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RANDOMIZED COMPARATIVE CLINICAL STUDY TO EVALUATE THE EFFICACY OF BOTH ARKA TAILA AND ARKA MALAHAR EXTERNAL APPLICATION IN THE MANAGEMENT OF VICHARCHIKA: A STUDY PROTOCOL

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ABSTRACT

Introduction: Ayurveda has identified Vicharchika as a skin condition similar to dry eczema. Various treatments are available in Ayurveda for Vicharchika, one of which is the Ayurvedic oil 'Arka Taila'. Previous studies have examined the local application of Arka Taila, and an ointment called Arka Malahar has also been developed in another study. This particular study suggests that Arka Malahara is convenient for use and equally effective in treating Vicharchika. However, there is a lack of research comparing the effectiveness of Arka Taila and Arka Malahara in treating Vicharchika. **Method:** This study will involve 60 randomly selected subjects with Vicharchika from DY Patil's Ayurvedic hospital in Pimpari, Pune. The participants will be divided into two groups: one group will receive Arka Taila applied locally to the eczema site, while the other group will receive Arka Malahar in a similar manner. The treatment duration will be 30 days. Results: Changes in the eczema condition before and after treatment will be observed and compared to the baseline. Subjective symptoms such as

itching (Kandu) and dryness (Rukshata) will be assessed as mild, moderate, or severe. The number and size of patches will be measured using scores, and moisture levels will be

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compared between summer and winter. Descriptive statistics, including mean, standard deviation for numerical variables, and range for categorical variables, will be presented. A Student's T test will be used to determine statistical significance, with a p-value of less than 0.05 considered significant. **Conclusion:** The study findings suggest that Arka Malahar is more effective than Arka Taila in managing Vicharchika across all assessment parameters.

KEYWORDS: Arka Malahar, Arka Taila, Eczema, Vicharchika.

INTRODUCTION

There are mahakushtha and 11 are khrudrakushtha. vicharchika is a type of khrudrakushtha which is found widely, maharshi Charaka described vicharchika Vicharchika, according to Ayurveda is Rakta Pradoshaja Vikara being involved of three Dosha with dominance of Kapha. Though it is Kshudra Kushtha, it runs a chronic course and has a tendency of exacerbations. Vicharchika can be co-related with eczema from the modern system of medicine standpoint which is a form of dermatitis, or inflammation of the upper layers of the Skin.

Vicharchika (Eczema^[1]) is a type of kshudrakustha often encountered by Ayurvedic Dermatologists characterized with symptoms, namely, kandu (itching), strava (discharge), Pidaka (vesicles), and Shyava varna (discoloration). Vicharchika is often correlated to eczema based on clinical presentations. Eczema is a very commonly occurring skin disorder in which there is an inflammation of the skin. There can be scaling and dryness or sometimes formation of the vesicles. The delayed type of hypersensitivity is seen in the pathogenesis of eczema. The term eczema has been used to the persistent or recurrent skin rashes with redness, skin oedema, itching and dryness with possible crusting, flaking, blistering, cracking, oozing or bleeding. With chronicity, there is dryness in eczema, scaling, hyperpigmentation and visible crises. disorders). Acharya Charaka, Sushruta and Vagbhata^[2,3] considered Vicharchika which is correlated to eczema. Vicharchika is seen as Kandu. Pidaka. Shyavata, Bahustrava, Lasikastrava, Raji, Ruja, and Rukshata, and Vicharchika^[4,5] is said to have a Kapha dominant disorder. Ayurveda described all the skin disorders under "Kushtha" and classified the Kushtha^[6,7] into 2 main categories, one is Mahakushtha (major skin disorders) and the other one is Kshudrakushtha (minor skin Modern dermatologists use topical corticosteroid, topical emollients etc. to give symptomatic relief and reoccurrence is more. Sneha, Siddha drugs have better pharmacokinetics action in comparison to other dosage form because of lipid nature of bio membrane as lipid soluble substance readily

permit into the cell. Arka Taila possesses certain inconvenience in application, transport and handling. Hence pharmaceutical modification is essential for better enhancement and acceptability of Arka taila into Arka malahar. This research is planned with objective to find out the individual and.

AIM

To determine whether the Artka Taila Malahara is more efficacious than Arka Taila in the management of Vicharchika.

OBJECTIVE

PRIMARY OBJECTIVE

- 1) To evaluate the efficacy of Arka Malahara in the management of Vicharchika.
- 2) To evaluate the efficacy of ArkaTaila in the management of dry eczema Vicharchika.
- 3) To compare the efficacy of ArkaTaila and Arka Malahara in the management of Vicharchika.

SECONDARY OBJECTIVE

1) To study the adverse effects of Arka Malahara.

RESEARCH QUESTION

Is there any difference between the efficacy of arka taila and arka malahar in the management of Vicharchika?

HYPOTHESIS

- Null Hypothesis (H₀) Both Arka Taila and Arka Malahar(ointment) are not effective in the management of vicharchika.
- Hypothesis (H₁₎- Arka taila is more effective than Arka Malahara in the management of vicharchika.
- Hypothesis (H₃) Arka Malahara is more effective than Arka Taila in the management of vicharchika.
- Hypothesis (H₄) Both Arka taila and Arka malahara are Equally effective in the management of vicharchika.

REVIEW OF LITERATURE

1. Samhitas

Sharngdhar samhita

Charak samhita

Madhay nidan

Sushrut Samhita

Ashtang Hriday

2. Reference books

Skin diseases and sexually transmitted diseases (uday khopkar)

3. others: Research Articles.

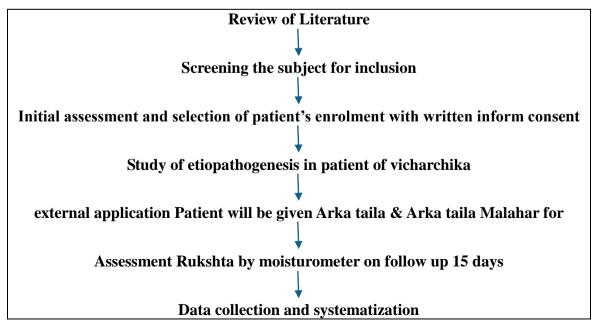
1) INCLUSION CRITERIA

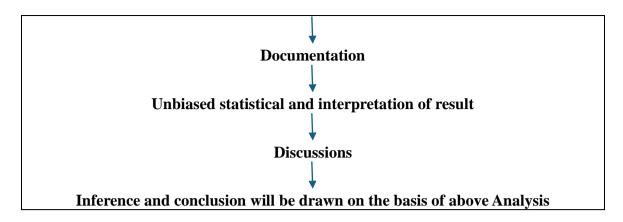
- a) Patients will be selected irrespective of sex, education, socio economic status, religion. Patients between the age group of 18 to 70yrs will be included in the study.
- b) Patients with complaints of Kandu, Pidika, Srava, Raji, Shyava, Rukshata, Utsedh.

2) EXCLUSION CRITERIA

- a) Patients on steroid ointments
- b) Patients having other skin diseases like leprosy, etc.
- c) Patient with (symptoms like redness, pustules, vesicle)

Textbox 1: steps involved in the research.





STUDY SETTING (Location of Study) - The patients will be selected as per inclusion criteria using simple random sampling method.

Randomized comparative open labeled clinical study of two groups A&B 60 PATIENTS (30 IN Each Group)

Case Record form Informed written consent The study will be conducted at OPD & IPD of institute. Dr.D Y Patil college of Aurved Hospital & Research Centre Pimpri Pune.

2. Duration of Study: Duration of study will be 18 months.

OPD and IPD attached to the Dr D Y Patil Ayurved Hospital & Research Centre, Pune.

Patients of vicharchika

$$\frac{N = Z^2 \times p (1-p)}{d^2}$$

$$\frac{(1.96)^2 \times 0.067 \times 1-0.067}{(0.09)^2}$$
=30

Literary Review

The literature regarding the topic will be studied from the relevant compendia of Ayurveda and modern science.

Data collection: - Source.

Participants will be selected from the OPD and IPD of our hospital. Clinical examination will be performed, and assessment will be done by Nidanpanchak of vicharchika

The data will be recorded in CRF and will be analyzed.

Conclusion will be drawn based on data obtained.

Case Record form will be prepared with title of study, participant name

Dietary) habits includes food intake pattern, viruddhahara etc., Viharaj (Lifestyle) Nidana includes stress, involvement in physical activities, daily routine, addictions etc.

CRF will be formed for srotas pariksha where 4 respective srotas will be examined, nidan panchak and vyadhi vinischaya will be done based on CRF.

Questions will be asked to participants in simple local language.

All the Responses will be noted with patients consent.

Table 1: Drug Details.

DRUG NAME:	Arka
FAMILY:	Apocynaceae
BOTANICAL NAME:	CALOTROPIS GIGANTICA
RASA:	Katu, Tikta
VIRYA:	Ushna
VIPAK:	KATU
GUNA:	Laghu-Ruksha
PROPERTIES:	KAPHAHARA,
UPAYUKTAANGA:	Ksheera

ARKA TAILA PREPARATION

Reference - SARANGADHARA SNEHA KALPANA 9/1,2

Medicated Sneha is prepared by mixing one part of Kalka, four parts of ghee, and four parts of decoction. (1:4:16)

The preparation was done according to the Snehapaka method Medicated Sneha is prepared by mixing one part of Kalka, four parts of ghee, and four of decoction. (1:4:16)

Assessment parameters will be followed as mentioned in the table below.

Table 2: Assessment parameters.

Parameter	0	1	2	3
Kandu (itching)	Absent	Mild	Moderate	Severe
Rukshata (dryness)	Absent	Mild	Moderate	Severe

Table 3: Assessment of patches.

Symptoms	Gradation	Score
Number of patches	No patches	0
	1-2 patches	1
	3-4 patches	2
	More than 5	3
Areas of patches	Between 0-10 sq.cm	0
	Between 10-20 sq cm	1
	More than 20 sq cm	2

Table 4: Assessment of moisture at the patches.

Moisture contents	Winter	summer
Normal	20	30
Mild	17-20	25-30
severe	<14	<20

RESULTS

The results will be drawn on the basis of observations and questionnaire Form and will be represented in the form of graphs, chart and tables.

Analysis will be done based on qualitative and quantitative data.

Appropriate tests of significance will be applied for both types of data.

DISCUSSION

Based on available data and statistical analysis, discussion will be done.

CONCLUSION

Conclusion will be based on the data collection and statistical analysis.

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