

Efficacy and Safety Evaluation of Sesa oil and Sesa Capsule In Different Hair Disorders

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Abstract

Hair loss can cause psychological stress to the patient. It may be prevented if early treatment is started. A holistic approach to stop hair fall would include not only therapeutic intervention but also an active search for associated nutritional deficits.

Aim: Purpose of this study was to evaluate the safety and efficacy of SESA oil and capsule in different hair disorders.

A prospective cohort study was conducted at Dr. D. Y. Patil College of Ayurved and Research Institute. Totally 40 individuals, (12 women and 28 men) with alopecia were enrolled. All the patients were advised to use SESA oil and SESA capsule as directed.

The efficacy was assessed on every monthly follow-up for 3 months. Patients showed a marked decrease in hair fall and increase in regeneration of hair. They also showed improvement in psychological condition and secondary parameters of hair disorders. There were no adverse reactions documented, neither reported nor observed, during the entire study period.

Therefore, it may be concluded that SESA oil and capsule are clinically effective and safe therapeutic regimens for the treatment of different hair disorders.

Keywords: SESA, Hair disorder, scalp disorder, Holistic approach to hair fall & Alopecia

Introduction

The word "Ayurveda" is composed of two Sanskrit terms, viz., "ayu" meaning "life", and "veda" meaning the "knowledge," and taken together, it means the "science of life.". However, in a limited sense, it is always used to imply "the science of medicine.". [1] It is the holistic alternative science from India, and is more than 5,000 years old. It is believed to be the oldest healing science in existence, forming the foundation of all others. Buddhism, Taoism, Tibetan, and other cultural medicines have many similar parallels to Ayurveda's individualized healing method. It has been preserved in India, whereas it has been lost or superseded in other cultures. [2] Hair loss is a relatively common chronic dermatological condition. Its etiology is still not fully understood and medical treatment has limited effectiveness. Iron deficiency anemia also may contribute to the hair fall. [3] The unpredictability of the condition together with its highly visible nature can result in considerable distress for individuals with alopecia. [4-6] Though losing hair is not usually health threatening, still it can scar one's vulnerable self-esteem by causing immense psychological and emotional stress not just to the patient, but also to the concerned parents.

Given the emphasis placed on appearance among women, it is hardly surprising that studies have found gender differences in response to alopecia, with women reporting more psychosocial problems and stress compared with men. [7] Furthermore, people with alopecia are more likely to have depression and anxiety. [8]

Thus, management of hair disorders can be quite a daunting task for the attending physician and mandates a holistic approach to the patient. Nevertheless, an organized diagnostic and management strategy can turn this challenging task into an interesting and fruitful exercise. [9] Alopecia often has no effective treatment. There are variety of treatment options available, but no single treatment is 100% effective. [10]

Considering that hair has essential psychosocial importance in our society, its loss results in distress for the patients, [11] the demand for drugs that alter hair growth and appearance has led to a multibillion dollar industry. [12] A holistic approach would include not just therapeutic intervention but also an active search for the associated nutritional deficits.

Regular hair care in the form of cleaning, oiling and combing not only keeps the hair in sound health, but also frees it from extraneous dirt and lice. Regular application (massage) of oil on the scalp, relieves one from headaches, and prevents baldness, graying of hair, and hair fall. It is also helpful in improving power

tone of the head and rest of the body. An oil massage on the head not only helps the hair to grow strong, dark black, soft, and shiny, but also relieves afflictions that can originate in the scalp. It helps to keep the mind cool and contented and also adds a glow of radiance to the face. Oil massage also enlivens the vital organs and rejuvenates the brain.

Materials and Methods

This investigation was conducted as a prospective cohort study conducted at Dr. D. Y. Patil College of Ayurved and Research Institute. The study protocol and all other required documents were submitted to the "Institutional Ethics Committee" and approved by the same. Each patient underwent complete clinical and laboratory examinations such as complete blood count (CBC), erythrocyte sedimentation rate (ESR), and urine (routine and microscopic) examination.

Inclusion criteria were patients suffering from hair loss and who were willing to give a written informed consent. Exclusion criteria were patients on any treatment for other indications which interacts with the study drug, patients who had used any other therapy for hair loss or scalp disorder in the near past, patients who were not willing to give the written informed consent, and patients found to be having systemic disease on laboratory investigations.

The patients underwent a thorough local and general hair and scalp examination including palpation and interrogation. A total of 40 patients (28 males and 12 females), with age ranging from childhood to geriatric, were included in the study and their demographic medical histories were recorded.

Dosage

Sesa oil: Gentle massage on scalp till it gets absorbed two times a day, i.e. morning and evening.

Sesa capsule: Two capsules orally two times every day after food.

Sample study parameters for calculation of hair distribution

10 mm × 10 mm area of normal healthy person was taken as the sample for finding out normal frequency of hair distribution per 100 mm² area. After analysis, it was concluded that there are approximately 200 hairs per 100 mm² area, which means 50 hairs per 25 mm² area. Therefore, for calculating the hair distribution on treated areas, 25 mm² area was considered (5 mm × 5 mm) as a standard base.

Efficacy assessment

The efficacy was assessed on every monthly follow-up for 3 months on the basis of following criteria: Regenerated hair Screening of scalp hair Changes in signs and symptoms The

assessment of therapeutic effect is made on four-point scale The color changing effect Arrest of new gray hair Safety assessment Treatment emerged adverse events - are the adverse events that are possibly treatment related and adverse events that are observed by the investigator or reported by the patient. A treatment emerged adverse event was defined as any adverse event that occurred after commencement of the allocated treatment or an adverse event that occurred prior to the allocated treatment but worsened in severity after commencement of the allocated treatment.

Results

As discussed in the section "Introduction" about patient's quality of life during alopecia, in this study too, initially 27 patients out of 40 were suffering from various psychological conditions such as tension, stress, and psychological stress. Before initiation of treatment, 34 patients out of 40 had dryness of hair; at the end of the third month, only two patients were left with dryness of hair. Six patients out of 40 were found to be anemic, and the hemoglobin (Hb) level was less than 10 gm%. Initially 5 (12.5%) patients were found with shining of nail, which increased to 16 patients (40%) patients at the end of study. Similarly, initially 5 (12.5%) patients had shined teeth, which increased to 13 (32.5%) patients. Tables in the result part are generated based on efficacy assessment done as per sample study parameter. In case of different types of alopecia, SESA showed over all statistical improvement [Table 1]. All signs and symptoms improved significantly at the end of the study [Table 2]. Effects of SESA on dandruff with itching and on regeneration on hair are shown in Tables 3 and 4, respectively. It was also found that SESA showed improvement in external keratin protein feature of the body [Table 5].

Discussion

SESA oil is made by a uniquely designed and one of the ancient Ayurvedic processes known as "*Kshir Pak Vidhi*". Sesa oil contains 18 herbs and 5 essential oils processed in milk. Milk is a source of fat which entraps the volatile oil and alkaloid present in the herbs and preserves the best of all herbs as it is. Sesa capsule contains nine herbs and they are oral hair nourisher which fights Hair Loss, premature graying and other problems by internal action like treating deficiency of iron, improper blood circulation at hair follicles as well as mental stress that leads to hair problems. One of the ingredient in Sesa capsule is *dhatri loh*, is a source of iron and acts as an iron supplement and prevents iron deficiency induced hair fall.

All 18 herbs and five essential oils present in Sesa oil and nine herbs present in Sesa capsule act synergistically against different hair disorders. *Eclipta alba* (Bhringraj) present in Sesa oil and Sesa capsule is a well-known herb and is well documented for its various uses in Ayurvedic system of medicine. The mechanism of action of



Ingredients in Sesa oil:

SR. NO.	ENGLISH NAME	LATIN NAME	PART USED	QTY %
1	TRAILING ECLIPTA	<i>Eclipta alba</i>	WHOLE PLANT	1.50 % W/V
2	INDIAN PENNYWORT	<i>Centella asiatica</i>	WHOLE PLANT	0.50 % W/V
3	JASMINE	<i>Jasminum officinale</i>	LEAVES	0.50 % W/V
4	INDIAN LICORICE (JEQUIRITY)	<i>Abrus precatorius</i>	SEED	0.25 % W/V
5	INDIAN DATURA (WHITE THORN APPLE)	<i>Datura metel</i>	PANCHANG	0.50 % W/V
6	CARDAMOM	<i>Elettaria cardamomum</i>	FRUIT	0.25 % W/V
7	TRUE INDIGO	<i>Indigofera tinctoria</i>	LEAVE	0.50% W/V
8	COLOCYNTH	<i>Citrullus colocynthis</i>	FRUIT	0.50% W/V
9	INDIAN VALERIAN	<i>Valeriana wallichii</i>	ROOT	0.25% W/V
10	PONGAMIA	<i>Pongamia pinnata</i>	SEED	0.25% W/V
11	NEEM (MARGOSA TREE)	<i>Azadirachta indica</i>	SEED	0.25% W/V
12	HENNA	<i>Lawsonia alba</i>	LEAVES	0.25% W/V
13	MANDUR	<i>Ferriper Oxidumrubrum</i>	MINERAL	1.50 % W/V
14	TRIFALA	<i>Embllica officinalis, Terminalia bellirica & Terminalia chebula</i>	FRUIT PERICARP	2.00 % W/V
15	DEODAR	<i>Cedrus deodara</i>	STEM/RESIN OIL	0.25 % W/V
16	PELLITORY ROOTS	<i>Anacyclus pyrethrum</i>	ROOT	0.25 % W/V
17	CUSCUS GRASS	<i>Vetiveria zizanioides</i>	WHOLE PLANT	0.25 % W/V
18	LIQUORICE	<i>Glycyrrhiza glabra</i>	ROOT	0.25 % W/V
19	MILK			10.00 % V/V
20	WHEAT GERM OIL	<i>Triticum aestivum</i>	SEED OIL	1.00 % V/V
21	NILIBHRUNGANDI OIL		PREPARED OIL	8.00 % V/V
22	SESAME OIL	<i>Sesamum indicum</i>	SEED OIL	25.00 % V/V
23	LEMON OIL	<i>Citrus medica</i>	FRUIT RIND OIL	1.00 % V/V
24	COCONUT OIL	<i>Cocos nucifera</i>	OIL	Q.S. TO 100 % V/V
25	C.I. NO 61565	<i>Quinazarine green ss</i>	POWDER	0.0004 % V/V
26	FRAGRANCE		OIL	2.00 % V/V

Ingredients in Sesa Capsule:

SR. NO.	ENGLISH NAME	LATIN NAME	QTY
1	DHATRI LOH	STANDARD COMPOSITION IN AYURVEDA	105 mg
2	GODANTI BHASMA	DO	100 mg
3	SUVARNA MAKSHIK BHASMA	DO	50 mg
4	MUKTA SUKTI BHASMA	DO	50 mg
5	GANDHAK RASAYAN	DO	40 mg
6	ABHRAK BHASMA	DO	10 mg
7	RAUPYA MAKSHIIK BHASMA	DO	1 mg
8	SHILAJEET	<i>Asphaltum panjabinum</i>	4 mg
9	TRAILING ECLIPTA	<i>Eclipta alba</i>	40 mg

Table 1: Effect of Sesa on Type of Alopecia

Type of Alopecia	Initial (no. of patients)			End of Study (no. of patients)		
	Mild	Moderate	Severe	Mild	Moderate	Severe
Alopecia Areta	-	1	5	1	-	1
Male Pattern Alopecia	-	2	5	-	6	1
Diffuse Pattern Alopecia	1	5	8	7	5	-

Table 2: Effect of Sesa on Sign & Symptoms

Sign & Symptoms	Initial (no. of patients)	End of Study (Relief in %)
Dryness	34	95 %
Roughness	27	100 %
Unctuousness	5	100%
Itching	24	100%

Table 3: Effect of Sesa on Dandruff with Itching

Dandruff with Itching	Initial (no. of patients)	1st Month (no. of patients)	2nd Month (no. of patients)	3rd Month (no. of patients)
Absent	17	17	22	40
Slight	1	15	17	
Moderate	8	16	1	
Severe	14	1		

Table 4: Effect of Sesa on regeneration of Hair

Regeneration	Initial (no. of patients)	1st Month (no. of patients)	2nd Month (no. of patients)	3rd Month (no. of patients)
Absent	40	12	2	2
Slight		25	15	5
Moderate		3	21	15
Better			2	18

Table 5: Effect of Sesa on External keratin protein of body

Sign	Initial (no. of patients)			End of Study (no. of patients)		
	Mild	Moderate	Severe	Mild	Moderate	Severe
Eating Nails	-	2	5	-	-	-
Cracking of Nail	1	4	1	-	1	-
Premature Graying of Hair	2	1	1	1	-	-



Fig 1(a): Alopecia Areata – Before



Fig 1(b): Alopecia Areata - After



Fig 2(a): Graying of Hair – Before



Fig 2(b): Graying of Hair – After



Fig 3(a): Hair line Alopecia – Before



Fig 3(b): Hair line Alopecia – After



E. Alba is believed to be its effect on follicular enlargement and prolongation of anagen phase.^[13] *Sesamum indicum* is an emollient, astringent, and hair-restorer, and is useful in baldness, alopecia, blackening of hair, and promoting hair growth.^[14]

Absence of a control group was a limitation of the study, although this deficiency was not too pertinent because results are compared on basis of situation at the time of enrollment and at the end of the study. In all the patients, there were no complications or adverse effects were neither reported by the patients nor observed by the investigator.

Conclusion

It is very common to males in their middle age with gradual onset of alopecia in parieto - occipital region. Hereditary, psychological, and hormonal factors; dandruff; infection; dryness; roughness; itching; un-nourished hair; cosmetics and soaps are the most common causes of hair disorders.

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At the end of the three month study based on the efficacy assessment, arrest of hair fall, improvement in structure, i.e. length, improvement in the nourishment of hair, improvement in nail cracking and shining, improved complexion, stoppage of graying of hair and partial reversal were observed. Psychological condition was improved by relief of tension, stress, and anxiety. Hair turned out to be more silky, bouncy, discrete, dark, and easily manageable.

Study indicated that the combination of Sesa oil and Sesa capsule produces an evident clinical improvement in hair and scalp disorders. It also improved quality of life in the majority of patients. Results confirmed marked regeneration of hair and safety with Sesa therapy.

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