.05151 (mean \pm SEM, P<0.0001; t=3.121) on Day 30 & on Day 45. By considering lower score, this result indicates

that *Rovaan Poshak Taila* is able to reduce dandruff Score to absent on day 30 from Visible dandruff into the scalp on Day 0 (Table No.6). However, there is non-significant improvement in dandruff score on day15 from Day 0 treatment.

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D. Hair Texture

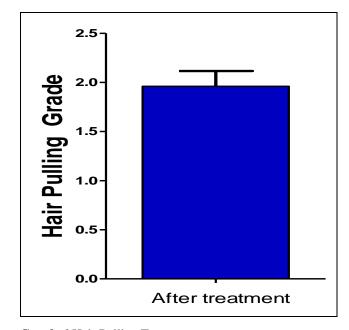


Graph-5 Hair Texture Score

Treatment with *Rovaan Poshak Taila* for 30 days resulted in improvement in hair texture score from 0.01852 ± 0.01852 to $0.6346 \pm 0.07281;1.080 \pm 0.1101$ & 0.9600 ± 0.1105 (mean \pm SEM, P<0.0001; t=5.217, t=8.898 & t=7.892) on Day 15, Day 30 & on Day 45. By considering lower score, this result indicates that *Rovaan Poshak Taila* is able to improve the hair texture Score to

greatly smoother hair from original rough texture in 30 days of treatment from Day 0 (Table No.7). However, the there is decease in texture of hair after dis-continuous of oil treatment to hair form day 30 to day 45.

E. Hair Pulling



Graph-6 Hair Pulling Test

Table 7 Overall assessment of scalp health: Hair Texture

Parameter	Response	(Day 0)	Day 15	Day 30	Day 45
	No improvement (Same texture) (0)		18(36%)	12(24%)	15(30%)
	Poor improvement (A little smoother) (1)		31(62%)	23(46%)	23 (46%)
Hair Texture	Fair improvement(Greatly smoother) (2)		1(2%)	14(30%)	11(24%)
	Extremely improvement (Smooth and shining) (3)		0	1 (2%)	1(2%)

Table 8 Overall assessment of scalp health: Hair pulling test

Parameter	Grade	Assessment Criteria	Response
_	Grade 0	No improvement	6 (12%)
Hair pulling test	Grade 1	Poor response <25% reduction	10 (20%)
	Grade 2	Moderate response 25-49 % reduction	17 (34%)
	Grade 3	Good response 50-74% reduction	14 (28%)

Treatment with *Rovaan Poshak Taila* for 30 days resulted to 25-49 % reduction in hair puling test with grade 2 in 30 days 1.960± 0.1564 (mean ± SEM), considering higher scale. The result was observed after the *Rovaan Poshak Taila* treatment for 30 days (Table No. 8).

DISCUSSION

Rovaan Poshak Taila is a polyherbal Ayurvedic formulation which contains herbs that have been proved effective in diffuse alopecia. Keshraj (Eclipta alba)-The methanol extract of whole plant when tested for hair growth promoting potential, exhibited dose dependent activity in September 10th 2021 Volume 15, Issue 2 Page 251





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C57BL6 mice²⁷. *Madhuyasthi* (*Glycyrrhiza* glabra) - Liquorices (*Glycyrrhiza* glabra) has a potent hair growth activity and after careful

checking of other safety parameters it can be used in herbal formulations to treat various types of Alopecia²⁸.

Table 8 Overall assessment of scalp health: Hair pulling test

Parameter	Grade	Assessment Criteria	Response
	Grade 0	No improvement	6 (12%)
Hair pulling test	Grade 1	Poor response <25% reduction	10 (20%)
	Grade 2 Moderate response 25-49 % reduction		17 (34%)
	Grade 3	Good response 50-74% reduction	14 (28%)

Vibhitaki (Terminalia bellirica) - The oil from seeds with the fruit is well known for its use in treating premature greying and also promoting hair growth²⁹. Amla (Embelica officinalis) - A fixed oil is obtained from amla, which is used to strengthen and promote hair growth. The dried fruit, which improves hair hygiene, has long been utilized as an important ingredient of shampoo and hair oil³⁰. Thus, the Indian gooseberry is used as a hair tonic in traditional recipes for enriching hair growth and pigmentation.

Nimba (Azadirachta indica) - Neem leaf and seed oil has regenerative properties which support healthy cell division and stimulate hair follicle growth function. oil's and Neem antiantibiotic, antioxidant inflammatory, and properties prevent baldness as it treats scalp issues. *Neem* oil contains several fatty acids – such as linoleic, oleic, stearic acids which nourish the scalp and hair. These fatty acids present in Neem oil revitalize and restore dry, under-nourished or rough hair. Neem oil is effective against these fungi due to its antifungal properties. Neem oil also provides relief from inflammation, itchiness, and irritation that results from dandruff.

Brahmi (Bacopa monnieri) - Brahmi contains alkaloids and proteins responsible for hair growth. Oil which contains brahmi is good for the scalp and also helps prevent and hair fall and strengthen the hair³¹. Brahmi is also rich in anti-oxidants and possess anti-inflammatory properties.

Neelinee (Indigofera tinctoria) - Topical application with the petroleum ether extract of I. Tinctoria Linn reduced the time required for hair growth initiation and β - sitosterol has been tested and established as a potent 5α -reductase inhibitor, is present in I. Tinctoria Linn in appreciable quantity³². 5α -reductase inhibition contributes in treatment of androgenic alopecia and therefore provides a lead for the use of I. Tinctoria Linn for the aforementioned purpose.

Indravaruni (*Citrullus colocynthis schard*) - Hair growth initiation and completion time was considerably reduced upon treatment with petroleum ether extract of C. colocynthis³³.

Rosemary (*Rosmarinus officinalis*) - C57BL/6 mice with testosterone-induced alopecia were treated topically with hydroalcoholic extracts of rosemary (2 mg/day/animal) and showed a significant increase in hair growth³⁴.





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Tila Tailaa (Sesamum indicum)- In the year 2003 and 2004 Mitaliya and Sakarkar respectively described the effect of oil on regular application on scalp and massaged well to prevent hair fall and for long life of hairs³⁵.

CONCLUSION

Treatment with Rovaan Poshak Taila for 30 days to 50 subjects resulted in significant decrease in Hair loss/day Score, decrease in Itching on scalp, decrease in Kesha Bhoomi Rukshata (Dryness on scalp), decrease in dandruff in 30 days of treatment. However, these factors are less effective after 15 days of treatment with Rovaan Poshak Taila. But Hair Texture Score was greatly enhanced after 15 days of treatment in the subjects with use of Rovaan Poshak Taila. Treatment shows a 25-49% reduction in hair pulling test after the treatment with Rovaan Poshak Taila for 30 days. The present report subjects were applied local application of Rovaan Poshak Taila have shown improvements in Kandu (Itching on scalp), Kesha Bhoomi Rukshata (Dryness on scalp), Darunaka (Dandruff), Keshchyuti (Hair loss/day), hair texture and hair pull test.

There were no adverse effects either reported or observed during the clinical study.



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