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COMPARATIVE CLINICAL EFFICACY OF ARK TAILA AND ARK CREAM APPLICATION IN THE MANAGEMENT OF VICHARCHIKA - AN OPEN LABELLED, RANDOMISED CONTROLLED CLINICAL TRIAL

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ABSTRACT

Vicharchika is one of *Kushtha* included under *Rakta Pradoshaja Vikaras*, recurrent and chronic in nature. Modern dermatologists use topical therapy such as topical corticosteroid; topical emollients etc. to give symptomatic relief but it cost in severe long-term toxicity, skin irritation and may cause skin cancer. *In Ayurvedic* texts, there are hundreds of medicaments as a successful and safer remedy for the chronic derma problems including *Vicharchika*. *Acharya Sharangdhar* had depicted one such formulation "*Ark Taila*" for treating *Vicharchika*. *Sneha Siddha* drugs have better pharmacokinetics action in comparison to other dosage form because of the lipid nature of biomembrane, as lipid soluble substances readily permeate into cells. **Aim and Objective:** To compare the efficacy of *Ark Taila and Ark cream* application in the management of *Vicharchika*. **Materials and Methods:** In this study, 30 patients of *Vicharchika* were selected and randomly allocated into two groups. In group A, *Ark Taila* (*n* = 15), and in group B *Ark* cream (*n* = 15) was given to patients for local application. Patients were assessed for relief in signs and symptoms at interval for fifteen days for sixty days. **Results:** Patients of group A has maximum

relief in sign and symptoms of *Vicharchika* in comparison of group B. **Conclusion:** The study concluded that *Ark Taila* is an effective formulation of choice for the management of *Vicharchika* as compared to *Ark* cream.

Keywords: Vicharchika, Rakta Pradoshaja Vikaras, Ark Taila

INTRODUCTION

Skin is a mirror that reflects internal & external pathology & thus helps in diagnosis of diseases. Skin complains affects all ages from the neonates to the elderly & cause harm in a number of ways, such as discomfort, disfigurement, disability, etc. All the skin diseases in Avurveda have been described under the heading of 'Kustha', which are further divided into Maha Kustha & Kshudra Kustha¹. Vicharchika is one of the Kshudra Kustha² runs a chronic course generally considered difficult to cure & even if it is cured relapses is common. According to most of Ayurvedic texts, all types of Kustha have been considered as 'Rakta Pradoshaja'Vikara³. Further Vicharchika is stated to be Tridoshaja with the dominance of Kapha Dosha⁴. Vicharchika consists of pimples itching, blackish and with excessive discharge⁵. Vicharchika can be co-related with the diseases 'Eczema'. The term 'Eczema' ⁶ is a group of diseases that results in inflammation of the skin. These diseases are characterized by purities, red skin and excessive discharge. Eczema is a common problem in all age group all over the world. Its incidence is 15-20% of children⁷ and 1-3% of adults worldwide. Acharya Sharangdhar had described "Ark Taila⁸" for treating Vicharchika. Ark Taila contains Ark Patra Swarasa, Haridra Kalka and Sarshapa Taila. All these drugs have Katu Tikta Rasa, Snigdha (unctuous), Ushna Guna (hot) Krimighna (wormicidal), Kandughna (anti-pruritic) and Kushthaghna properties which helps in treatment of Vicharchika. Ark Taila possess certain inconvenience in application, transport and handling. Hence pharmaceutical modification is essential for better enhancement and acceptability of Ark Taila into Ark cream. This research was planned with the objective to find the individual and comparative clinical efficacy of two formulations, i.e. Ark Taila and Ark. This type of comparative study was not done before to establish the efficacy of *Ark Taila* and *Ark* cream in the management of *Vicharchika*.

Aim and Objectives: To assess comparative clinical effect of *Ark Taila* and *Ark* cream in the management of "*Vicharchika*."

Materials and Methods

Preparation of *Ark Taila*: *Ark Taila* was prepared according to the reference of *Sharangadhar Samhita Madhyama Khand* ⁹with 1:4:16 proportion of *Kalka, Swarasa and Taila* respectively. Details of the ingredients of drugs are presented in Table no 1

Table 1

Ingredients	Quantity
Ark Patra Swarasa	4 L
Haridra Kalka	250gm
Sarshapa Taila	1L

Preparation of Ark cream

POLYSORBATE 80, CETOMACROGOL BP was added to *Ark Taila*. This mixture was then heated at 60°C on hot plate till CETOMACROGOL BP gets dissolved. Oil phase was prepared by this method. Glycerine was added to water and mixed with help of spatula. This mixture was heated at 60°C on hot plate for 5 minutes. Water phase was prepared by this method. Water phase was incorporated into oil phase slowly and was mixed with help of Pulversier machine for 30 min and left for cooling. A mixture of Carbopol and water was added to make mixture thick. This homogeneous mixture was then packed in sterile tubes for further uses. Details of ingredients of Ark cream is shown in Table no 2

Table 2

Ingredients	Quantity
Ark Taila	900 ml
Polysorbate 80	263 gm
Cetomacrogol BP	263 gm
Glycerine	789 gm
Water	526 ml
Carbopol	13.5 gm

Selection of patients: The patients of *Vicharchika* were selected from outpatient department inpatient department of *R.S & B.K & Kayachikitsa*, Uttarakhand Ayurveda University, Rishikul Campus, Haridwar. The study was conducted on the patients randomly divided into two groups by computerized randomization method. The study was started after approval of Institutional Ethics Committee, UAU/RC/IEC/2017-18/05. The study was registered in CTRI as CTRI/2018/04/013255. Selection of patient was done on detailed clinical history, physical examination & other necessarily desired investigations irrespective of their gender, caste.

Dose and Duration

The patients were treated with *Ark Taila* and *Ark* Cream in quantity sufficient dose twice a day for local application. Duration of treatment was 60 days.

Criteria of Diagnosis

The patients were diagnosed on the basis of as classical signs and symptoms of *Vicharchika* described in Ayurvedic classics.

Inclusion Criteria

Patients belongs to age group between 20 to 70 years were included in this study with classical symptoms of

a) <i>Kandu</i> (itching)

Vicharchika as *Kandu, Srava, Vaivarnya, Daha, Rukshta, Pidikotpatti.* Chronicity of disease should not be more than 10 years.

Exclusion Criteria

Patients of age less than 20 & more than 70 years were excluded. Patients having diabetes mellitus, hypertension, and thyroid were also excluded.

Laboratory Investigation

Following investigations were carried out before & after the treatment to assess the general condition of the patient & to rule out any other pathology: haemo-globin, total leukocyte count, differential leukocyte count, erythrocyte sedimentation rate, random blood sugar, routine urine examination.

Criteria for Assessment

All the patients were examined at the interval of 15 days during the treatment. Criteria of assessment will be on the basis of relief in the sign and symptoms of the disease *Vicharchika*. For this purpose, cardinal signs and symptoms will be given scores according to their severity before and after the treatment which were given below is present continuously

0	No itching
1	Mild itching not disturbing normal activity
2	Occasional itching disturbs normal activity
3	Itching present continuously & even disturbing sleep.
b) Daha (burning)	
0	No burning sensation
1	Mild type of burning not disturbing normal activity
2	Occasionally burning disturbing normal activity
3	Burning present continuously & even disturbing sleep.
c) Srava (discharge)	
0	No discharge
1	Moisture on the skin lesion
2	Occasionally discharge
3	Discharge
$1 \rightarrow D$, $1 \rightarrow 1$, $4 \rightarrow 1$	

d). Rukshta

0	No dryness
1	Dryness with rough skin (Rukshta)
2	Dryness with scaling
3	Dryness with cracking

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e). Pidikotpatti	
0	No eruption in the lesion
1	Scanty eruptions in few lesions
2	Scanty eruptions in at least half of the lesion
3	All the lesions full of eruption
f). Vaivarnya	
0	Nearly normal skin colour
1	Brownish red discoloration
2	Blackish red discolouration
3	Blackish discolouration

Grouping of patients

After confirming the diagnosis, selected 30 patients were randomly categorized by computer generated randomization into 2 groups. Group A–*Ark Taila* Group (n = 15): in which patients were subjected for local application of *Ark Taila* over diseased area at two times in a day. In the same manner Group B–Ark Cream Group (n = 15) was also applied.

Follow-up period

After treatment completion for next two months, patients were asked for follow up months to observe reoccurrence or any other complications due to treatment. *Pathya-Apathya* was advised to the patient as per classics.

Statistical analysis

Statistical tests such as the Wilcoxon signed-rank test was applied to the nonparametric statistical data for evaluating the difference in the before treatment and after treatment as well as weekly treatment follow-up. The Man-whitney test was applied to nonparametric

Table 3:

statistical data for evaluation of difference between two groups.

Observation and Results

Total 30 patients were registered; among them 26 patients completed the treatment and 4 discontinued due to their personal reasons. Almost 36% of patients belonged to the age group of 20-30 years; among the registered patients, only 13.33% were male and 36.66% were females and about 96.67% of the patients in the present study belonged to Hindu religion, whereas 3.33% belonged to Muslim religion, 73.33% were educated, 63.33% belongs to urban area, 73.33% belongs to middle class, 53.33% patients were having irregular bowel habits, 63.33% were having disturbed sleep, in 80% patients family history of Vicharchika was absent, 43.33% were having Vata-Kaphaja Prakriti and 46.66% of patients were service man by occupation. Effect of therapy, on chief complaints and associated complaints of group A and group B is shown in [Table 3] and [Table 4] respectively.

		Symptoms	Median		Wilcoxon Sign Rank W	P-Value	% Effect	Result
S.N	Ν		BT	AT				
1.	15	Kandu	2	1	105	< 0.001	66.66	Highly Significant
2.	15	Daha	2	0	91	< 0.001	100	Highly Significant
3.	15	Srava	1	0	21	< 0.01	87.5	Significant
4.	15	Rukshta	2	1	28	< 0.01	42	Significant
5.	15	Pidikotpatti	1	0	45	< 0.05	78.57	Significant
6.	15	Vaivarnya	2	1	66	< 0.001	41.37	Highly
								Significant

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	N	Symptoms	Median		Wilcoxon Significantned	P-Value	% Effect	Result
S.NO			BT	AT	Rank W			
1.	15	Kandu	2	1	78	< 0.001	66.67	Highly Significant
2.	15	Daha	2	0	28	< 0.01	100	Significant
3.	15	Srava	1	0	15	< 0.01	83.33	Significant
4.	15	Rukshta	1	1	14	< 0.01	41.17	Significant
5.	15	Pidikotapatti	1	0	36	< 0.05	77.78	Significant
6.	15	Vaivarnya	2	1	28	< 0.01	37.5	Significant

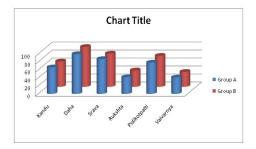
Table 4:

Intergroup comparison among the groups is shown in [Table 5] which shows non-significant results.

Table 5

S.NO	Subjective Parameter	Group	N	Median	T-value	P-Value	Result
1.	Kandu	Group A	15	2	245	< 0.050	Not significant
		Group B	15	2	_		
		Total	30				
2.	Daha	Group A	15	2	66.500	< 0.050	Not significant
		Group B	15	1.5	_		
		Total	30				
3.	Srava	Group A	15	1	30.500	<0.050	Not significant
		Group B	15	1			
		Total	30				
4.	Rukshta	Group A	15	1	153.000	<0.050	Not Significant
		Group B	15	0			
		Total	30				
5.	Pidikotpatti	Group A	15	1	76.500	<0.050	Not Significant
		Group B	15	1			
		Total	30				
6.	Vaivarnya	Group A	15	1	266.00	<0.050	Not Significant
		Group B	15	0			
		Total	30				

Comparative Assessment Of % Relief in Subjective Parameters is shown in [figure 1].



On Comparative assessment of % relief in Subjective Parameters it was observed that patients got better relief in Group A than Group B respectively.

DISCUSSION

There was not significant result between intergroup comparisons of two groups. On the basis of percentage relief in subjective parameters group A showed better result in comparison of group B. The *Ark Taila* formulation is composed *Ark Patra Swarasa, Haridra Kalka* and *Sarshapa Taila* where *Sarshapa Taila* forms the base. *Sarshapa Taila*¹⁰ is having *Snigdha* (unctuous), *Ushna Guna* (hot) and *Kapha Vataghna* (pacify to *Kapha* and *Vata Dosha*) properties and possesses *Krimighna* (wormicidal), *Kandughna* (antipruritic) and *Kushthaghna* (treating skin diseases) properties. *Ark Patra*¹¹ is having *Katu-Tikta Rasa*, *Laghu*, *Ruksha guna*, *Tridoshahara*, *Kushthahara*, *Shophahara* (anti-inflammatory), *Kanduhara*, *Krimihara*, *Vranashodhaka* property. *Haridra*¹² is having *Katu-Tikta*, *Kushthaghna*, *Kandughna*, *Krimighna*, *Vranaropak Vishaghna Sthanik Shothhara* property

Cetomacrogol¹³ helps to retain moisture on the skin and reduce dryness. Glycerol¹⁴ helpful in wound healing and smoothening of dry, cracked skin, enhances skin appearance, helps in reducing symptoms of eczema, repairs infected tissue and cells more quickly.

Probable mode of action

Ark Patra due to Katu-Tikta Rasa reduces Kandu and Pidika. Due to its Laghu, Ruksha guna it penetrates deeply in skin and subsides the disease symptoms. Due to Vishaghna property it subsides allergies causing allergic contact dermatitis. Antioxidant property is due to flavonoids¹⁵. Aqueous, methanol, ethanol and petroleum ether extracts of the leaves of C. gigantea were reported to possess antimicrobial and antiinflammatory activity. The extract of leaves of Calotropis gigantea have Wound healing property.¹⁶ Haridra due to its Vishaghna property, subsides allergies causing allergic contact dermatitis. Due to Sthanik Shothhara property it relives the local inflammation of skin. Due to Katu-Tikta Ras it absorbs the Srava (discharge) to reduce Klinnata. Curcumin possess antiinflammatory property¹⁷ and protects the skin by increased collagen deposit, angiogenesis and improved wound healing. Due to its Tikshna, Snigdha guna, it penetrates deeply into skin and increases skin hydration. Sarshapa Taila due to its Katu-Tikta Rasa has Vranashodhaka, Vranaropaka property also subsides kandu. Dustha Krimihar, Kanduhara therapeutic property of Sarshapa helps in relives of Kandu and kill the Sukshma krimi i.e. bacteria. It increases drug absorption by skin through lipophilic pores. Sarshapa Taila has high levels of vitamin E, which helps improve skin health. It can help protect the skin against free radical damage from ultraviolet light and pollution, and can even help reduce the look of fine

lines and wrinkles. Additionally, when rubbed into the skin, the vitamin E in the oil can help promote circulation and immunity¹⁸. It also possesses antifungal, antibacterial, anti-inflammatory properties.

CONCLUSION

It was concluded from the clinical trial that *Ark Taila* application is a better choice for the management of *Vicharchika* in comparison of Ark cream. During treatment no adverse reactions were observed. This study carried out on a small sample size for limited period as an observational study Results are encouraging and hence should be further verified for longer duration on a large sample size with controlled clinical trial.

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