

CLINICAL EVALUATION OF ANKOLADI TAILA IN THE MANAGEMENT OF SEBORRHEIC DERMATITIS”

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ABSTRACT

Background: Due to increasing incidence and prevalence of scalp skin and hair disorders such as Seborrheic Dermatitis in children, there is a need for effective and safe drug for management of childhood Seborrheic Dermatitis. We can correlate Seborrheic Dermatitis with *Arumshika* in our text which is a *Shirokushtha*. In *Sahastrayogam* texts, *Ankoladi Taila* has been mentioned a good remedy for *Shiro Kushtha*. A clinical trial was undertaken to evaluate efficacy of *Ankoladi Taila* in the management of Seborrheic Dermatitis in pediatric practice. **Methods:** interventional, open label masking, control (randomized) trial, trial was carried out on 20 patients of either sex in between the infantile to 16 years of age at P.G. department of *Kaumarbhritya*, National Institute of Ayurveda. The duration of

treatment was 60 days. Clinical evaluation done by assessment criteria and photography.

Results: Result showed highly significant results regarding subjective parameters – flaking/scaling, Redness, itching and discharge with % relief of 88.70%, 97.01%, 93.28%, 97.29% and significant result in burning and boils with % relief of 95%, 73.17%.

Conclusion: It can be concluded that *Ankoladi Taila* is highly effective in the management of Seborrheic Dermatitis (*Arumshika*). The drug is quite safe and acts as anti-fungal, antibacterial, anti-inflammatory and anti-allergic.

KEYWORDS: *Arumshika*, *Ankoladi Taila*, Seborrheic Dermatitis.

INTRODUCTION

“A thing of beauty is joy forever.” So, the concept of beauty (*Saundarya*) is gaining more and more attention globally and hair plays an important role in it, as it has been said that hair

is a barometer of one's beauty. So, it has a great aesthetic value and it is the crowning glory of any person. Therefore to keep the healthy hairs in healthy state is entirely the duty of human beings. Even thousand years ago, in *Ayurvedic* literature, so many types of daily regimens for scalp skin care have been described in the chapter of *Dinacharya* and *Ritucharya*, which includes some procedures like *Moordha Taila*, *Nasya*, *Snana*, *Rasayana Sevan* etc.

In the present world today people are more conscious about their children's health and appearance. Scalp skin and hair plays an important part in the personality or the appearance of the people. Today, changed life style and junk food habits resulting in such type of problems. Over conscious parents with increased awareness regarding hair care, and indulgence in faulty treatment modality for fast cure might have been the cause for same.

The prevalence rate of Seborrheic Dermatitis is 3-5%, with a worldwide distribution. Dandruff, the mildest form of this dermatitis, is probably far more common and is present in an estimated 15-20% of the population.^[1] The prevalence of Seborrheic Dermatitis in HIV-positive and AIDS patients is between 34%^[2] and 83%^[3] as opposed to 3% in the general population.

Seborrheic Dermatitis is a common chronic inflammatory papulosquamous condition that usually occurs in sebum rich areas, including the scalp, face, upper chest, trunk and back. Dandruff is a mild form of Seborrheic Dermatitis. It is also common during infancy, known as cradle cap involving the scalp. Cradle cap usually resolves by eight to 12 months of age. Intermittent, active phases of Seborrheic Dermatitis manifest with burning, scaling, and itching, alternating with inactive periods.

In modern medicine Dandruff/Seborrheic Dermatitis is treated by multiple antifungal or topical steroidal anti-inflammatory agents but these line of management have limitations, due to the cost factor, poor cosmeticity, and adverse effects of steroidal agents, relapsing nature of disease.

This generates a requirement to discover and employ ancient knowledge of *Ayurveda* to locate accurate solution of the disorder which is easy to use in children, preventive as well as curative, cost effective, long lasting, devoid of adverse effect. Because ideal treatment is one

which cures the disease completely and does not give any side effects which may be the cause of another disease.

Due to discoloration and disfiguration of skin is basic requirement for categorization under *Kushtha* practically but predominantly it is occur over scalp (*Kapala/Murdha Pradesha*) so it can be counted under *Shiro Kushtha*. Review of different classical references infers that, *Arumshika* can be classified under the heading of *Shiro Kushtha*.

Trial drug (*Ankoladi Taila*) in present study is taken from *Sahastrayogam* book a famous clinical oriented reference book from Kerala wrote based on experiences of *Astha Vaidhya*'s of Kerela. This book quote effectiveness of *Ankoladi Taila* in *Shirokushtha* which can be better co-related with *Arumshika*. *Phalashruti* was given as “*Shiro Kushtha Vinashanam*”.

In the light of above background the present study aimed to evaluation of the efficacy of *Ankoladi Taila* in the management of Seborrheic Dermatitis in pediatric practice.

MATERIAL AND METHODS

The present clinical study was a single group, Interventional study type, open label masking, sample size of 20 patients.

Inclusion criteria

1. Patients of infantile age to 16 years was selected.
2. Patients with pigmentary changes in the scalp region with associated with scalp infection.
3. Patients with secondary bacterial infection and candidiasis with localized scalp involvement and devoid of systemic manifestation.

Exclusion criteria

1. Patients above 16 years of age.
2. Extensive involvements of deeper skin tissue and tendency towards Psoriasis was excluded.
3. Patients associated with other generalized skin disorders of varied etiology and manifestations was excluded from the study.
4. Skin disorders with hereditary, metabolic, other chronic disorders and secondary lesions was excluded.
5. Patients who are on long term drug therapies was excluded.

6. Patients with Seborrheic Dermatitis extending to face shoulder & back region was excluded.

Assessment criteria

- A Standard grading system was developed to assess the improvement in treated cases based on Symptomology of the Seborrheic Dermatitis.
- Photographic evidences were made to assess the pigmentory changes & overall improvement.

To grade dandruff/ Seborrheic Dermatitis severity, the scalp is divided into six anatomical sections (frontal, right parietal, left parietal, right temporal, left temporal, occipital). Shaving of scalp or a comb is used to part the hair in each area to give a clear view of the scalp. Each section was assessed for 6 subjective parameters i.e 1) Flakes, 2) Redness, 3) Itching, 4) Burning, 5) Discharge, 6) Boils that are adhering to the scalp skin using a 0 to 3 scale. Loose flakes in the hair are not considered in the grading. The final, or total score is the sum of the grades for all six scalp sections, which results in a scale ranging from 0 to 18.

Table no. I assessment criteria

S.No.	Symptom	Criteria	Severity	Grading
1.	Flaking/Scaling	No flaking	No	0
		slightly flaking	Mild	1
		flakes with erythema	Moderate	2
		scaly pimples appear	severe	3
2.	Redness	No redness	no	0
		Mild redness at site	Mild	1
		Redness with elevated edge at the site and erythema	Moderate	2
3.	Itching	Redness with congestion and swelling	Severe	3
		No itching	No	0
		Rarely itching	mild	1
		Itching subside after application of oil	moderate	2
4.	Burning	Itching doesn't subside after application of oil	Severe	3
		No burning	No	0
		Mild type of burning in localized area	Mild	1
		Burning in localized area & adjacent area	Moderate	2

		Continuously burning in generalized area	Severe	3
5.	Discharge	No discharge	No	0
		Watery oozing from lesion	Mild	1
		Oozing with thick purulent discharge	Moderate	2
		Continuous thick purulent blood mixed discharge	Severe	3
6.	Boils	No boil formation	No	0
		1-2 boils at site of itching	Mild	1
		Multiple boils (crops) with clear fluid	Moderate	2
		Multiple boils (crops) with exudate	severe	3

Study design and duration

The present clinical study was a single group, Interventional study type, open label masking, and sample size of 20 patients. The duration of treatment was 60 days. In this group Trial drug *Ankoladi Taila (Sahastrayogam Taila Prakarana)* used for External application, twice daily 10ml/day for the effected part of the scalp after shaving the scalp hairs.

Ankoladi Taila (Batch No.-A0069). The medicine was manufactured at National institute of Ayurveda pharmacy.

Statistical analysis

- The information gathered on the basis of observation made about various parameters was subjected to statistical analysis in terms of Mean, Standard Deviation and Standard error (SE). All the results calculated by using software: GraphPad InStat 3.
- All data was nonparametric so **Wilcoxon matched-pairs signed ranks test** is used, and results calculated in each group.
- For calculating the inter group comparison, **Mann-Whitney Test** was used. The result was interpreted as.
- Non-significant : $P > 0.05$
- Significant: $P < 0.05$
- Highly significant : $P < 0.01$, $P < 0.001$, $P < 0.0001$

OBSERVATIONS AND RESULTS

- 9-12 years age group was the most affected group.
- Males were more prone to Seborrheic Dermatitis as compared to females.

- Maximum numbers of cases were belonging to urban area, Hindu religion, vegetarian diet, middle socio-economic status and graduated family.
- Maximum number of cases exhibited Chronicity of 1-2year, no family history, and aggravation in winter season and relieved by local measures.
- Maximum patients of trial were *Vata-Kaphaja Prakriti, Mandagni, Madhyama Koshtha*, and excess intake of *Lavana- Amla Rasa*.
- Maximum patients of trial belongs to poor personal hygiene, irregular head wash and frequently change their hair oil for *Shiro Abhyanga*.
- The present study shows maximum patients were belongs to positive history of Infantile Seborrheic Dermatitis (Cradle Cap).
- Maximum patients done their first hair cut in less than one year of age.
- Maximum patients had flaking as a chief Complaint followed by itching, redness discharge and Boil. Incidences of flaking/ scaling observed maximum in left parietal area of scalp while Boils was maximum in Right Parietal and occipital area of scalp.
- *Ruksha* hair quality and occasionally hair fall was observed in maximum patients of trial.
- Maximum patients were belongs to dry/Scaly lesion, irregular border, normal to dull red in color and rough skin texture.

Table No. II: Showing effect of therapy in subjective parameters.

(Wilcoxon matched paired single ranked test)

Variable	Mean		Mean Diff.	% Relief	SD±	SE±	P	Intp.
	BT	AT						
Flaking	6.20	0.70	5.50	88.70	2.14	0.47	<0.0001	HS
Redness	3.35	0.10	3.25	97.01	3.09	0.69	<0.0001	HS
Itching	7.45	0.50	6.95	93.28	3.22	0.71	<0.0001	HS
Burning	1.00	0.05	0.95	95	1.50	0.33	<0.05	S
Discharge	1.85	0.05	1.80	97.29	2.62	0.58	<0.01	HS
Boil	2.05	0.55	1.50	73.17	2.54	0.56	<0.05	S

Table no. III pharmacological activities of content of *Ankoladi Taila*

S. no.	Drug	Part used	Action and properties	Indication
1.	<i>Ankola</i>	seed	Antifungal ^[8] antibacterial activity. ^[9]	<i>Krimi, Sarpavisha, Swavisha, Kushthaghna, Visarpa, Twagdosha, Jwara</i>
2.	<i>Maricha</i>	seed	antimicrobial agent. ^[10] anti-inflammatory effect. ^[11]	<i>Agnimandhya,, Shula, Shothavedanayukta Vikara, Krimi, Kushtha</i>
3.	<i>Kushtha</i>	root	anti-inflammatory. ^[12] anti-oxidant effect. ^[13]	<i>Shotha, Shula, Kushtha, Varnavikara, Agnimandhya</i>

4.	<i>Bakula</i>	leaves	anti-bacterial. ^[14] , antifungal. ^[15] , antimicrobial. ^[16]	<i>Visha, Krimi</i>
5.	<i>Jambira</i>	Fruit juice	antibacterial activity ^[17] , antifungal activity ^[18] , cytotoxic effects ^[19] antimicrobial activity. ^[20] anti-dandruff activity. ^[21]	<i>Krimi, Agnimandhya</i>
6.	<i>Tila Taila</i>	Seed oil	wound contraction. ^[22] Insecticidal Activity ^[23] antioxidant activity. ^[24]	<i>Khalitya, Palitya, Krimi</i>

DISCUSSION

Maximum content of *Ankoladi Taila* having *Vata Kapha Shamaka* property. Further *Taila* itself having *Vata-Kapha Shamaka* effect due to *Laghu* and *Snigdha Guna* which helps to alleviate the pathology of flaking.

Redness (*Raga*) due to *Pitta Prakopa* and *Rakta Dushti*. *Arumshika* is basically considered as *Shirogata Kushtha*. In present study *Arumshika* is having involvement of *Tridoshas* with *Rakta* and *Pitta* contribute for redness. As *Ankoladi Taila* having *Pitta Shamaka* and *Rakta Shodhaka* property.

Twak Avaddharana mediated by increased *Vata* and *Kledatva* of *pitta* may be even contribute to itching (*Kandu*). *Kandu* caused by vitiated *Kapha*^[4] and *Pitta Dosha*^[5], contains of *Ankoladi Taila* have *Kandughna* property due to *Katu Rasa*.

In *Arumshika Daha* symptom is due to *Pitta* and *Raktadushti*. *Ankoladi Taila* having *Dahaprashmana* and *Pittashamaka* effect. Presence of burning sensation is a one of the presentation of *Arumshika* has been attributed to *Pitta Dosha* and its relationship with *Rakta*. There will be local increase in temperature with increased blood flow and scalp skin will be vitiated by abnormal *Pitta* causing burning sensation.

Abnormal *Kleda* when collected in between hairs and not clean properly leads to further consequences. *Katu Rasa* and *Shoshaka* properties in *Ankoladi Taila* stops the production of *Mala Rupa Kleda (Upahanti Kleda)* and *Tikta Rasa* dries up the discharge (*Kleda Upashoshana*).^[6] As *Ankoladi Taila* is more effective in relieving discharge symptom of *Arumshika*.

Drug *Ankoladi Taila* having *Vranaropaka (Ankola, Kutha, Tila)* and *Grahi (Bakula)* property due to *Katu* and *Tikta Rasa*. Study suggests *Bakula* is anti-acne plant.^[7]

CONCLUSION

Ankoladi Taila is effective in reducing the severity of symptoms of Seborrheic Dermatitis/ Arumshika. Route of administration is easy, safe, and effective in children and shaving of scalp (*Mundana*) is helpful in early and immediate effect of drug. The study drug “*Ankoladi Taila*” is effective in reducing maximum symptoms of childhood Seborrheic Dermatitis. No adverse effect, of the study drug was observed during the study. Further double-blind placebo-control study in a higher population is recommended.

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