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A COMPARATIVE CLINICAL TRIAL TO EVALUATE THE EFFICACY OF *TRIPHALADI TAILA* AND *GUNJA TAILA* IN THE MANAGEMENT OF *DARUNAKA* W.S.R TO DANDRUFF AND SEBORRHEIC DERMATITIS

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ABSTRACT

Introduction: Dandruff is a skin condition that mainly affects the scalp. Dandruff is the most common scalp disorder in adolescence (post-pubescence) and adulthood, but is rare and mild in children. It is characterized by flakes, itching, dryness and hairfall. This disease have a high prevalence rate and frequent relapses. Dandruff is found to affect 50% of the world population. In *Ayurveda* the nearest correlation of dandruff can be made with "*Darunaka*". *Darunaka* is the non-inflammatory type of Seborrheic dermatitis. It is a disease concerned to hair root which is the most common cause for hair loss. Keeping all these facts in the background, the present clinical study is designed to evaluate the effect of two different classical *yoga* described by the *Acharya* in their respective texts for the management of *Darunaka* which are – *Triphaladi taila* and *Gunja taila.* **Material and Method:** The study was conducted in 60 clinically diagnosed patients having classical sign and symptoms of *Darunaka* in two groups. Group-A comprising of 30 patients administered with *Triphaladi taila* (ext. application) and Group-B comprising 30 patients administered with *Gunja taila* (ext. application) for 30 days. **Result:** From the observations and results it can be concluded that both drugs shows highly significant results in almost all the classical signs and symptoms of *Darunaka* very effectively, but the result in group B is ahead of result in Group-A.

KEYWORD: *Darunaka*, Dandruff, Seborrheic Dermatitis, *Triphaladi taila, Gunja taila.*

INTRODUCTION

Ayurveda is one of the most ancient systems of life, health and care. The first intend of ayurveda is to maintain the healthy status of the people with the prevention of unborn diseases and second one is to treat the already arisen diseases. *Ayurveda* is the most ancient among the holistic health science donated to humanity by the perfect Indian heritage. This is the era of holistic medicines, and *Ayurveda* is the only medical science which has the time tested knowledge base, right from the Vedic period till date which has been documented systematically and organized scientifically in *Samhita* and *Nighantu*. Modern day lifestyle, feeding habits, pollutants, stress level, decreased immunity etc have all caused a considerable increase in diseases, mostly related to lifestyle, stress and allergy specifically involving the skin and respiratory system. There are nineteen diseases described by *vagbhaṭṭ* in *shiroroga Pratishedha adhyaya*, they are 9 *kapala Roga*[1] and 10 *śiroroga.*[2] According to *vagbhatt*[3] and *sharangadhara.*[4] *Darunaka* is a *kapalagataroga* but *sushruta*[5] and other *Acharya* explained this disease under *kshudra Roga*. *vagbhatt* has described this disease in the *shiroroga*, the 23[rd]chapter of *Uttar Tantra.*[6] *Acharya sushruta* mentioned about this disease in *Nidana Sthana* chapter 13, *kshudraroga.*[7] *Acharya charaka* has not mentioned the disease directly, however in the 26[th] chapter of *chikitsasthana*, *Samprapti* of *Darunaka* is given in *śirah kapalagataroga*[8] without naming. *Madhavanidana*[9] has mentioned this disease in chapter 55 of second part named *kshudrarogaprakaran*. In *sharangadhara samhita*, the disease is mentioned in the 7[th] chapter of 1[st] Khaṇḍa.In *Bhava prakasha*, *Darunaka* is described in *Kshudraroga adhikar.*[10]

Dandruff is a skin condition that mainly affects the scalp.[11] Dandruff is the most common scalp disorder in adolescence (post-pubescence) and adulthood, but is rare and mild in children.[12] Historically, it was thought that about 50% of humans were affected to some degree, with onset at puberty and peak incidence and severity at about 20 years of age and becoming less frequent after the age of 50.[13] Dandruff and Seborrheic Dermatitis are

common disorders affecting the scalp that is often associated with itching[14] and can be an embarrassing condition. These two diseases have a high prevalence rate and frequent relapses. Dandruff is found to affect 50% of the world population. In *Ayurveda* the nearest correlation of dandruff and Seborrheic dermatitis can be made with "*Darunaka*". *Darunaka* is the non-inflammatory type of Seborrheic dermatitis.It is a disease concerned to hair root which is the most common cause for hair loss.

Darunaka is characterized by *Tvak sphutana* (scaling of the scalp) *kandu* (itching),*Keshabhumi Rukshata* (dryness and roughness of scalp), *keshachyuti* (diffuse hair falling), *Daruna* (difficulty in tolerance), *svapa* (loss of touch sensation) and all these symptoms are due to vitiation of *vata* and *kapha* dosha.

AIMS AND OBJECTIVES

1. To compare and evaluate the effects of *Triphaladi Taila* and *Gunja Taila* as Local Application in the management of *Darunaka* w.s.r to Dandruff and Seborrheic dermatitis.

MATERIALS AND METHODS

Selection of the patients: In this study the patients presenting with *Darunaka* (Dandruff and Seborrheic Dermatitis) registered from OPD and IPD of NIA Hospital, Satellite and Bombaywala Hospitals and outreach camps organized by NIA was taken. The selection of cases was done on the clinical features and supported by laboratory findings. In this study non-inflammatory type of seborrheic dermatitis patients were taken into considerations. A written information and consent form had been given to the patients. The patients were explained about the purpose, procedures and possible side-effects of the trail. Total 60 patients were registered for the study and had completed the trial.

Study Design

- Interventional
- Comparative
- Prospective
- Randomized
- Open Label
- Parallel Group

Selection Criteria

(a) Inclusion criteria

1. Male or female between age 16 to 70 years and willing to give their written informed consent.
2. No major systemic disease involved.
3. Patients who have signs and symptoms of Darunaka. (Dandruff and Seborrheic Dermatitis).

(b) Exclusion criteria

1. Patients having other skin diseases like psoriasis, atopic dermatitis, pregnancy, lactation, immunodeficiency states and hypersensitivity.

Assessment criteria

Subjective Parameters

The assessment will be done on the basis of following parameters according to Proforma.

1. *Tvak sphutana* (Scaling or Flakes).
2. *Kandu* (Itching).
3. *Kesha bhumi rukshata* (Dryness).
4. *Keshacyuti* (Hair fall).
5. *Daruna* (difficulty in tolerance).
6. *Svapa* (loss of touch sensation).

Objective Parameters

CBC, ESR, FBS/RBS, AEC, KOH test.

Trail Drugs: Drug A - *Triphaladi Taila*[15] (Bh. R. *Kshudraroga chikitsa* 55/126).

S. No	Name of the constituent	Botanical Name	Part used	Ratio
1.	*Amalaki*	Emblica Officinalis Gaertn.	Fruit	1 part
2.	*Haritaki*	Terminalia Chebula Retz.	Fruit	1 part
3.	*Bibhitaka*	Terminalia Bellerica Roxb.	Fruit	1 part
4.	*Bhṛingaraja*	Eclipta alba Hassk.	*Panchanga*	1 part
5.	*Nila kamala*	N. stellate willd	*Puṣhpa*	1 part
6.	*Anantamula*	Hemidesmus indicus R.Br.	*Mula*	1 part
7.	*Loha Bhasma*	Iron		1 part
8.	*Saindhava Lavaṇa*	Rock salt		1 part
9.	*TilaTaila*	Sesamum indicum Linn.		4 parts

- **Dose** – 10-15 ml.
- **Duration** - One month daily.
- **Route of administration**- Local application on head (*shiroabhyanga*).

Drug B - *Gunja Taila*[16] (Bh.R.Kshudraroga chikitsa 55/128).

S. No	Name of the constituent drug	Botanical Name	Part used	Ratio
1.	*Gunja*	Abrus precatorius Linn.	Fruit	1 Part
2.	*Tila Taila*	Sesamum indicum Linn.	Seed	4 Part
3.	*Bhṛingaraja*	Eclipta alba Hassk.	*Panchanga*	16 part

- **Dose**- 10-15 ml.
- **Duration** - One month daily.
- **Route of administration**- Local application on head (*shiroabhyanga*).
- **Duration of the trail:** 6 weeks (Drug intervention for 4 weeks & follow up for 2 weeks).

RESULTS

Results of the treatment will be tabulated and analyzed statistically with relevant tests and level of significance was reported.

Data Documentation and Statistical Analysis

Data were analyzed using Graph Pad Instat (version 3.10, 32 bit for windows created July 10, 2009). Paired't' test was used for the parametric data and Wilcoxon matched pair rank test for non-parametric data in individual groups. For comparison between the groups, Parametric unpaired t-test and Non-Parametric Mann Whitney test were applied.

Table No.1: Intergroup comparison of Group A and Group B on subjective parameter variable.

Variable	Group	N	Mean	S.D	S.E	P	S
Tvak sphutana	**A**	30	2.300	0.6513	0.1189	0.0625	N S
	B	30	2.600	0.5632	0.1028		
Kaṇḍu	**A**	30	2.100	0.7589	0.1385	0.9344	N S
	B	30	2.133	0.5713	0.1043		
Kesha bhumi rukshata	**A**	30	1.767	0.7279	0.1329	0.0072	V S
	B	30	2.267	0.7397	0.1350		
Keshachyuti	**A**	30	1.967	0.6687	0.1221	0.0239	S
	B	30	2.367	0.6687	0.1221		
Daruna	**A**	30	1.533	0.5074	0.0926	0.1369	N S
	B	30	1.233	0.8976	0.1639		
Svapa	**A**	30	0.7333	0.5833	0.1065	0.1524	N S
	B	30	1.000	0.7428	0.1356		

(Mann Whitney Test)

Kandu

In Group A and B the P-value is 0.9344 i.e>0.05 which is statistically non significant which shows that there is no statistical difference in efficacy of both treatments on *Kandu*.

Kesha bhumi rukshata

In Group- A and B, the P-value is 0.0072 i.e <0.05 which is statistically significant which shows that there is statistical difference in efficacy of both treatments on *Kesha bhumi rukshata.*

Keshachyuti

In Group- A and B, the P-value is 0.0239 i.e <0.05 which is statistically significant which shows that there is statistical difference in efficacy of both treatments on *Keshachyuti.*

Daruna

In Group- A and B, the P-value is 0.1369 i.e >0.05 which is statistically non significant which shows that there is no statistical difference in efficacy of both treatments on *Daruna*.

Svapa

In Group A and B the P-value is 0.1369 i.e >0.05 which is statistically non significant which shows that there is no statistical difference in efficacy of both treatments on *svapa*.

Table no. 2: Comparison of Overall Effect of Therapy on Subjective Parameter between Group A and Group B.

Sign and symptoms	Group I		Group II	
	% Improvement	P	% Improvement	p
Tvak Sphutana	79.31	<0.0001	88.64	<0.0001
Kandu	88.71	<0.0001	90.11	<0.0001
KeshabhumiRukshata	83.80	<0.0001	88.60	<0.0001
Keshachyuti	71.79	<0.0001	82.56	<0.0001
Daruna	91.96	<0.0001	78.68	<0.0001
Svapa	91.62	<0.0001	79.94	<0.0001

On comparing the results of both the groups on subjective parameters it was observed that percentage of relief in *Tvak sphutana* in Group A and Group B was 79.31% and 88.64%. *Kandu* showed 88.71% in Group A and 90.11 in Group B. *Kesha bhumi rukshata* showed 83.80% in Group A and 88.60 in Group B. *Keshachyuti* showed 71.79% in Group A and 82.56 in Group B. *Daruna* showed 91.96% in Group A and 78.68 in Group B. *Svapa* showed 91.62% in Group A and 79.94 in Group B. This showed that *Gunja Taila* gave more relief in percentage in *Tvak sphutana*, *Kandu*, *Kesha bhumi rukshata* and *Keshachyuti* as compared to *Triphaladi Taila.*

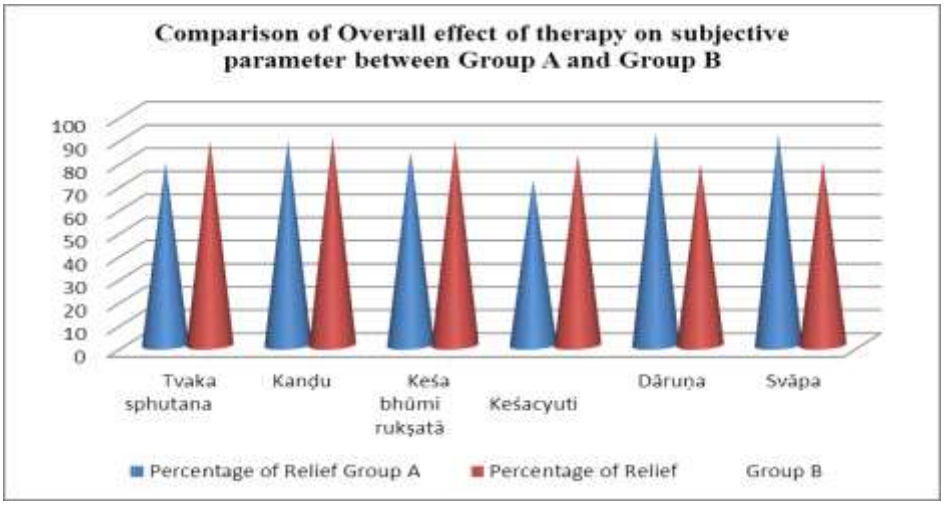

Table No.3: Intergroup comparison of group A and group B on objective parameters.

Variable	Group	N	Mean	S.D	S.E	T	P	S
HB	**A**	30	4.969	0.4402	0.0803	1.229	0.2242	N S
	B	30	0.1900	0.7237	0.1321			
TLC	**A**	30	36.667	238.51	43.545	0.8799	0.3826	N S
	B	30	90.000	230.96	42.168			
ESR	**A**	30	-0.2333	1.331	0.2430	0	0.9999	N S
	B	30	-0.2333	0.9353	0.1708			
Neutro	**A**	30	0.2333	1.094	0.2181	1.386	0.1711	NS
	B	30	-0.2667	1.574	0.2874			
Lympho	**A**	30	0.6667	2.264	0.4134	1.783	0.0798	N S
	B	30	-0.2000	1.400	0.2555			
Eosino	**A**	30	0.4333	1.478	0.2699	1.383	0.1719	N S
	B	30	0.0000	0.8710	0.1590			
Mono	**A**	30	0.4333	1.478	0.2699	1.728	0.0892	NS
	B	30	-0.4333	2.315	0.4226			
Baso	**A**	30	0	0	0	0	0	-
	B	30	0	0	0			
TRBC	**A**	30	0.0750	0.2068	0.0377	0.0510	0.9595	NS
	B	30	0.0723	0.1982	0.0361			
TPLC	**A**	30	-0.0326	0.1703	0.0310	0.7637	0.4481	NS
	B	30	-0.0833	0.0380	0.0069			
TEC	**A**	30	0.5667	2.515	0.4591	0.0968	0.9232	NS

	B	30	0.9000	18.683	3.411			
PCV	**A**	30	-0.0766	0.1251	0.0228	0.2039	0.8391	NS
	B	30	-0.0933	0.4299	0.0784			
MCV	**A**	30	-0.2300	0.7544	0.1377	1.490	0.1416	NS
	B	30	-0.0233	0.0897	0.0163			
MCH	**A**	30	-0.0066	0.0944	0.0172	2.819	0.0066	S
	B	30	-0.1200	0.1990	0.0363			
MCHC	**A**	30	-0.2100	1.682	0.3070	1.432	0.1576	NS
	B	30	0.3667	1.428	0.2607			
RBS	**A**	30	0.4000	3.201	0.5845	0.9298	0.3563	NS
	B	30	-1.500	10.725	1.958			

(Unpaired 't' Test)

On comparison between Group- A and Group- B, it was observed that all the objective parameters showed non – significant result (i.e $p \geq 0.05$) except MCH which showed significant result.

PROBABLE MODE OF ACTION OF DRUGS

- The mode of action of *taila* as *shiroabhyanga* increases the blood circulation in the scalp and hence impure blood is exchanged by fresh blood and thus due to the different properties of *taila* like *snigdha guna, katu, tikta rasa, uṣṇa virya* removes vitiated *dosha* from the *srotas* and helps in curing the disease.
- *Darunaka* occurs mainly due to vitiation of *vata* & *kapha dosha*. There may be assistance of vitiated *rakta* & *pitta.*
- *Kaṇḍu* is one of the symptom in *Daruṇaka*. This is due to the factors like accumulation of *mala* on the scalp. Both *taila* have *kaṭu, tikta rasa, katu vipaka* & *ushṇa virya. Tila Taila* also have *tikta rasa* and *ushṇa virya*.Hence due to *kaṇḍughna, krimighna* properties; it gives relief in *Darunaka* by relieving *kaṇḍu* & killing *krimi*. Overall *katu rasa* helps in relief, by pacification of vitiated *kapha*.
- *Tikta Rasa* acts in a similar way as it is *a krimighna, vishapaha*, pacifies vitiated *kapha* & *laghu* in property. Hence *Katu, tikta rasa, ushṇa virya* and *kaphahar* property of *gunja taila* and *Tila Taila* help in pacifying *Kapha* and reduces *kaṇḍu* symptom in *Darunaka.*
- *Rukshata* in *Darunaka* is due to *abhyangadvesha* and other *Vata* vitiating *nidana* which causes roughness of scalp. *Rukshata* is pacifying by *Snigdha Guna* of both the oil.
- *Tvak sphutana* in *Darunaka* is the result of the vitiated *vata dosha*. *Uṣhṇa virya* of the drugs plays a role in pacifying vitiated *vata dosha*. *Tikta Rasa* provides stability to *tvak* & tissues, which might help in reducing *tvak sphutana* occurring in *darunaka.* As *tikta* is *rukṣa* in property it dries *pitta* & pacifies it. Hence associated *daha, raga* settles down. Hence *Triphaladi taila* and *Gunja Taila* reduce *tvak sphuṭana* by its *snigdha guna, tikta rasa, ushṇa virya* and *vatahara* property.
- *Keshachyuti* (Hair fall) is another symptom of *Darunaka.* The hairfall in *darunaka* may be due to lack of *snigdhata* caused by vitiated *vata*. The hair becomes dull and rough; owing to their abnormal dryness they become short, thin and fall out easily. *Triphaladi taila* and *gunja taila* both reduces hair fall by their *snigdha guna, tikta rasa* and *vata kaphahara* property. *Tikta rasa* dries vitiated *pitta dosha* with *ruksha* property & pacifies *pitta dosha*. *Ushṇa virya* of the drug is responsible for pacification of vitiated *vata dosha*, which reduces hairfall.
- *Daruna* (difficulty in tolerance) is another symptom of *darunaka*.This is due to lack of *snigdh guna* caused by vitiated *vata*. Hence *Katu, tikta rasa, ushṇa virya* and *kaphahar* property of *gunja taila* and *Triphaladi taila* help in pacifying *kapha*.

Discussion on effect of therapy on Subjective Parameters

➢ ***Tvak sphutana***

Effect of therapy of Group A had reduced the ***tvak sphutana*** by 79.31% which was statistically significant ($p<0.0001$). It indicate that the *snigdhata* of the oil counter acts and helps in reducing the *tvak sphutana*, hence it got highly significant values in *Triphaladi Taila* group.

Group B had reduced the *tvak sphutana* by 88.64% which was statistically highly significant ($p<0.0001$). It indicate that the snigdhata of the oil counter acts and helps in reducing the *tvak sphutana*, hence it got highly significant values in *Gunja Taila* group.

On comparison between Group A and Group B the P-value is 0.0625 i.e >0.05 which is statistically non significant which shows that there is no statistical difference in efficacy of both treatments on *tvak sphutana.*

➢ ***Kandu***

Effect of therapy on Group A had reduced *Kandu* by 88.71% which was statistically highly significant ($p<0.0001$).

Group B had reduced *Kandu* by 90.11% which was statistically highly significant ($p<0.0001$).

On comparison between Group A and Group B the P-value is 0.9344 i.e >0.05 which is statistically non significant which shows that there is no statistical difference in efficacy of both treatments on *Kandu*.

- ***Kesha bhumi rukshata***

Effect of therapy on Group A had reduced *keshabhumi Rukshata* by 83.80% which was statistically highly significant (p<0.0001). It indicates that *Triphaladi Taila* showed significant result in curing *keshabhumi rukshata* with its *Vatakaphahara* property and *Snigdha Guna.*

Group B had reduced *keshabhumi rukshata* by 88.60% which was statistically highly significant (p<0.0001). Tila Taila also showed significant result in curing *keshabhumi rukṣhata* with its *Vatakaphahara* property and *Snigdha Guna*.

On comparison between Group A and Group B the P-value is 0.0072 i.e <0.05 which is statistically significant which shows that there is statistical difference in efficacy of both treatments on *keshabhumi rukṣhata.*

- ***Keshachyuti***

Effect of therapy on Group A had reduced *Keshachyuti* by 71.79 % which was statistically highly significant (p<0.0001). Group B had reduced *Keshachyuti* by 82.56% which was statistically highly significant (p<0.0001).

On comparison between Group A and Group B the P-value is 0.0239 i.e <0.05 which is statistically significant which shows that there is statistical difference in efficacy of both treatments on *Keshacyuti*.

- ***Daruna***

Effect of therapy on Group A had reduced *Daruṇa* by 91.96 % which was statistically highly significant (p<0.0001). Group B had reduced *Daruṇa* by 78.68 % which was statistically highly significant (p<0.0001).

On comparison between Group A and Group B the P-value is 0.1369 i.e >0.05 which is statistically non significant which shows that there is no statistical difference in efficacy of both treatments on *Daruṇa.*

- **Svapa**

Effect of therapy on Group A had reduced svapa by 91.62% which was statistically highly significant (p<0.0001). Group B had reduced *svapa* by 79.94% which was statistically highly significant (p<0.0001).

On comparison between Group A and Group B the P-value is 0.1369 i.e >0.05 which is statistically non significant which shows that there is no statistical difference in efficacy of both treatments on *svapa*.

From the comparison of results between both groups it is observed that *Gunja Taila* gives more percent relief on symptoms, i.e., *kesha bhumi Rukshata, Kandu, keshachyuti, tvak sphutana* as compare to *Triphaladi Tail*.

Discussion on Objective parameters in Group A and Group B (Paired t-test)

In this study, it was observed that almost all the objective parameters in Group A and Group B showed statistically non significant results except PCV in Group A which showed significant result.

Discussion on Objective parameters in intergroup comparison (Unpaired t-test)

On comparison between Group A and Group B, it was observed that all the parameters showed non –significant result except MCH which showed significant result.

Discussion on KOH Test: The sample was analyzed on the basis of direct microscopy of the collected sample of hair and scalp. Scalp scrapings were examined as wet mounts in 10% KOH containing dandruff which showed hyphae and conidiospores exhibiting the characteristic of thick-walled round, yeast-like cells alongside short angular hyphae which are characteristic features of Malassezia species.

CONCLUSION

1. Both the drugs i.e. *Triphaladi Taila* and *Gunja Taila* showed statistically highly significant results in various sign and symptoms of *Darunaka*.
2. *Gunja Taila* showed better results in symptoms like *Kandu, Rukshata, Tvaka sphutana, keshachyuti*, while as *Triphaladi Taila* showed better results in symptoms like *Daruṇa* and *Svapa.*

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