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ACONTROLLED CLINICAL STUDY TO EVALUATE THE EFFICACY OFAPPLICATION OF GUNJATAILA IN DARUNAKA IN CHILDREN

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ABSTRACT

In classics *Darunaka* is mentioned as one of the *Shiro Kapalagata Rogas* exhibiting symptoms like *Kandu*, *Keshachyuti*, *Rukshata*, *Twaksphutana*. As features are similar to Pytiriasis Capititis *Darunaka* is corelated to the same which is also known as Dandruff. Even though it affects every age group it seems very common in Pre-Pubertal & Pubertal age group. High Harmonal activity is the important factor for prevelance in this age group. Various Anti-Dandruff shampoo available in the market which cause harm than benefiting sensitive scalp, Hence this study is conducted to research Safe & Effective drug for Chidren group. As Ketoconazole is widely used to treat the condition it has been included in the study for comparision.

KEYWORDS: *Darunaka, Gunja taila*, Ketoconazole, Dandruff.

INTRODUCTION

Shiras is considered as *Uttamaanga* by our *Acharyas*. It is the seat of vital breath of living beings & also all the sense organs^[1], & which is Pradhana & one among Trimarma^[2] of all organs. Thus, disease affecting the *Shira* negatively affects the quality of life. There are 19 disease explained by *Acharya Vaghbhata* in *Shiroroga Pratishedhaadhyaya*,^[3] they are 10 *Shiroroga* & 9 *Kapala roga*^[4] & *Acharya Sushruta* included *Darunaka* under *Kshudra rogas*.^[5] In classics Darunaka is mentioned under *Shiro Kapalagataroga* exhibiting features like *Kandu*, *Keshachyuti*, *Rukshata*^[6] which occurs by vitiation of *Kapha-Vata dosha*. Dandruff having similar features of *Darunaka* affects about 18.38% of Pre-Pubertal &

Pubertal age group of Children.^[7] The yeast Malessezia is found in every human being in scalp which triggers Dandruff.^[8] Transformation of the Yeast to Hyphal forms facilitates invasive disease, Hair loss & Seborrheic dermatitis. Malassezia associated skin diseases of the head & neck can be effectively managed with Ketoconazole widely. Hence, this study includes Ketoconazole as a comparative drug. *Shiroabhyanga, Shirodhara, Shirobasti, Shirolepa, Nasya & Raktamokshana* is the line of treatment for *Darunaka* in the classics.^[9] Where, *Raktamokshana* is completely contra-indicated in Peadiatric group & rest all can be adopted. *Shiroabhyanga* is convenient to use among other procedures in Children group. *Gunjataila Abhyanga* is mentioned in *Darunaka chikitsa* by *Bhavaprakasha*^[10], *Chakradatta &Vangasena* which pacifies *Darunaka, Kandu, Kustha* by its *Kapha-Vatahara, Shrotho shodhaka, Twak prasadhaka, Balya, Keshya* property. There are numerous hair products available in the market which are mostly worsen the condition instead of benefitting. Hence, This study is conducted in this regard to research safe, effective, easy administering & affordable medicine for *Darunaka* for Children age group.

OBJECTIVES OF THE STUDY

- 1. To Study the efficacy of Gunja Taila in Darunaka.
- 2. To Compare the efficacy of *Gunja Taila* with Ketoconazole Solution in *Darunaka*.

MATERIALS AND METHOD

SOURCE OF DATA

- LITERARY SOURCE: Classical Ayurvedic textbooks, textbooks of contemporary sciences & articles from periodical journals & other magazines, websites & other sources was referred.
- DRUG SOURCE: Raw drugs required was identified & collected from the available
 local market & the Taila was prepared according to the textual reference, in the
 Rasashastra & Bhaishajya Kalpana Lab, Alva's Ayurveda Medical College, Moodbidri.
- SAMPLE SOURCE: Subjects was selected randomly from High Schools in & around Moodbidri, special medical camps & other sources.

DESIGN OF STUDY: A randomized controlled clinical study.

- **SAMPLING:** Sampling was done using lottery method.
- DIAGNOSTIC CRITERIA
- ShiroKandu

- Kesachyuthi
- Shirorukshana
- Twaksphutana

INCLUSION CRITERIA

- Subjects full-filling diagnostic criteria.
- Age group 8-16 years irrespective of gender, religion & socio economic status.

EXCLUSION CRITERIA

- Patient with other scalp diseases.
- Dandruff associated with systemic involvement.
- Allergic manifestation.

INTERVENTIONS

GROUP	MEDICINE	DOSE	APPLICATION	FREQUENCY	DURATION
A	Gunja Taila	Quantity sufficient	2 hours	Twice in a week	28Days
В	Ketoconazole	Quantity sufficient	Before head bath	Twice in a week	28Days

STUDY DURATION

- Treatment duration: 28 days.
- Ist 28 days Group–A given with *Gunja Taila* & Group–B given with Ketoconazole scalp Solution. Assessment of subjects will be done before treatment, 14th day, 29th day& 42nd day.

ASSESSMENT CRITERIA

SUBJECTIVE PARAMETERS: Kandu, Keshachyuti.

OBJECTIVE CRITERIA: Rukshata, Twaksphutana.

Table No 18: Showing Grading.

Lakshana	0	1	2	3
Kandu	No itching	Mild itching	Moderate tolerance	Severe intolerable
Kesha	1-5 Hairs fall on	Mild: Less than 20	Moderate: More than 20	Severe: Less than 20
		hairs fall on	hair fall on	hairs fall on simple
chyuthi combing/washing	combing /washing	combing/washing	hand strength	
Rukshata	No drymage	Mild: Dryness with	Moderate: Dryness with	Severe:Dryness with
Kuksiiata	No dryness	rough skin	scaling	cracking skin
Twaksph	No scaling	Mild: Scaling less	Moderate:	Severe:scaling
utana	ino scainig	than 1/4th part	Scaling is more than ½ part	(All over the head)

METHOD OF ASSESSMENT: The data obtained will be recorded, tabulated & analyzed statistically using wilcoxon signed rank test & Mannwhitney u test.

RESULTS Effect of treatment in signs & Symptom on 28th day in Group A.

signs &	Mean		%	SD ± SE	"p" value	
Symptoms	BT	AT	70	SD ± SE	p value	
Kandu	2.650	0.350	87%	0.587+/-0.131	< 0.001	
Keshyachyuti	2.000	0.250	87%	0.725+/-0.162	< 0.001	
Rukshata	2.000	0.450	84%	0.513+/-0115	< 0.006	
Twaksphutana	2.500	0.450	92%	0.513+/-0.733	< 0.002	

There was statistically significant change in all the signs & symptoms with p< 0.05.

Effect of treatment in signs & Symptom on 28th day in Group B.

signs &	Mean		%	SD ± SE	%n" valua	
Symptom	BT	AT	70	SD ± SE	"p" value	
Kandu	2.650	0.150	96%	0.587+/-0.131	< 0.001	
Keshyachyuti	2.00	0.725	63.7%	0.725+/-0.162	< 0.001	
Rukshata	2.050	0.605	72%	0.605+/-0.135	< 0.021	
Twaksphutana	2.500	0.300	88%	0.513+/-0.172	< 0.031	

There was statistically significant change in all the signs & symptoms with p< 0.05.

Comparative effect of Treatment in signs&Symptoms in both groups on 28th day.

signs &	Mean difference		Percentage relief		"p"	Remarks
Symptoms	Group A	Group B	Group A	Group B	value	Kemarks
Kandu	3.000	1.000	87%	96%	=0.309	N.S
Keshachyuti	2.000	2.000	87%	63.7%	< 0.078	significant
Rukshata	2.00	1.000	84%	72%	=0.424	N.S
Twaksphutana	2.000	2.000	92%	88%	=0.714	N.S

There was no significant changes in Kandu, Rukshata, Twaksphutana in between the group with p Value =0.309, p=0.424, p=0.714 respectively & There was a significant change in Keshachyuti with p<0.078.

Comparative Effect Of The Treatment.

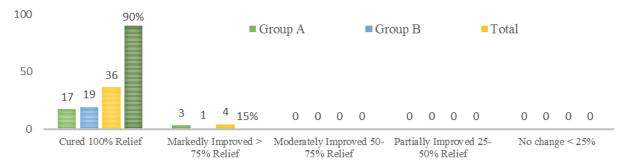
Effect of Therapy	Group A	%	Group B	%
Cured 100% Relief	17	85%	19	90%
Markedly Improved > 75% Relief	3	15%	1	10%
Moderately Improved 50-75% Relief	0	0	0	0
Partially Improved 25-50% Relief	0	0	0	0
No change < 25%	0	0	0	0



On comparision between the groups, in Group A 17(85%) Subjects found complete relief, 3(15%) subjects got marked relief. In Group B 19(90%) Subjects found Complete relief & 1(10%) got Marked relief.

Over All Effect of Treatment

Effect of Therapy	Group A	Group B	Total	%
Cured 100% Relief	17	19	36	90%
Markedly Improved > 75% Relief	3	1	4	10%
Moderately Improved 50 - 75% Relief	0	0	0	0
Partially Improved 25-50% Relief	0	0	0	0
No change < 25%	0	0	0	0

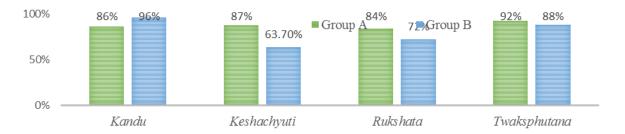


On comparing overall effect, complete relief found in 36(90%) Subjects & Markedly relief found in 4(10%) subjects.

DISSCUSSION ON RESULTS

Comparative Effect of Both treatment in signs & Symptoms after Treatment.

signs	Mean di	fference	Percentage	e relief	"p" value	Remarks	
&Symptoms	Group A	Group B	Group A	Group B	p value	Kemarks	
Kandu	3.000	1.000	87%	96%	=0.309	N.S	
Keshachyuti	2.000	2.000	87%	63.7%	< 0.078	significant	
Rukshata	2.00	1.000	84%	72%	=0.424	N.S	
Twaksphutana	2.000	2.000	92%	88%	=0.714	N.S	



- * KANDU-This shows that both groups are effective in treating Kandu but Group B [Ketoconazole] was more effective than Group A. This might be due to Fungicidal property of Ketoconazole. Relief in Kandu in Group A[Gunja taila] may be because of Kandughna, Krimighna & Kapha -Vata hara properties of the drugs in Gunja Taila.
- ❖ KESHACHYUTI- This shows that Group A [Gunja taila] shown clinically more effective than Group B [Ketoconazole]. The Hairfall in Darunaka may be due to lack of Snighdata caused by vitiated Vata. Ushna Virya of Taila help to reduce Vata Dosha & also Keshya property of Taila may be helped in reducing Hair fall.
- * RUKSHATA- suggests both the groups are effective in treating *Rukshata* but Group A [*Gunja taila*] was more effective than Group B [Ketoconazole]. *Rukshata* in *Darunaka* is due to *Abhyanga Dwesha* & other *Vata* vitiating *Nidanas* which causes roughness of Scalp. *Rukshata* is pacified by *Vata hara* & *Snighdha* properties of *Gunja taila* by which it balance snigdhata in *Twak hence reducing Rukshata*.
- * TWAKSPHUTANA-Both the groups are effective in treating Twaksphutana but Group A is more effective. This indicates that Gunja taila shiro abhyanga is better than Ketoconazole solution application. Twaksphutana in Darunaka is due to vitiated Vata Dosha. Ushna virya of the drugs plays a role in pacifying vitiated Vata Dosha. Tikta rasa provides stability to twak & tissue which may help in reducing twaksphutana in Darunka.

DISCUSSION ON OBSERVATION

FEATURES	OBSERVATION [Predominance]	DISCUSSION
Age	40% 12- 16 years	This may be due to excess sweat due to hyper activity of Sebaceous glands which is influenced by various growth Harmones, Stress factors, Improper cleansing of scalp, Intake of excess junk food, using & changing various Chemical products with eagerness to get early relief.
Gender	50% each	Darunaka is caused by excessive sweating, which is more common in adolescent boys since they are more exposed to sunlight & participate in physical activities than girls, but it can also equally seen in girls because of improper scalp hygiene due to long hairs.
Religion	97.5% Hindu	This may be because Hindu resides more in this regionality.

Economic Status	85% Middle class	Might be due to the regional prominence with middle class.				
Food Habits	70% Mixed	As non-vegetarian foods are over fried, contains excess oil & spicy, which vitiates Vata & Pitta dosha.				
Based On Oil	55% Coconut oil	Suggests that the currently available oils have no therapeutic impact on Darunaka.				
Based On Cosmetic Use	57.5% Anti-Dandruffbr&ed shampoo	This study suggests that using Anti-Dandruffshampoo & other hair-cleansing cosmetics on a daily basis does not prevent Darunaka.				
Nidana	85% Rajasevana [dust]	Rajasevana being major impact for Darunaka followed Atapasevana, Gurubhojana. This could be because people this age range are more likely to engage in outdoor playf activities, hence production of excess sweat leading manifestation of Darunaka.				
Symptoms	100% Twaksphutana	This means that Twaksphutana will emerge on the scalp as white fine scales & will also fall freely over the shoulder, making it one of the significant & diagnostic cause of the disease. If there is Twaksphutana, there will be apparent Rukshata of Scalp, & if it is not cleansed properly, it will collect over time, leading to Kandu, which will further impede nutrition, resulting in hair fall.				
Prakriti	45% Vata-kapha	This may be that dominant Vata & Kapha individuals are vulnerable to this disease.				

DISCUSSION ON MODE OF ACTION OF GUNJA TAILA

ON EXTERNAL APPLICATION: Darunaka is a *Twak vikara* affecting 3rd layer (Shweta) of skin which can be corelated to Stratum granulosa of Epidermis.

❖ So in epidermal skin diseases local application of medicine works faster than internal medicine. The *Gunja taila* is one such external application which is used in treating *Darunaka*. Vayu dominates in the Sparshanendriya, Abhyanga performs vatahara karma & as Indriya are in close contact of mind abhyanga stimulates mind & pacifies various emotional factors.

Dravya	Guna & Karma	Lakshana
Gunja&Bhringaraja	Tikta rasa, Kapha hara, Krimighna & Kandughna	Kandu
Gunja, Bhringa raja & Tila Taila	Keshya & Twachya	Keshachyuti
Tila Taila	Singdha guna, <i>Vata hara</i> , <i>Twachya</i>	Rukshata
Gunja,Bhringa raja & Tila Taila	Tikta rasa , Madhura rasa, Vata hara, Snighdha guna, Twachya	Twaksphutana

DISCUSSION ON CHEMICAL CONSTITUENTS

1. GUNJA^[1]- Abrin^[2]- protein toxic fat splitting enzyme kills micro-organisms. Extracted oil said to be stimulates hair growth. Hypophorine^[3] - counteracts the activity of indole 3 Acetic acid & helps in Root elongation.

- 2. **BHRINGA RAJA**^{[4]-} Wedelolactone^[5] stimulates follicular Keratinocytes proliferation. Hentriacontanol^{[6]-} Hair tonic, delays terminal differentiation.
- 3. **TILA TAILA**^[7]- Linoleic acid^[8], Essential Omega fatty acid,has wound healing property. Saponins^[9] are responsible for antibacterial activity.

PROBABLE MODE OF ACTION OF GUNJA TAILA

❖ Upon topical *Abhyanga* i,e Circular movements upon the Skin helps the active principle in *Taila* gets readily penetrates to the deeper layers of the skin & stay intact for longer duration brings *Snigdhata.Taila* being *Sukshma*, *Tikshna* & *Ushna* gets absorbed through the *Swedavaha srotas* & allows the local toxins [*krimi*] to flow out through excessive *swedana* thus clearing the micro-channels.

CONCLUSION

- ❖ The Etiology & the clinical features are nearly similar in *Darunaka* & Pityriasis Capitis. In the current study it was noticed that *Darunaka* was more prevalent in those who indulge in *Rajo sevana*, *Atapa sevana* which affects from externally & internaly affecting *Nidanas* i,e *Sheeta ahara sevana* or *Kaphavardaka* ahara like excess *Madhura ahara sevana* & some emotional factors. Darunaka mainly occurs due to manifestation of *Krimi* due to various *Nidana sevana* So one should create an awareness in Children about maintaince of Hygiene to prevent the Disease.
- ❖ Both *Gunja taila* & Ketoconazole solution application has significant effect in pacifying the symptoms of *Darunaka* & reduction in clinical symptoms.
- ❖ There was no topical & systemic adverse drug effects at the end of the study. & this preparation is definitely have the potential effect to treat *Darunaka*.
- \diamond Hence Null Hypothesis \mathbf{H}_0 can be rejected & Alternate Hypothesis \mathbf{H}_1 is accepted.

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