

EFFICACY AND SAFETY EVALUATION OF SESA OIL VS COCONUT OIL IN DIFFERENT HAIR & SCALP AILMENTS: PROSPECTIVE, OPEN LABEL, RANDOMIZED COMPARATIVE STUDY

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ABSTRACT

Ailments associated with hair & scalp can cause psychological stress to the patient. These ailments may be prevented if early management is started. A scientific approach to overcome ailments associated with hair & scalp would include therapeutic intervention especially in the area of Ayurveda, where ample of herbs available for such kind of indications. Purpose of this study was to evaluate safety and efficacy of SESA oil vs Coconut oil in different Hair & Scalp Ailments. A Prospective, Open label, Randomized Comparative study was conducted at MAHARASHI AYURVEDA HOSPITAL. Total 50 individuals, 28 women and 22 men with hair or scalp ailments were recruited. All the patients were divided in to two groups of SESA oil and Coconut oil group, advised to use SESA oil and Coconut oil as directed. Efficacy was assessed on every monthly follow up for 3 months. Patients from SESA oil group showed a marked improvement (87.5 %) in hair & scalp related ailments as compare to coconut oil group (17.4%). It also showed improvement in psychological condition. There were no adverse reactions documented, neither reported nor observed, during the entire study period. Therefore, it may be concluded that SESA oil is five times more effective than Coconut oil. In addition to that it is found to be safe therapeutic regimen.

Keywords: Hair ailment, dandruff and itching scalp, sesa oil, coconut oil

INTRODUCTION

Blow-drying, straightening, highlighting, and perming regularly can cause destruction of hair, leaving it brittle, broken, and unmanageable. Split ends and dry hair are just two casualties of over styling. Excessive styling and heat can cause split ends, which occur when the protective outermost layer of hair (the cuticle) is damaged and peels back.

To fully understand hair ailments, a basic knowledge of normal hair growth is necessary. The normal hair cycle is divided into four phases: the active growth anagen phase, followed by a brief catagen phase, the resting telogen phase and finally the shedding exogen phase¹. Typically, 85–95% of hairs are in the anagen phase, which lasts approximately 3 years. Less than 1% of hairs are in catagen, the transitional phase, which lasts from a few days to weeks. The telogen phase (which accounts for 5–15% of hairs and lasts about 3 months) ends when the new anagen hair emerges from the follicle.

Hair & scalp related ailments are 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 ailment². The unpredictability of the condition together with its highly visible nature can result in considerable distress for individuals³⁻⁵. Though ailment associated with hair & scalp 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 responses to Hair care, with women reporting more psychosocial problems and stress compared with men⁶. Furthermore, people with hair & Scalp ailments are more likely to have depression and anxiety⁷.

Thus, management of hair & scalp disorders can be quite a daunting task 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 exercise⁸. Hair and Scalp related ailments often have no effective treatment. There are varieties of products available in market claiming usefulness in hair disorders.

Considering that hair has essential psychosocial importance in our society, resulting in distress for patients⁹, the demand for drugs that alter hair growth and appearance has led to a multibillion dollar industry¹⁰. A holistic approach would include not just therapeutic intervention but also an active search for associated nutritional

deficits. Traditional use of Coconut oil for different hair care ailments in India is very popular.

Regular hair care in the form of cleaning, Oiling & combing not only keeps hair in sound health, but also frees it from extraneous dirt & lice. Regular application (massage) of oil on the scalp, relieves one from headaches, prevents baldness graying of hair, and hair fall. It is also helpful in improving power tone of head and rest of the body. An oil massage on the head not only helps the hair grow strong, dark black, soft and shiny, it also relieves afflictions that can originate in the scalp. It helps to keep the mind cool & contended and also adds a glow of radiance to the face. Oil massage also enlivens the vital organs & rejuvenates the brain.

METHODS AND MATERIAL

This investigation was conducted as a Prospective, Open label, Randomized Comparative study at MAHARASHI AYURVEDA HOSPITAL. Each patient underwent complete clinical examination.

Inclusion Criteria

Inclusion criteria were patients suffering from at least one of the following hair or scalp ailments such as dry hair, rough hair, damaged hair, dandruff & itching of scalp and who were willing to give a written informed consent.

Exclusion Criteria

Exclusion criteria were patients on any treatment for other indication interacting with study drug, patient who had used any other therapy for hair loss or scalp disorder in near past, patients who were not willing to give the written informed consent and patient found to be having systemic disease interfering with study result.

Study Design

The patients underwent a thorough local and general hair & scalp examination including palpation and interrogation. A total of 50 patients of both gender (31 male and 19 female), with age ranging from adolescent to geriatric were included in the study and their demographic medical histories were recorded. After patient satisfying inclusion criteria they were enrolled in the study and randomly allocated to either Sesa oil or coconut oil group.

Dosage: SESA Oil: Gentle massage on scalp till it gets absorbed two times a day i.e. morning and evening

Coconut Oil: Apply coconut oil two times a day i.e. morning and evening

Also, patient in SESA oil group were requested to use SESA hair protein shampoo or SESA anti-dandruff shampoo if they had dandruff in scalp and no instruction was given to patient in Coconut oil group regarding the use of shampoo. Apart from this they were instructed not to apply any other chemical or preparation to hair or scalp.

Efficacy Assessment:

Overall efficacy assessment of therapeutic effect is based on four point scale (i.e. bad, average, good & excellent) for hair & scalp related ailment. Patient underwent monthly follow up for 3 months on the basis of following criteria:

Hair- dryness, roughness and texture of hair

Scalp- Dandruff and itching of scalp

Safety Assessment

Treatment emerged adverse events - 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 allocated treatment or an adverse event that occurred prior to the allocated treatment but worsened in severity after commencement of the allocated treatment.

RESULTS

Total of 50 patients were enrolled in the present study out of which 22 were male and 28 were female (Table-1). If we segregate patient according to indication, 31 patients enrolled in the study were complaining about dry, rough and/or damaged hair were 19 of them were complaining about dandruff and itching of scalp (Figure-1). After completion of randomization 25 patient were enrolled in each group (Table - 2). At the end of the study there were total 3 drop offs from the study out of which one patient was from SESA oil group with hair ailment and two patients were from Coconut oil group one with hair ailment and another with dandruff & itching of scalp.

Table 1: Patient demographic data

Gender	No. of Patients	Age in years (Mean)
Male	22	31.5
Female	28	34.5

Table 2: Patient allocation after randomization

Group	SESA	Coconut
	Oil	Oil
No. of Patients with hair ailment	15	16
No. of Patients with scalp ailment	10	9
Total No. of Patients enrolled Initially	25	25
Total No. of Patients completed studied after drop offs	24	23

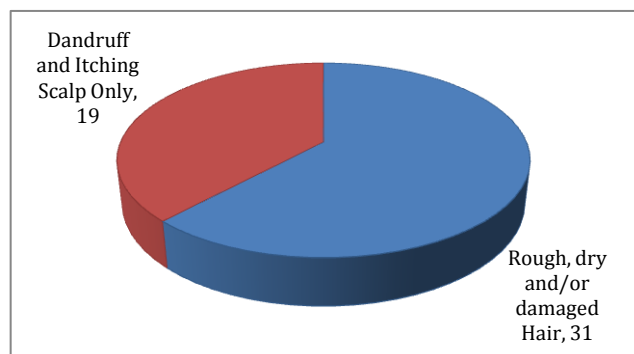


Figure 1: Indication of patient enrolled in the study

Total of 14 patients completed study in SESA oil group with hair ailments out of which at the end of three months 5 patients got excellent result and 7 patients got good result (Table-3). Total of 10 patients were enrolled in the SESA oil group for dandruff & itching of scalp out of which at the end of the three months 5 patients got excellent result and 4 patients got good result (Table-4). Total of 15 patients completed study in Coconut oil group with hair ailments out of which at the end of three months 1 patient got excellent result and 2 patients got good result (Table-5). Total of 8 patients were enrolled in the coconut oil group for dandruff & itching of scalp out of which at the end of the three months no patient got excellent result and only 1 patient got good result (Table-6).

Table 3: Overall assessment of hair done by investigator for sesa oil group

Condition of Hair	Enrollment	First follow up	Second follow up	Third follow up
Bad	7	5	3	1
Average	7	4	2	1
Good	-	4	6	7
Excellent	-	1	3	5

Table 4: Overall assessment of scalp done by investigator for sesa oil group

Condition of Scalp	Enrollment	First follow up	Second follow up	Third follow up
Bad	6	3	1	-
Average	4	2	1	1
Good	-	3	4	4
Excellent	-	2	4	5

Table 5: Overall assessment of hair done by investigator for coconut oil group

Condition of Hair	Enrollment	First follow up	Second follow up	Third follow up
Bad	7	6	5	4
Average	8	8	7	8
Good	-	1	2	2
Excellent	-	-	1	1

Table 6: Overall assessment of scalp done by investigator for coconut oil group

Condition of Scalp	Enrollment	First follow up	Second follow up	Third follow up
Bad	4	4	4	3
Average	4	4	3	4
Good	-	-	1	1
Excellent	-	-	-	-

DISCUSSION

Although ailments associated with Hair & scalp is not a life-threatening condition, it can impair quality of life by negatively impacting on self-confidence and self-esteem. In line with social stereotypes, men were less likely to express concern, whereas women were more concerned with the social impact of such a visible condition. Current study found that, people reported feeling upset, angry and worried in relation to their condition. Since nature of the condition itself, as unpredictable, with uncertain etiology and limited treatment Stress and worry were also seen. Not surprisingly, patient felt that they had little control over their condition and treatment.

It is clearly visible from the result that people from SESA group showed very good improvement in different Hair & Scalp Ailments as compared to the Coconut oil group. As SESA oil is made by uniquely designed and one of the ancient ayurvedic process known as "Kshir Pak Vidhi". SESA oil contains 18 herbs and 5 essential oils processed in milk. Milk is source of FAT which entraps the volatile

oil and alkaloid present in the herbs, preserve the best of all herbs as it is.

Eclipta alba (Bhringraj) present in SESA oil is well known herb and well documented for its various uses in Ayurvedic system of medicine. Suspected mechanism of action of *Eclipta Alba* is found to be acting on Follicular enlargement and prolongation of Anagen phase.¹¹ *Sesamum indicum* is emollient, astringent, hair-restorer and useful in baldness, alopecia, to blacken the hair and to promote hair growth.¹²

In all the patients there were no complications or adverse effects was neither reported by the patients nor observed by the investigator.

CONCLUSION

In today's lifestyle there are different numbers of factors such as environmental conditions, air pollution, use of wrong or harsh hair care products, frequent hair styling treatments, disruption of hair growth cycle & under nourishment may contribute to hair & scalp related ailments.

At the end of the three month study efficacy evaluation has shown that only 4 patients out of 23 patients from Coconut oil group got good or excellent result i.e. 17.4 % result, whereas 21 patients out of 24 patients from SESA oil group got good or excellent result i.e. 87.5 %. Results at the end of the study clearly indicates that SESA oil is more effective than Coconut oil in different Hair Ailments such as dry hair, rough hair, damaged hair, dandruff & itching of scalp.

Study indicates that use of SESA oil produces an evident clinical improvement in hair and scalp ailments. It also improved quality of life in the majority of patients and establishes safety of SESA oil.

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