Combine Effect of Tribal Black Tablet and Tribal Black Hair Oil in the Management of Khalitya (Hair Fall)" open level Randomized Clinical Trial

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Abstract - Hair fall has been emerging as a global issue during past few decades. It is although a health issue but affects the cosmetic appearance of individuals. The natural crown that enhances the adorning appearance of the people especially the teenagers and young adults, "Hair" has been lost by few individuals due to various life style disturbances. According to Ayurveda vitiation of Vata and Pitta Dosha leads to Khalitya which has been closely related with Hair fall. Ayurveda classics have offered efficacious herbs that correct this annoyance caused due to hair fall. One such combination has been prepared by combination of some wonderful herbs Tribal Black Tablet and Tribal Black Hair Oil for curing Hair fall. Thirty patients were enrolled and oral consumption of Tribal Black Tablet along with application Tribal Black Hair Oil was administered for thirty days. The patients were also advised to avoid oily and spicy diet, the results were observed according to the subjective, objective criteria and observations by patient themselves. The results were markedly significant with improvement of their hair texture as well. Patients were highly satisfied by the improvement in their hair quality and the results regarding hair fall and re-growth of lost hairs

Keywords - Khalitya, Hair fall, Tribal Black Tablet, Tribal Black Hair Oil

INTRODUCTION

Every strand of hair on head has a lifespan about 3 to 5 years. Hair follicles have a cycle of active growth, transition, and rest. Hair loss occurs when hair's growth cycle is disrupted. Hair loss is most commonly genetical and becomes more common in men and women with age. This condition occurs when more of hair enters the rest cycle, during which it falls out.

Hair loss is a common and distressing symptom. There is neither any specific treatment available for diffuse hair loss, or full understanding of the pathophysiology of this common disorder but dandruff is said to be the common cause of it. According to Ayurveda, hair fall occurs due to vitiation of Vata Dosha along with Pitta Dosha in the body. Shaaririk and Mansik Nidanas include, consumption of Ushna, Tikshna, Ruksha, Katu, Amla, Lavana Rasa in diet ignites Khalitya where as Mansik Bhavas like Krodha, Shok, Bhaya aggravate Vata and Pitta further adding to exacerbation of Khalitya. It has also been observed while enrolling the patients that they were regular

users of harsh chemical shampoos, hair styling tools etc. Also it was observed that females were more afflicted than males in case of hair fall.

As Ayurveda has numerous magical herbs for correcting this disorder. The use chemotherapeutic agents also cause hair fall.1 Management of hair fall is extremely complex. Although no sweeping cure exists for hair loss, a number of treatments are available to depending on their unique reasons for experiencing hair loss. The aim of present study was to evaluate etiological factors responsible for hair fall and the assessment of efficacy of Tribal Black Tablet and Tribal Black Hair Oil. The oral medication Tribal Black Tablet is a combination of various herbs like Bhringaraaj, Brahmi which are Rasayan, Jatharagni provides Corrector and mental improvement in quality and quantity of hair by affecting and rejuvenating body's cells. Massage with Tribal black Hair Oil, will work on scalp and hair

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roots, its massage will improve the blood circulation, thus increasing the health of the hair and also scalp.

AIMS & OBJECTIVES

 To assess the efficacy of Tribal Black Tablet and Tribal Black Hair Oil in the Management of Khalitya (hair fall)

MATERIALS AND METHODS (STUDY DESIGN)

Sample source:

Patients presenting with signs and symptoms *Khalitya*, were selected from the OPD and IPD of Shubhdeep Ayurved Medical College and Hospital (P.G Institute) Indore (M.P.)

Method of collection:

A minimum of 30 patients fulfilling the diagnostic and inclusion criteria of either sex were selected for the study.

Diagnostic criteria

The patients were diagnosed on bases of the following clinical features.

- Hair fall
- Roughness of hair
- Splitting of hair ends
- Dandruff

A. Inclusion criteria

- Patients between age group of 18-50 years.
- Patients fulfilling diagnostic criteria selected, irrespective of sex.

B. Exclusion criteria

- Patients below the age of 18 and above the age of 50 years.
- Patient suffering from any systemic illness like HIV, diabetic mellitus etc.
- \bullet Patients on chemotherapy or radiation therapy.

C. Drug Details

- Tribal black tablet
- Tribal black hair Oil

- License number: MP/25D/15/398
- Marketed by-Saptarishi Herbals LLP
- 307 Atulya IT Park Indore
- Manufactured: Mangal Murti Herbals Indore

D. Treatment Protocol

TRIBAL BLACK TABLET (VATI)

S. No.	Name of Ingredients	Botanical Name	Part	Each100m g.
1-	Avala	Phyllanthus emblica	FRUIT	5 mg
2-	Bhrangraaj	Eclipta alba	PLANT	20 mg
3-	Bhrammi	Bacopa monnieri	PLANT	15 mg
4-	Harar	Terminalia chebula	FRUIT	5 mg
5-	Bahera	Terminalia bellirica	FRUIT	5 mg
6-	Anantmool	Hemidesmus indicus	ROOT	9 mg
7-	Kale til	Sesamum indicum L.	SEED	15 mg
8-	Abhrak bhasm		-	12 mg
9-	Loh bhasm		-	5 mg
10	Expitiens		-	Q.S.

Dose: - Tribal Black Tablet 1 BD after Meal with Luke warm water daily.

TRIBAL BLACK HAIR OIL

S. no.	Name of ingredients	Botanical name	Part used	Quantity (each 100ml contains)
1	Kaladana	Ipomoea Hederacea	Seeds	4 gms
2	Kalaagar	Aquilaria Agallocha roxb	Kast	3gms
3	Kali musli	Curculigo Orchioides	Root	3gms
4	Kali haldi	Curcuma Caesia Roxb.	Root	3gms
5	Bhringraj	Eclipta Alba	Plant	3gms
6	Brahmi	Bacopa Monnieri	Plant	4gms
7	Amla	Embilica Officinalis	Fruit	2gms

8	Pyaj	Allium Cepa	Seed	5gms
9	Chandan	Santalam Album	Kast	1gm
10	Vanshlochan	Bambusa Arundinacea	Gum	10gms
11	Tulsi	Ocimum Sanctum	Plant	2gms
12	Neem	Azadirachta indica.	Plant	2gms
13	Bargad jata	Ficus Benghalensis	Jata	2gms
14	Jatamansi	Nardostachys Jatamansi	Root	4gms
15	Amar bel	Cuscuta Reflexa	Plant	4gms
16	Gudahal	Hibiscus rosa-Sinensis	Flower	2gms
17	Indrayan	Citrullus Colocynthis Root		2gms
18	Methidana	Trigonella Foenum Graecum Seed		2gms
19	Bakayan	Melia Azedarach Fruit		2gms
20	Khus	Chrysopogon Zizanioides	Plant	4gms
21	Bakuchi	Psoralia Corylifolia	Seed	3gms

22	Ashwagandha	Withania Somnifera	Root	2gms
23	Kantkari	Solanum Xanthocarpus Schrad and Wendl	Plant	3gms
24	Marodfali	Helicteres Isora	Phali	3gms
25	Halo	Lepidium Sativum Linn	Fruit	3gms
26	Fragrance and colour	-	-	q.s
27	Base oil	-	-	q.s

Direction for Application

- Men:-Apply 5-6 ml of Tribal Black Hair Oil on scalp and massage gently for 1-2 minutes daily.
- Women:-Apply 8-10 ml of Tribal Black Hair Oil on scalp and massage gently for 1-2 minutes thrice a week.
- Study duration: 30 days
- Follow up: On 15th and 30th day.

Assessment criteria:

Detail proforma adopted standard methods of scoring subjective and objective parameters were analyzed statistically.

Subjective parameters:

- Hair fall
- Roughness of hair
- Splitting of hair ends
- Dandruff

OBJECTIVE PARAMETERS

KOH, CBC, Sr. Creatinine, S. Bilirubin, SGOT, SGPT, ESR were carried out before and after the treatment to rule out any other pathological condition or safety of tribal black tab.

Grading for Assessment Criteria:

Α	Hair Falling	
	Symptoms	Gradation
	No Hair Fall	0
	Mild Hair fall(Hair Fall on Washing)	1
	Moderate Hair fall (Hair Fall on combing)	2
	Severe Hair fall (Hair Fall on Milled pulling)	3
В	Roughness	
	Smooth hair surface	0
	Occasional Hair Surface	1
	Slight Rough Surface	2
	Very Rough Surface	3

С	Splitting of Hair ends	
	No Visible	0
	Splitting end visible with difficulty	1
	Splitting end visible with easily	2
D	Dandruff	
	No Dandruff	0
	Dandruff seen on scalp only	1
	Dandruff visible on scalp and hair	2
	Dandruff visible on neck and back	3

FINAL ASSESSMENT OF RESULT

A detailed proforma according to disease was prepared and all the subjective and objective values recorded and result was generated. Assessment was also done according to the observations made by the P.I and experiences of the patients while following the one month treatment protocol.

TABLE NO 1

Combine effect of Tribal Black Tablet (Vati) and Tribal Black Hair Oil on Subjective Criteria Sign And Symptoms

Ci 8 C	Mean Score		% Of	S.D.	SE	_	N	Р	Df
Sign& Symptoms	B.T.	A.T.	Relief	3.0.	3E	'	N		וט
Hair Fall (Kesh Patan)	2.233	0.733	67.16	0.5085	0.0128	16.15	30	<0.0001	29
Roughness (Kesh Rukshtva)	2.000	0.700	65	0.5350	0.0976	13.31	30	<0.0001	29
Splitting of Hair Ends (Kesh Sphutan)	1.433	0.600	58.13	0.6477	0.1183	7.047	30	<0.0001	29
Dandruff (Darunaka)	1.300	0.500	61.53	0.7144	0.1304	6.13	30	<0.0001	29

TABLE NO 2

 Combine effect of Tribal Black Tablet (Vati) and Tribal Black Hair Oil On Objective Criteria

Objective Criteria	Mean Score		% Of	S.D.	SE	Т	N	Р	Df
objective official	B.T.	A.T.	Relief	0.5.	-	·			
КОН	0.400	0.100	75	0.4661	0.0851	3.52	30	0.0014	29
HB%	11.447	11.453	0.32	0.4230	0.077	0.47	30	0.6385	29
SGOT	22.400	21.367	4.61	4.930	0.9002	1.1148	30	0.2604	29
SGPT	22.433	21.267	5.2	3.724	0.6799	1.716	30	0.0968	29
Total Bilirubin	0.5960	0.5900	1.00	0.1530	0.0280	0.2140	30	0.8321	29
ESR	4.700	4.400	6.38	0.149	0.2098	1.430	30	0.1635	29
Sr. Creat.	0.7467	0.7227	3.21	0.6463	0.1180	2.034	30	0.0512	29

DISCUSSION

Both male and female have been suffering from hair fall worldwide. The patients of hair fall have increased since passed few years due to increasing cases of Hormonal changes, auto-immune disorders, thyroid diseases and the leading cause of today's era disturbed lifestyle as well as stress are pre-cursors and catalysts for hair fall. Unhealthy packed and junk food strongly affects the hair health.

According to Ayurveda, hair fall occurs due to vitiation of Vata Dosha along with Pitta Dosha in the body. Shaaririk and Mansik Nidanas include, consumption of Ushna, Tikshna, Ruksha, Katu, Amla, Lavana Rasa in diet ignites Khalitya where as Mansik Bhavas like Krodha, Shok, Bhaya aggravate Vata and Pitta further adding to exacerbation of Khalitya. Acharya Charak mentions that the Tejas with the help of the Vatadi Doshas scorches the scalp rapidly so as to cause Khalati to a person. In Khalitya, Bhrajaka Pitta⁴ sites in skin and Roma Kupa (opening of hair follicle) get vitiated and enter in skin through Roma Kupa with vitiated Vata Dosha due to which hair fall occurs, after that vitiated Rakta and Kapha Dosha blocks the opening of hair follicle due to which production of new hair stop. Overall in Khalitya, hair fall occurs and new hair does not appear that leads to baldness. Khalitya is Pitta Pradhana Tridoshaja Vyadhi i.e. Vata, Pitta, Kapha with Rakta Dosha. All Doshas are vitiated but have predominance of Pitta and Rakta Dosha mainly. Acharya Sushruta considering it as Kshudra Roga⁵ says that the Pitta provocated by its own factors penetrates into the Roma Koopa and there it unites with the Vata to shatter the hair. Out of total 30 patients 40% were male and 60% of patients were female. As females opt for more hair styling chemicals and tools as compared to males, it might be a reason for more hair fall. Out of total 30 patients enrolled 83.34% were suffering from anxiety and mental stress while 16.66% were stable mentally. As mental stress leads to vitiation of Vata and Pitta Dosha which is a triggering factor for hair fall therefore 83.34% more patients of stress suffer from hair fall. Out of total 30 patients enrolled 13.34% patients were from rural habitat and 86.66 % were from Urban Habitat. As people receding in urban area are more exposed to pollution, chemicals and hair styling tools which leads to comparatively more hair fall. Out of total 30 patients enrolled 33.30 % were of upper class, 16.70 % patients were of middle class, and 70% were of poor class. As malnutrition is also a dominant reason for hair fall the people who suffer from malnutrition face more hair fall. Out of 30 patients, 40 % patients were student, 30 % patients were of working class, 20% patients were homemaker, 7 % patients were farmer, 3 % patients were worker. It has been observed that patients who are involved in mental activities like studying, IT sector jobs have comparatively more stress and disturbed lifestyle again a triggering factor for hair fall.

It has also been observed while enrolling the patients that they were regular users of harsh chemical shampoos, hair styling tools etc. Also it was observed that females were more afflicted than males in case of hair fall

As the treatment protocol has been advised Tribal Black Tablet and Tribal Black Hair Oil after the completion remarkable changes were observed.

Tribal Black Tablet:-

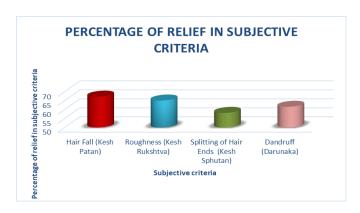
Tribal Black Tablet is a herbo-mineral combination prepared exclusively for hair health and regeneration of hair follicles. The ingredients of the tablet overall promotes hair growth, fights dandruff, nourishment of scalp and improves hair quality. Triphala is a wellknown poly herbal formulation. Triphala is considered as a Rasayana drug due to it's nutritive and regenerative properties. Triphala is one among the Ayurvedic medicinal herbal formulation mostly preferred by medical practitioners for curing a wide spectrum of diseases³. As Amla is good for hair health, Haritaki and Vibhitaki is good for Gut health, hence improves hair health from in and out. Bhringaraaj is also known as Kesharaj which means "Ruler of the hair". It is rich in proteins, vitamins and antioxidants which help protect the body against certain infections. Lauha Bhasma strengthens the body and improves the production of RBCs. The person who suffers from low hemoglobin level suffers from the consequences like pale skin, hair fall, loss of memory, fatigue etc. Being Rasayan Aushadhi it helps in enhancing the hair cells and reduces hair fall.

This potent mineral formulation is blessed with the ability of pacifying the Tridoshas, i.e. Vata, Pitta and Kapha. Being a powerful Rasayani Dravya or ingredient, Abhraka Bhasma not only provides adequate energy to carry out various activities but also has a calming effect on both the mind and body. Over all the ingredients of Tribal Black Tablet enhances the Jatharagni, Pacifies and balances Tridoshas, increases the hair growth and improves quality of hair hence reducing the hair fall.

Tribal Black Hair Oil:-

The ingredients like Ashwagandha, Amla, Musli, Kali Haldi being Rasayan in nature helps to nurture scalp

RESULT AND OBSERVATION



Percentage of Improvement of objective criteria

Objective Criteria	Percentage of Improvement
КОН	75 %
НВ	0.32 %
SGOT	4.61 %
SGPT	5.2 %
Total bilirubin	1.00 %
ESR	6.38 %
Serum Creatinine	0.72 %

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