



Research Article

A RANDOMIZED CLINICAL TRIAL OF RASAPUSHPADI MALAHARA ON VICHARCHIKA W.S.R. TO ECZEMA

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ABSTRACT

Skin disorders are most common occurring diseases in places where humidity prevails throughout the year. *Vicharchika* and *Eczema* both having resemblance in set of their clinical signs. *Rasapushpadi Malhara* (RPM) is Rasa preparation described in *Rasa tarangini* which is indicated in some skin disorders like *Phirang*, *Vrna*, *Vicharchaika* etc. In present study two samples of *Rasa Pushpa* (RP) has been prepared by two methods i.e. *Kupipakva* method and *Damru yantra* method. Both the samples were further used to prepare two samples of *Rasapushpadi Malhara* using *Siktha taila* as base and ratio of *Siktha* & *Til taila* was taken in ratio of 1: 5 according to the season. The randomized control clinical trial was carried out in between two groups. Both groups showed significant results on different clinical parameters like *Kandu*, *Daha*, *Srava*, *Rukshta*, *Pidika*, *Vaivaranyata*, *Pidika*, *Raji*, but group B showed highly significant result in EASI Score, which indicates severity of eczema. Level of significance in Group B for EASI Score is, $P < 0.00001$. *Rasapushpadi Malahara* is very potent in treatment of *Vicharchika* as it contains mineral and herbal drugs like *Parada*, *Kasisa*, *Saindhava*, *Sphatika*, *Wax*, *Tila taila*, all having good antibacterial and antifungal properties. So this formulation showed significant results only by external application.

KEYWORDS: *Vicharchika*, *Eczema*, EASI, *Rasapushpadi Malahara*, *Rasa Pushpa*.

INTRODUCTION

The use of metals and minerals in therapeutics in the form of *Rasayoga* has been started from the period of classical texts. However their use has flourished only after the development of *Rasashastra*. Scholars of *Rasashastra* have preferred *Rasayoga* over herbal preparations because of their supremacy in providing quick relief and even treating the incurable diseases.

Rasapushpadi malhara^[1] is one such preparation mentioned in *Rasa tarangini* containing ingredients like *Parada*, *Saindhava*, *Kasis* and *Siktha taila* having indications like *Phiranga*, *Vicharchika*, *Vrana* etc. In the present study *Rasapushpa* was made by *Kupipakwa*^[2] and *Damroo yantra* method.^[3] After it was used for preparation of *Rasapushpadi Malahara* by using *Siktha* and *Tila taila* in the ratio of 1:5 according to season.^[4]

Skin disorders are most common occurring diseases in places where humidity prevails throughout the year. According to Charak^[5] *Vicharchika*, the skin lesion with itching boil (eruption), darkness and profuse oozing. *Acharya Vagbhata*^[6] further mentioned *Lasikadhya* instead of *Bahusrava*. According to Shushrut^[7] condition in

which skin is dry with severe itching & marked linings present in *Vicharchika*.

Aims and objectives

Present Research work has been undertaken with the following objectives.

Clinical efficacy of 2 samples of '*Rasapushpadi malhara* made by 2 different methods in the management of *Vicharchika*.

Material and Methods

Selection of Cases: A total 30 patients of *Vicharchika* were randomly selected for the present study, from the OPD and IPD of NIA, Jaipur.

Inclusion criteria

1. Patients willing for trial.
2. The patients who ages in between 16-70 years were selected.
3. The patients having clinical signs and symptoms of *Vicharchika*.
4. The patients having complained less than 10 year duration.

Exclusion criteria

1. Below the age of 16 years and above 70 years.
2. Patients with illness >10 year.

3. Patients with long term Steroid and cytotoxic treatment.
4. Patients having concomitant illness like HTN, DM-II, Chronic Neurodermatitis.
5. Patients with evidence of malignancy.
6. Pregnant or lactating women.

Criteria for Diagnosis

Classical signs & symptoms of *Vicharchika* according to *Ayurveda* and Modern system of medicine.

A special proforma was prepared incorporating all the signs & symptoms of *Vicharchika* (Eczema) as well as the *Dushti Lakshana* of *Dosha*, *Dushya*, *Srotas* and *Agni* etc. On the basis of the Performa, all the patients of the present study were examined in detail.

Subjective parameter

Ayurveda is a subjective science. To give results, objectively and for statistical analysis, following signs and symptoms of *Vicharchika* was adopted:

Scoring criteria

1. *Kandu* (pruritis)

- 0 - No itching
- 1 - Mild itching not disturbing normal activity
- 2 - Occasional itching disturbs normal activity
- 3 - Itching present continuously & even disturbing sleep

2. *Daha* (burning)

- 0 - No burning sensation
- 1 - Mild type of burning not disturbing normal activity

Ingredients



Parada



Kasisa



Sphatika



Saindhava



Siktha



Tila Taila

- 2 - Occasionally burning disturbing normal activity
- 3 - Burning present continuously & even disturbing sleep

3. *Srava* (oozing)

- 0 - No discharge
- 1 - Occasional discharge after itching.
- 2 - Occasional oozing without itching.
- 3 - Excessive oozing making clothes wet

4. *Ruksha* (Dryness)

- 0 - No dryness
- 1 - Dryness with rough skin (*Ruksha*)
- 2 - Dryness with scaling (*Khara*)
- 3 - Dryness with cracking (*Parusha*)

5. *Pidikotpatti* (eruption)

- 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

6. *Vaivaranyata* (Discoloration)

- 0 - Nearly normal skin colour
- 1 - Brownish red discoloration
- 2 - Blackish red discoloration
- 3 - Blackish discoloration

7. *Raji* (Thickening of skin)

- 0 - No thickening of skin
- 1 - Thickening of skin but no criss-cross marking
- 2 - Thickening with criss-cross marking
- 3 - Severe lichenification

Showing Pharmaceutical study of Rasapushpadi malahara



Parada shodhana



Sphatka sodhana



Kasis nirjalikaran



Rasapushpa preparation by Damroo yantra method



Rasapushpa preparation by Kupa pakwa method



Reducing Rasapushpa in to fine powder



Rasapushpadi malahara preparation

EASI (Eczema Area and Severity Index) score

A representative area of eczema is selected for each body region. The intensity of redness (erythema), thickness (induration, papulation, oedema), scratching (excoriation) and lichenification (lined skin) of the eczema is assessed as none (0), mild (1), moderate (2) and severe (3). Half scores are allowed.

Table 1: Showing EASI score

Intensity	Absent	Mild	Moderate	Severe
Redness	 Score 0	 Score 1	 Score 2	 Score 3
Thickness	 Score 0	 Score 1	 Score 2	 Score 3
Scratching	 Score 0	 Score 1	 Score 2	 Score 3
Lichenification	 Score 0	 Score 1	 Score 2	 Score 3

Table 2: Showing calculation of EASI Score

Head/ Neck	E+I+Ex+Lx Area x0.1	(+ + +)x x0.1	
Upper limb	E+I+Ex+Lx Area x0.2	(+ + +)x x0.2	
Trunk	E+I+Ex+Lx Area x0.3	(+ + +)x x0.3	
Lower limb	E+I+Ex+Lx Area x0.4	(+ + +)x x0.4	
EASI	Sum of all above body area		Total score

Grouping and Administration of Drug

30 clinically diagnosed and registered patient of *Vicharchika* were divided randomly into 2 groups. Each group has 15 patients.

Group A- 15 clinically diagnosed and registered patient of *Vicharchika* were treated twice daily by *Rasapushpadi malahara sample 1st (RPM₁)*, made by *kupi pakwa method*. External Application was done on lesions.

Group B- 15 clinically diagnosed and registered patient of *Vicharchika* were treated twice daily by *Rasapushpadi malahara sample 2nd (RPM₂)*, made by *Damru yantra vidhi*. External Application was done on lesions.

Study design

Study type: Randomized open trial

Purpose: Treatment

Masking: Open label

Timing: Prospective

End point: Efficacy and safety

No. of group: Two

Number of patients for completed the clinical trial: 30, from the OPD and IPD of NIA Jaipur.

Follow-up Study: Follow-up of patient was done on 15th and 30th days of treatment. Improvement in the symptoms if any and other effects were noted down.

Statistical Analysis

The information gathered on the basis of observation made about various parameters was subjected to statistical analysis in terms of Mean, Standard Deviation and Standard error (SE). In Stat Graph Pad 3 software was used & For Nonparametric Data Wilcoxon matched-pairs signed ranks test is Used While for Parametric Data Paired 't' Test is used and results Calculated. Paired t test was carried out at $p < 0.05$, $p < 0.01$, $p < 0.001$.

For intergroup comparisons, for the nonparametric variables we used MANN-WITNEY Test for statically analysis. The results were calculated.

- Insignificant: $P > 0.05$
- Significant: $P < 0.05$
- Highly significant: $P < 0.01$, $P < 0.001$, $P < 0.0001$

RESULTS

All the Results are calculated by using Software: **InStatGraphPad 3**.

- For Nonparametric Data **Wilcoxon matched-pairs signed ranks test** is used while for Parametric Data **Paired 't' Test** is used and results Calculated in each group.
- For calculating the Inter group comparison, **Mann-Whitney Test & Unpaired 't' Test** was used.

Table 3: showing effect of therapy on subjective parameters (wilcoxon matched pairs single ranked test)

Variable	Gr.	Mean		Mean Diff.	% Relief	SD±	SE±	p value	S
		BT	AT						
<i>Kandu</i>	Gr. A	2.53	.87	1.67	65.79	1.06	.653	p<.00001	HS
	Gr. B	2.73	.73	2.0	73.17	1.14	.460	p<.00001	HS
<i>Daha</i>	Gr. A	2.33	0.67	1.67	71.43	1.04	.635	p<.00001	HS
	Gr. B	2.0	0.60	1.40	70.00	.92	0.503	p<.00001	HS
<i>Srava</i>	Gr. A	1.20	0.27	0.93	77.78	1.08	1.203	p=0.007584	S
	Gr. B	1.33	0.33	1.00	75.00	0.83	0.679	p=.000173	S
<i>Rukshta</i>	Gr. A	.47	0.53	0.93	3.64	1.02	0.656	p=.004666	S
	Gr. B	.53	0.47	1.07	69.57	0.83	0.612	p=.000046	S
<i>Pidikotpatti</i>	Gr. A	.13	0.73	1.40	65.63	0.90	0.433	p<.00001	HS
	Gr. B	1.67	0.60	1.07	64.00	0.73	0.485	p<.00001	HS
<i>Vaivaranya</i>	Gr. A	2.47	2.13	1.33	13.51	0.60	0.479	p=.063828	NS
	Gr. B	2.07	1.60	0.47	22.58	0.83	0.673	p=0.063723	NS
<i>Raji</i>	Gr. A	1.40	0.60	0.80	57.14	1.02	0.542	p=0.014257	S
	Gr. B	0.93	0.27	0.67	71.43	0.67	0.631	p=.002327	S
EASI Score	Gr. A	2.94	1.65	1.29	43.99	1.16	0.571	p=.000516	S
	Gr. B	3.16	1.49	1.67	52.74	1.21	0.522	p<.00001	HS

(HS: Highly Significant S: Significant NS: Non Significant)

Table No.4 showing details of symptom wise results

Subjective parameters	% Relief in Group A	% Relief in Group B
<i>Kandu</i>	65.79	73.17
<i>Daha</i>	71.43	70.00
<i>Srava</i>	77.78	75.00
<i>Rukshata</i>	63.64	69.57
<i>Pidika</i>	65.63	64.00
<i>Vaivaranyata</i>	13.51	22.58
<i>Raji</i>	57.14	71.43
EASI	43.99	52.74

Discussion: Above data shows some findings as follows

➤ In present study Group B showed **highly significant** in EASI Score while Group A showed **significant result** (which is main criteria of assessment of Eczema). In *Kandu, Daha, Pidika* both group A & B showed highly significant result clinically as well as statistically (P<0.001) while in *Srav, Rukshata & Raji* group A & Group B Highly Significant and *Vaivaranya* shown Non Significant result. However intergroup comparison shown that there is no major difference in efficacy of both drugs.

➤ In overall assessment of therapy RPM₁ shown better results in *Daha, Srava, Pidika* while RPM₂ shown better result in *Kandu, Rukshata, Vaivaranya, Raji & EASI*.

Probable Modes of Actions of the Drug

Selection of trial drug is milestone in any research project because success of the project is totally depends on that. Selection of drugs was the most difficult job in this trial. While selecting the trial the following points was taken into consideration.

- ❖ Trial drug should be effective, safe & economic & easily available.

- ❖ As recurrence is the most serious problem so it must have some property to check the relapse of disease.
- ❖ Drug should be easy for administration.

Rasapushpadi malahara

Rasapushpadi malahara contains drug *parada, Kasisa, Saindhava, Sphatika, wax & Til taila*.

Parada is *Tridoshghana. Kushtaghana* by *prabhav*. And *Ushna Veerya* properties & can be used locally to treat the *Vicharchika* (Eczema) which has *Kapha* dominance.

Kasisa is *Kapha vatashamak, Khsar amla* and *Kashay rasa, Ushna virya, Rakta shodhana* and *Kustaghana* properties so can be used locally to treat the *Vicharchika* (Eczema) which has *Kapha* dominance.

Saindhava lavana have *Tridoshaghana* property. Acts as synergist of another drug so we can use it with *Parada and Kasisa*.

Base used in Malahara kalpana - In Indian system of Medicine *ghee, Navneet, tail, Siktha, Gandhviroja, Raal, Tutha, Sphatika* etc can be used as a base of *Malahara kalpana*.

Ghrita, Navneet, Taila, Siktha, Raal etc are oleaginous bases & have high degree of compatibility with a variety of medicaments. Bases of these types are occlusive, increase skin hydration by reducing the rate of loss of surface water. Skin hydration on the other hand may increase drug activity. These oleaginous bases also minimize temperature effects. These bases solely can be used for their skin moisturizing effect.

Upon topical application, the active principle of the *Malahara/Malaham* reaches to the deeper tissues through *Siramukha & Swedavahi Srotasa* by virtue of its stains it with its *Sukshma & Tikshna* property. Due to its *Ushna, Laghu, Ruksha* properties it removes the obstruction in *Swedavahi Srotasa &*

allows the local toxins to flow out through the *Sweda*, thus clearing out the micro channels.

Siktha has *Jantughna, Vranaropana, Sandhaniya, Kushtahara, Vipadikahara, Vataraktahara*.

CONCLUSION

Following conclusions can be drawn from current research project

- As it has mentioned in the Ayurveda classics, in *Rasashastra, Alpamatraupyogitwhat.....* hence it is clear that *Rasaushadhi* shows better result than the *Kashtaushadhi* as it possess much greater potential and hence also require in the small quantity. It was also proved in the study drug *Rasapushpadi malahara*.
- *Charak* also has mentioned the *Parada* in the skin disease hence it is clear that *Parada* is in use in skin diseases since long time.

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Fig 1: Showing clinical effect of RPM¹ on Vicharchika



Before Treatment

After Treatment

Fig 2: Showing clinical effect of RPM² on Vicharchika



Before Treatment

After Treatment



Before Treatment

After Treatment