



Research Article

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AN OPEN LABEL UNCONTROLLED STUDY OF EFFICACY OF RASASINDURA OINTMENT IN MANAGEMENT OF VICHARCHIKA WITH SPECIAL REFERENCE TO DRY ECZEMA

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ABSTRACT

Ayurveda texts describe Vicharchika as a blackish macula-papular rash with severe itching and serous discharge. This Kapha dominant disease can be correlated with eczema which shows similar symptoms itching (kandu), rash (pidaka), oozing (lasika strav), discoloration (shyavata), pain (vedana), dryness (rukshata), burning sensation at lesion (daha), pus discharge (paka) and cracking of skin (pani pada sphutanam). *Rasasindura* is a classic Kupipakwa Rasayana preparation indicated in management chronic skin diseases. A study was conducted to evaluate its efficacy as topical preparation which is the most preferable drug delivery method in the management of skin disorders. The statistical analysis of the obtained results revealed that there is significant improvement in symptoms Kandu and Daha along with Shyavata, Vedana Rukshata, Pani-pada sphutanam and Twak Utsedha ($p < 0.001$ at t_{29}).

Keywords: Ayurveda, Rasasindura, Kustha, Eczema, Vicharchika, Malahara

INTRODUCTION

Skin diseases have a high prevalence throughout the world. In developing countries infectious diseases such as tuberculosis, leprosy and onchocerciasis are common, whereas in developed countries inflammatory disorders such as eczema and acne are common.^{1,2} Skin disorders can be inherited, e.g. Ehlers-Danlos syndrome,³ a part of normal development, e.g. acne vulgaris, or may present as part of a systemic disorder, e.g. systemic lupus erythematosus (SLE).⁴ In the developed world eczema accounts for a large proportion of skin disease, both in hospital and community-based populations. It is estimated that 10% of people have some form of eczema at any one time and up to 40% of the population will have an episode of eczema during their lifetime.⁵ The general causes for this are itching or pain, which can affect people's capability to function ordinarily or to sleep; excoriation which can cause nervousness, depression and lack of self-confidence and can lead to communal separation if obviously noticeable; and an inability to work, because certain skin lesions (such as allergic hand eczema in a constructor or barber) can inhibit or prevent working. According to Ayurveda texts Vicharchika is a blackish maculopapular rash with severe itching and serous discharge.⁶ This Kapha dominant disease can be

correlated with eczema which shows similar symptoms itching (kandu), rash (pidaka), oozing (lasika strav), discoloration (shyavata), pain (vedana), dryness (rukshata), burning sensation at lesion (daha), pus discharge (paka) and cracking of skin (pani pada sphutanam).⁷

Rasasindura is a classic preparation which has distinctive properties to pacify diseases such as diabetes, fistula, fever, lack of appetite, anemia, edema and chronic skin diseases etc.⁸ Topical preparation is the most preferable drug delivery method is used in the management of skin disorders. So, an attempt was made to prepare ointment of Rasasindura and conduct clinical trial on to evaluate its efficacy in Vicharchika with special reference to dry eczema.

Objectives

- To review the classical and modern literature, Rasa Sindura, Malahar Kalpana and Vicharchika.
- To evaluate efficacy of Rasasindura Ointment in Vicharchika with special reference to Eczema.

MATERIALS AND METHODS

Preparation of Drug Rasasindura Ointment [Reference: Rasa Tarangini]

Ingredients

Rasa Sindura (Samaguna)	100 g
Bees wax	200 g
Sesame oil (6 parts)	1800 ml

Procedure

Step 1

Sesame oil was heated in vessel and bees wax was added in that slowly to get liquid mixture. This mixture was then strained through double fold cotton cloth. Then this mixture again kept on fire and stirred continuously to mix it well. Then this mixture was poured in jar and keeps it for cooling; after cooling semi solid (butter like) mixture was obtained called as Siktha Tailam.

Step 2

Rasa Sindura fine powder (120 mesh) is first intimately mixed with a small amount of Siktha tailam [1:20] and then remaining of Siktha tailam is incorporated gradually till the homogenous preparation is obtained.

Method for the clinical evaluation of Rasa Sindura Ointment

The present study was aimed at the clinical evaluation of Rasa sindur Ointment in the established cases of Vicharchika. Detailed review of ancient and modern literature of Vicharchika was also performed to acquire the complete knowledge of Vicharchika.

Design of Study: Open uncontrolled type of study.

Place of Study: OPD and IPD of M. A. Podar Hospital, Worli, Mumbai, Maharashtra, India

Ethical clearance

Institutional Ethics Committee Approval and Regulatory Compliance

Before the initiation of the study, the study protocol and related documents were reviewed and approved by Institutional Ethics Committee at R. A. Podar Ayurved (Med) College, Mumbai, Maharashtra, India. The study was conducted in accordance with Schedule Y of Drugs and Cosmetics act, India, amended in 2005 and ICMR ethical guidelines for biomedical research on human participants 2006. IEC Clearance no –RAP/VV-2/PG/7817/2005 Dated: 20.12.2005.

Criteria for Diagnosis

Criteria for diagnosis were done on the basis of signs and symptoms available in the Ayurvedic and Modern texts as well as with the help of following parameters.

Criteria of Inclusion

1. All Age group patients
2. Sex – Males and females
3. Patients having classical Vicharchika symptoms like Kandu, Shyavata, and Rukshata etc.

Criteria of Exclusion

1. DM, HIV, Skin diseases other than eczema.
2. Pregnant and lactating women.

Selection of Patients

The patients were selected from OPD and IPD of M. A. Podar Hospital. The patients were primarily assessed for the establishment of Vicharchika by general and Strotas Pariksha.

Consent: A written consent of all patients included in trial in language best known to then be taken before entering them in the trial.

Mode of application: Topical application on skin to cover the lesion with wooden spatula

Dose: Applied four times daily

Diet: No new diet restrictions or any type of behavioral restrictions were advised to the patients.

Duration of treatment: 6 weeks.

Follow up: After every week

Investigations: All base line investigations were carried out initially and at the end of study.

Parameters for assessment

The clinical efficacy of drug was assessed on the basis of symptomatic improvement in the due course of the treatment. Established cases of Vicharchika were selected and number of symptoms was recorded.

Gradation of symptoms for assessment efficacy of drug

Kandu, Daha and Vedana	Score
Causing disturbed sleep	4
Not able to tolerate	3
Able to tolerate	2
Mild	1
No Kandu/Daha.	0

Shyavata, Rukshata, Laseekastrav, Pani-pada sputanam, Twak utsedha	Score
Present	2
Mild relief	1
Not present/ relief	0

Criteria for assessing the total effect

Considering the overall improvement had shown by the patient in sign and symptoms, the total effect of the therapy has been assessed as below.

Improvement	Relief in sign and symptoms
Totally cured	100%
Cured	75 – 100%
Markedly Improved	>50%
Improved	25% – 50%
Unchanged	Up to 25%

Statistical Analysis

All data generated and collected during the study was subjected to statistical analysis to reach the final results and conclusion. Statistical parameters like Students “t test”, graphical presentations.

Clinical study

Demographic Data

Thirty subjects who satisfied the selection criteria were recruited. The demographic data are summarized in (Table 1). There was no drop out noted till the end of the study. Out of 100 patients, maximum 53.33% patients were having Chronicity 6 -12 months and above, followed by 26.66% patients were having Chronicity of > 2 years, 20% patients were having Chronicity of 1-2 years. Symptom score of cardinal symptoms observed during study is also summarized in (Table 2).

Table 1: Demographic Data

Demographic Parameters	No. of Patients	Total Patients
Age group (years)		
10-20 years	1	30
21-30 years	9	
30 to 40 years	10	
41 to 50 years	6	
51 to 60 years	4	
Sex		
Male	15	30
Female	15	
Religion		
Hindu	21	30
Muslim	6	
Christian	3	
Diet		
Veg	9	30
Mixed	21	
Prakriti		
Pitta-Kapha	9	30
Kapha-Pitta	7	
Pitta-Vata	5	
Vata-Pitta	0	
Kapha-Vata	1	
Vata-Kapha	8	
Chronicity (months)		
0 – 12 months	16	53.33%
1 – 2 years.	6	20%
> 2 years and above	8	26.66%

Table 2: Symptom Score of cardinal symptoms of Vicharchika observed during study

Score/Symptom	Kandu	Shywata	Vedana	Rukshata	Daha	Pani pada/ sphutanam	Twak/Utsedha
BT	86	73	33	69	32	47	47
AT	36	32	2	30	3	18	11

BT: Before Treatment, AT: After Treatment

Table 3: Effect of Rasasindura ointment on Cardinal Symptoms of Eczema

Cardinal Symptoms	n	Mean Score		± SD	± SE	't'	'p' at t ₂₉
		B.T.	A.T.				
Kandu	30	2.86	1.2	0.711159	0.129845	12.83585	p < 0.001
Shywata	30	2.43	1.06	0.668675	0.122088	11.19413	p < 0.001
Vedana	25	1.32	0.08	0.668675	0.122088	8.463851	p < 0.001
Rukshata	30	2.3	0.1	0.534983	0.097678	13.30902	p < 0.001
Daha	27	1.18	0.11	0.413841	0.07556	12.7934	p < 0.001
Pani pada sphutanam	24	1.95	0.75	0.614948	0.112278	8.609564	p < 0.001
Twak Utsedha	29	1.62	0.37	0.714384	0.130433	9.200091	p < 0.001

BT: Before Treatment, AT: After Treatment

DISCUSSION

According to Ayurveda Vicharchika is Rakta Pradoshaja Vikara having association of three Dosha with preponderance of Kapha.⁹ Starting from etiology of this disease we found that the major etiological factors which lead to this disease were food habits like non-veg; daily consumption of curd, excessive sour and salty food stuff, humid conditions of Mumbai region, exposure to chemicals and mental stress.¹⁰ The ailment can be contemporaneous with eczema in the light of conventional medicine which is a form of dermatitis i.e. inflammation of the upper layers of the skin. The term eczema is roughly applied to an array of importunate or repetitive skin rashes pigeonholed by redness, itching and dryness with blistering, cracking, oozing or bleeding and skin edema. Skin discoloration sometimes exemplifies healed lesions, although scarring is atypical.¹¹

Demographic details of these patients suggest following things

Age

It was seen from patient data there is increasing incident of these disease in 31 – 40 years age group

Religion

There max no. of patients i.e. 21 were Hindus. This data is not significant to draw any conclusion as there is no relation of this with religion and also study center is located in Hindu predominant area.

Diet

Diet wise analysis showed 21 were taking mixed type of diet, thus we can say that non-veg diet has a role in pathogenesis of Vicharchika due to vitiation of Pitta – Kapha dosha.

Deha Prakruti

Maximum no. of patients has i.e. Pitta – Kapha Prakruti, thus we can say that Pitta kapha Prakruti is more prone to Vicharchika disease.

Clinical efficacy of Rasasindura Ointment

As suggested by Sadanand Sharma in his text Rasa Tarangini, Rasasindura is a key ingredient in various formulations which is used for correcting metabolic changes occurs in the body.¹² It also showed antimicrobial property.¹³ In this trial, all 30 patients were presented with symptom Kandu, which is a main symptom result of vitiation of Kapha and Vata.¹⁴ As this ointment contains oleaginous base which is possessing Snigdha as well as kaphaghna property which helped in improving the kandu symptom in patients.¹⁵ As a result, percentage of relief of Kandu proved to be 58.14 %. Being Kaphahara and possessing keratolytic property¹⁶ this ointment also helped in removing superficial dead cells of the lesion resulting reduction in discoloration hence, Shyavata symptom improved by 56.16%; Vedana or pain in ezema due to irritation of nerve ending because of inflammatory changes. The base of the Ointment contains beeswax and sesame oil is soothing and Rasasindura helped in reduction of inflammation which gave 93.93% relief in Vedana. Percentage relief in symptom Rukshata, Daha, Pani-pada Sphutanam and Twak Utsedha were 56.52%, 90.62%, 53.19%, and 23.40% due to anti-inflammatory and olio genic property of the ointment.

After completion of 6 weeks trial, 5 patients (16.66%) were cured i.e. 75 – 100% relief. Next to it 23 patients (76.66%) showed markedly improvement i.e. 50 – 75% and 2 patients (6.66%) were improved i.e. 25 – 50%. There was no patient who remained unchanged and also no patient who totally cured.

The clinical symptoms which showed significant improvement excluding associated symptoms i.e. Kandu, Shyavata, Vedana, Daha, Rukshata, Pani-pada sphutanam and Twak utsedha were subjected to analysis. The statistical analysis reveals that there is significant improvement in symptoms Kandu and Daha along with Shyavata, Vedana Rukshata, Pani-pada sphutanam, and Twak Utsedha (P < 0.001 at t₂₉).

In the light of observation, we definitely state that this Rasa Sindura Ointment has been shown moderate results in the disease Vicharchika.

CONCLUSION

We can conclude from this data is that, Rasa Sindur Ointment is not a first drug of choice for shushka Vicharchika. The period of treatment should be increased from 6 weeks to 8-10 weeks to rule out further changes in symptoms or this Ointment can be used as supportive therapy along with oral medication to improve its efficacy. As the region of conduction of study is humid in nature, it may not be effective in humid conditions. The study carried out without changing patient's food or work habits to see effect of medicine. So, it may be possible that this Ointment can give better results when Apathya Ahar Vihara stopped at the time of treatment period. One should carry out antimicrobial study of this Ointment so one can use this Ointment in secondary infection condition of Vicharchika.

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