

A CLINICAL STUDY TO EVALUATE THE EFFICACY OF SIDDHARTHAKADI AGAD IN VICHARCHIKA (ECZEMA)

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ABSTRACT

Aims and Objectives of the study: To evaluate the efficacy of *Siddharthakadi Agad Vati* and *Siddharthakadi Lepa* in *Vicharchika*. The objectives are to provide an economic & safe herbal formulation in *Vicharchika* and to study the adverse effect of the drug during the clinical trial. **Materials and Methods:** Total 40 Patients were selected irrespective of their age, sex, religion, occupation etc and simple random sampling technique was followed. *Siddharthakadi Agad Vati* and *Lepa* give internally or externally for 60 days total of 40 individuals who were diagnosed as having *Vicharchika*. The dose of *Siddharthakadi Agad* given orally twice a day and the duration of the trial was 2 months. The response of the treatment in the patients were recorded on a weekly basis and therapeutic effect was evaluated through symptomatic relief. **Statistical Analysis Used-** Wilcoxon signed-rank test was used to check the significance of subjective criteria & objective criteria. **Results:** *Siddharthakadi Agad* preparation which was found to be

effective against all the clinical symptoms of *Vicharchika* like *Kandu* (itching), *Pidika* (papular eruptions), *Vaivarnyata* (discoloration), *Daha* (burning sensation), *Srava* (oozing) and *Rukshata* (dryness). After analysing the data, 37 patients were statistically showed highly significant improvement in *Pidika*, *kandu* or erythema. **Conclusion:** *Siddharthakadi agad*

proved quite effective in managing the patients of *Vicharchika* due to its *Doshashamaka*, *Srotoshodhana*, *Raktaprasadaka*, *Twakdoshar* and *Rasayana* properties. The result shows that if treatment is done according to *Ayurveda*'s principles with proper dosages and duration as well as follow of *Pathya* and *Apathya Ahara* it leads to success as in these cases of *Vicharchika*.

KEYWORDS: *Siddharthakadi agad*, *Vicharchika*, *Eczema*, *Kandu*.

INTRODUCTION

Vicharchika

- *Vicharchika* is classified as a *Kshudra Kushtha*.^[1]
- As per *Acharya Charaka* *Vicharchika* is characterized by *Kandu*, *Shyava*, *Pidika*, *Bahusrava*.^[2]
- *Acharya Sushruta* has described *Vicharchika* as a condition in which the skin has characterized by *Rukshata* with *Kandu* and *Raji*.^[3]
- *Acharya Vagbhata* has mentioned symptom as blackish eruptions with intense itching and watery discharge.^[4]
- *Acharya Kashyapa* has described *Vicharchika* as blackish brown eruption with intense itching and pain.^[5]

PREVELANCE- Globally, *Eczema* affects 15-20% of children and 1-3% of adults, with a point prevalence of 6.75% in India.^[6]

NEED FOR STUDY

Eczema is a complex disease with a wide spectrum of clinical presentations and tendency of recurrence to allopathic medicines. The long-term treatment with this medication is associated with several side effects.

1. AIM AND OBJECTIVES

- To evaluate the efficacy of *Siddharthakadi agad Vati* and *Siddharthakadi Lepa* in *Vicharchika*.
- To Prepare *Siddharthakadi agad Vati* and *Siddharthakadi agad Lepa*.
- To conduct pharmaceutical study of *Siddharthakadi agad Vati*.
- To provide a reliable safe and cost effective *Ayurvedic* treatment for *Vicharchika*.

2. MATERIALS AND METHODS

PLAN OF STUDY

a) Conceptual Study

Detailed study of *Vicharchika* was studied from various sources of *Ayurveda* and Modern science, previous & ongoing research works, journals, and publications.

b) Subjects And Sampling Technique

Patients were selected irrespective of their age, sex, religion, occupation etc. and simple random sampling technique was followed.

c) Source of Patient

Clinically diagnosed patients of *Vicharchika* who fulfil inclusion criteria were selected from *Agadtantra* OPD no 2 of associated hospital, Rishikul Campus Hospital (Haridwar).

d) STUDY DESIGN

- A single group clinical trial, a minimum sample of 40 patients diagnosed with *Vicharchika*.

Group	Registered patients	Completed Treatment	Formulation	Dose and Duration
Single	40	37	<i>Siddharthakadi agad Vati and Lepa</i>	500mg BD for 45 days

Type of study: Randomized open clinical trial.

- **Period of study:** 60 days

a) **With Drug** – 45 days

b) **Without Drug** – 15 days.

- **Follow up:** There are 2 Assessment: Each at the interval of 15 days and a subsequent follow-up without medicine 15 days.

Inclusion Criteria

- Patients were diagnosed on the basis of classical symptoms of *Vicharchika* as per classical Ayurvedic texts: *Kandu, Srava, Shyavata, Rukshata, Pidikotpatti*
- Patients of age group between 20-60 years were selected for the study.
- Chronicity not more than 2 years.

Exclusion Criteria

- *Kushtha* other than *Vicharchika*.
- Pregnant and lactating women.
- Patients of diabetes mellitus.
- Patients with systemic illness which might interfere in the present study.

Criteria for withdrawal

- Personal matter
- Intercurrent illness
- Aggravation of symptoms
- Leave against medical advice (LAMA)

Dietary Restrictions

Diet- Diet is very important along with treatment.

Thus, *Pathya-Apathya* guidance for diet and daily routine were advised to all patients.

Pathya- *Laghu anna, Purana dhanya, Jangala mamsa, Mudga, Patolam, Nimba, Triphala, Shali, Shastika, Yava, Khadira Kashaya, Bakuchi* etc.

Apathya- *Guru anna, Dadhi, Aanupa mamsa, Guda, Tila, Kulatha, Masa, Ikshu vikara, Vidahi, Vishtambhi, Viruddha ahara, Vishama ahara. Diva swapna, Ativyayam, Vegadharana, Papa karma.*

Method of Preparation of Test Drugs

*Siddharthakadi Agad*⁷ formulation comprises of 18 ingredients *Sarsapa, Karanj, Manjistha, Shirish, Sweet Shirish, Haridra, Daruharidra, Shunthi, Pippali, Marich, Priyangu, Devdaru, Vacha, Hingu, Haritaki, Aamlaki, Bibhitaki, Aprajita*. mixed all these ingredients in equal quantity and make powdered then triturated in goat urine, and then prepared tablets and *Lepa* from the mixture.

ASSESSMENT CRITERIA

a) **On the basis of Subjective Parameters:** The following clinical finding was assessed before and after treatment.

Kandu (Itching)	Score
No itching	0
Mild itching not disturbing normal activity	1
Occasional itching, interferes with daily routine	2
Severe itching with scratch marks /bleeding	3

<i>Shyavata (Discolorations)</i>	Score
Normal skin color	0
Brownish red discoloration	1
Blackish red discoloration	2
Blackish discoloration	3

<i>Srava (Discharge)</i>	Score
No discharge	0
Moisture on the skin lesion	1
Weeping from the skin	2
Weeping from the skin lesion followed by crusting	3

<i>Pidika (Eruption)</i>	Score
No eruption in the lesion	0
Scanty eruption in few lesion	1
Scanty eruption in at least half of the lesion	2
All the lesion full of eruption	3

<i>Rukshata (Dryness)</i>	Score
No dryness	0
Dryness with rough skin	1
Dryness with scaling	2
Dryness with cracking	3

b) Objective Parameter

EASI criteria (Eczema area and severity index)^[8]- EASI (Eczema area and severity index) score is a tool used to measure the extent area and severity of Eczema.

Within each area severity is estimated by 4 clinical signs:

1. Redness (erythema, inflammation).
2. Thickness (Induration, papulation, swelling- acute Eczema)
3. Scratching (excoriation)
4. Lichenification (lined skin, furrowing, prurigo nodules- chronic Eczema)

Body regions- The body is divided into four regions:

- Head and neck-
 - face occupies 33% (17% each side),
 - neck 33% (17% front and back)
 - scalp 33% of the head and neck region
- Trunk (including genital area)
 - front occupies 55% and back 45% of the trunk
- Upper limbs

- Each arm occupies 50% of the upper limb's region (front or back of one arm is 25%)
- Lower limbs (including buttocks)
- Each leg occupies 45% (front or back of one leg is 22.5%) and Buttocks 10% of the lower limb's region.

Erythema	Score
None	0
faintly detectable erythema, very light pink	1
Dull red, clearly distinguishable	2
Deep, Dark Red	3

Papules/Edema	Score
None	0
Barely perceptible elevation	1
Clearly perceptible elevation	2
Extensive elevation	3

Excoriation	Score
None	0
Mild excoriation, No erosion or crust	1
Several linear mark, some erosion or crust	2
Many erosive or crusty lesions	3

Lichenification	Score
None	0
Slight thickening of skin discernible only by touch with skin markings minimally exaggerated	1
Definite thickening of skin	2
Prominent skin thickening with deep furrows	3

AREA INVOLVED

AREA SCORE	PERCENTAGE OF SKIN AFFECTED BY ECZEMA IN EACH REGION
0	No active Eczema in this region
1	1-9%
2	10-29%
3	30-49%
4	50-69%
5	70-89%
6	90-100% the entire region is affected by Eczema

INVESTIGATIONS

- Hb%, TLC, DLC
- ESR
- SGOT

- SGPT
- Serum creatinine
- Random blood sugar level

STATISTICAL ANALYSIS: For comparison of subjective and objective criteria before and after treatment The Wilcoxon signed-rank' test was applied.

THE OBTAINED RESULTS WERE INTERPRETED as

Sr. No.	P-value	Significance
1	> 0.05	Not Significant
2	$\leq 0.05, > 0.001$	Significant
3	≤ 0.001	Highly Significant

THE OVERALL ASSESSMENT SCALE

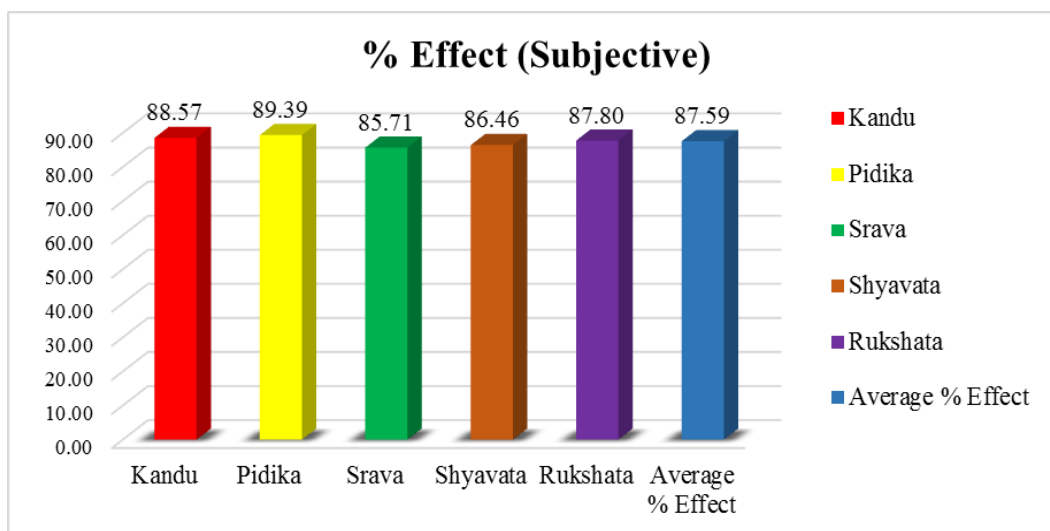
- Complete improvement: 100% relief
- Markedly improved: 76-99% relief
- Moderately improved: 51-75% relief
- Mild improvement: 26-50% relief
- Unchanged: < 25% relief

Discussion on the Effect of Treatment

In this study 40 patients were registered. Out of 40 patients, only 37 patients have completed their follow-up and treated by *Siddharthakadi Agad*.

Table 01: Subjective Parameter.

Parameter (Subjective)	% Effect	SIGNIFICANCE
<i>Kandu</i>	88.57	Highly Significant
<i>Pidika</i>	89.39	Highly Significant
<i>Srava</i>	85.71	Highly Significant
<i>Shyavata</i>	86.46	Highly Significant
<i>Rukshata</i>	87.80	Highly Significant
Average % Effect	87.59	Highly Significant

**Table 02: Objective Parameter.**

PARAMETER (OBJECTIVE)	% EFFECT	SIGNIFICANCE
Erythema	84.69	Highly Significant
Induration	92.86	Highly Significant
Excoriation	80.00	Highly Significant
Lichenification	88.57	Highly Significant
Area score	78.26	Highly Significant
Average % Effect	84.88	Highly Significant

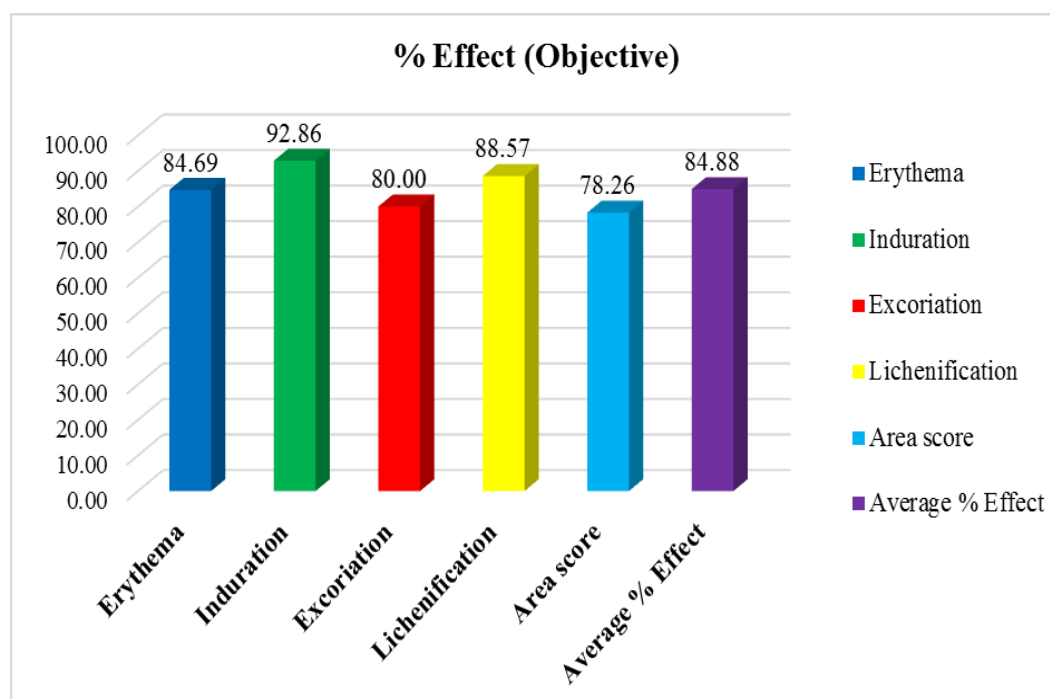
**TOTAL EFFECT OF TREATMENT MODULE IN THIS STUDY**

Table 03: Showing Improvement in Subjective Criteria.

Subjective	Mean		Median		SD		Wilcoxon W	P-Value	% Effect	Result
	BT	AT	BT	AT	BT	AT				
<i>Kandu</i>	2.84	0.32	3.00	0.00	0.44	0.47	-5.461 ^b	0.0000000047	88.57	HS
<i>Pidika</i>	1.78	0.19	2.00	0.00	0.92	0.40	-5.225 ^b	0.000000175	89.39	HS
<i>Srava</i>	0.57	0.08	0.00	0.00	0.96	0.28	-2.994 ^b	0.002755077	85.71	HS
<i>Shyavata</i>	2.59	0.35	3.00	0.00	0.60	0.48	-5.465 ^b	0.0000000046	86.46	HS
<i>Rukshata</i>	2.22	0.27	3.00	0.00	1.08	0.45	-5.045 ^b	0.0000000453	87.80	HS

Table 04: Showing Improvement in Objective Criteria.

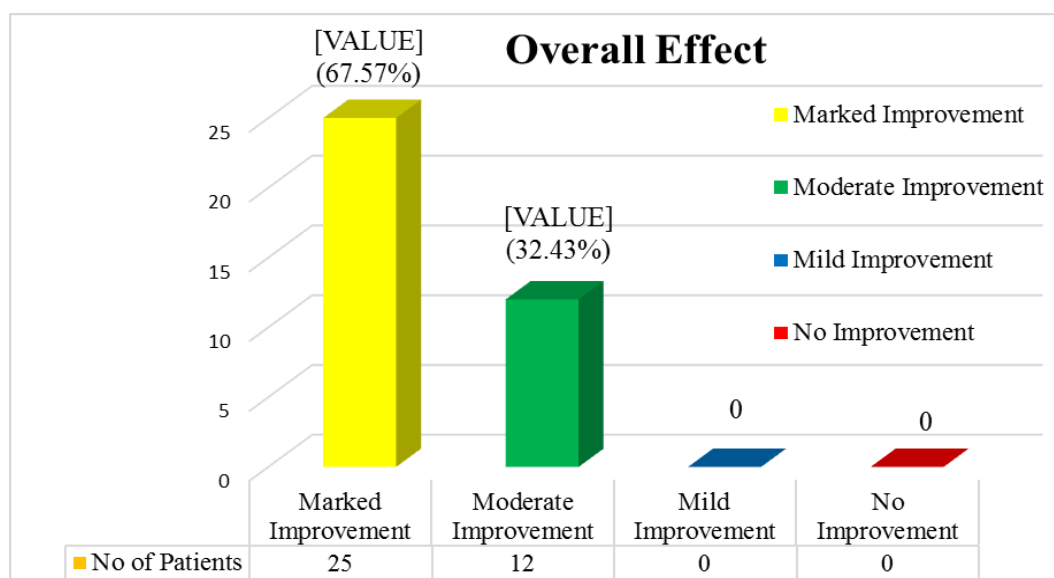
Objective	Mean		Median		SD		Wilcoxon W	P-Value	% Effect	Result
	BT	AT	BT	AT	BT	AT				
Erythema	2.65	0.41	3.00	0.00	0.59	0.50	-5.504 ^b	0.0000000037	84.69	HS
Induration	1.89	0.14	2.00	0.00	0.74	0.35	-5.436 ^b	0.0000000054	92.86	HS
Excoriation	1.89	0.38	2.00	0.00	0.74	0.49	-5.451 ^b	0.0000000050	80.00	HS
Lichenification	1.89	0.22	2.00	0.00	0.84	0.42	-5.420 ^b	0.0000000060	88.57	HS
Area score	1.86	0.41	2.00	0.00	0.98	0.50	-5.472 ^b	0.0000000045	78.26	HS

OVERALL EFFECT OF THE TREATMENT MODULE

Overall Effect	No of Patients	Percentage
Marked Improvement	25	67.57%
Moderate Improvement	12	32.43%
Mild Improvement	0	0.00%
No Improvement	0	0.00%
TOTAL	37	100.00%

After full observation of treatment modules, it was found that

- This study showed that 25 patients (67.57%) had marked improvement.
- 12 patients had Moderate Improvement (32.43%).





DISCUSSION

Effect on Dosha: In *Vicharchika* there is predominance of *kapha dosha*. The most of drugs of *Siddharthakadi Agad* are *Tikta* and *Kashaya Rasa* dominant which are *Kapha-Pitta Shamaka*. The formulation's efficacy in reducing *Kapha* is due to its significant *Katu Vipaka* and *Ushna Virya* qualities. Because of these characteristics of *Siddharthakadi Agad* its primary effect is to balance the *Kapha Dosha*.

Effect on Dushya

- *Twak, Rakta, Mamsa* and *Lasika* are *Dushya* of *Vicharchika* (*Kushtha*).
- *Siddharthakadi Agad* has *Laghu, Ruksha* and *Tikshna Guna, Tikta Rasa* and *Ushna Virya* so it works as *Kaphahara* and *Deepana* and *Pachana* so it causes *Rasa-Rakta Shuddhi* and balances vitiated *Pachaka Pitta*. *Pachaka Pitta* controls the other *Pitta* including *Bhrajaka Pitta* which is vitiated in *Vicharchika*.
- *Siddharthakadi Agad* have *Tikta, Katu* and *Kashaya Rasa Pradhanta* which causes *Lekhana* of *Pravruddha Mamsa Dhatu*. *Lekhana Guna* due to *Katu, Kashaya Rasa* and *Laghu Guna* helps to scrap out the excess tissue from the skin in *Vicharchika*.
- *Katu Rasa* in *Siddharthakadi Agad* stops the production of *Kleda* (*Upahanti Kleda*) and *Tikta- kashaya* dries up the discharge (*Kleda Upashoshana*). *Ruksha Guna* has *Shoshana Shakti*, so they dry up the discharge.

Effect on Srotas: *Rasavaha, Raktavaha, Mamsavaha* and *Swedavaha srotasa* are vitiated in *Vicharchika*.

- Most of drugs of *Siddharthakadi Agad* have *Deepana, Pachana, Laghu, Ruksha, Ushna* and *Tikshna* properties. So, they remove *sanga* from *Srotas* and are effective in *Srotomukha Vishodhana*.

Effect on Vyadhi

- In *Charaka Samhita* it is clearly mentioned that *Vicharchika* is a *Kapha* predominant *Tridoshaj Vyadhi*.
- The properties of *Kushthagna* and *Kandughna* are found in maximum drugs of *Siddharthakadi Agad* so they act on *Vicharchika*. Most of drugs are *Laghu, Ruksha, Ushna* and *Tikshna* so, they effect on *Sravi* nature of *Vicharchika*.
- *Haritaki, Amalaki* and *Bhibhitaki* acts as a *Rasayana*. The assimilation of *Dosha & Dushya* leads to formation of disease when the *Agni* is reduced and quality of *Dhatu* is deteriorated (*Shithilikarana*).
- Most of the drug of *Siddharthakadi Agad* maintains the *Agni* and improves the quality of *Rasadi Dhatu* thus prevent the disease formation. Therefore, it works as a *Rasayana* that enhances the nature of relief & stops the recurrences of disease.

CONCLUSION

On the basis of above-mentioned literary review, clinical study, observation, results and discussion the final conclusion of the present work are as follows-

- Industrialization has brought about numerous benefits but it also has a dark side. One of the unintended consequences of industrialization is the rise of eczema, dermatitis etc.
- The increased use of harsh chemicals in manufacturing processes, pesticides in agriculture and pollution in the air and water have led to a significant rise in eczema cases worldwide. These toxins can alter the skin's natural barrier function making it more susceptible to irritation, inflammation and cause dermatitis that can be comparable to *Vicharchika*.
- It can occur at any age, but it is more frequent among young people due to occupational environmental variables and mental work stress. All of these aggravating elements probably play an important part in the manifestation of *Vicharchika* and in the rapid progression of this disease.

- In present study we found that *Vicharchika* is *Tridoshaja Vyadhi (kapha pradhana)*, *Dushya* were *Twaka, Lasika, Rakta* and *Mamsa*.
- *Siddharthakadi Agad* has *Kushthaghna, Kandughna, Krimighna*, anti-inflammatory, anti-microbial, anti-allergic, anti-itching and Immuno-modulating properties that works against inflammation, itching and enhance immunity. Hence *Siddharthakadi Agad* proves to be beneficial in the management of *Vicharchika*.
- The medicine was well tolerated by all patients and no unwanted side effects were observed in any individuals.

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Conflict of Interest: None Declared.

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