



EFFICACY OF CHITRAKADI LEHA IN THE MANAGEMENT OF VATAJA KASA W.S.R TO PULMONARY EOSINOPHILIA: A CLINICAL STUDY

Ayurveda

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ABSTRACT

Background: Kasa is one commonest complain in day-to-day practice. Among Vataja Kasa is very vulnerable now a day and creating illness major part in the society. Vataja Kasa is although not life threatening, it troubles as it hinders the day-to-day activity of the person. In modern science the Vataja Kasa can be correlated with Simple pulmonary eosinophiles. Due to excessive intake of Ruksha (dry), Sheeta (cold), and Laghu (light) Ahara, and suppression of natural urges which leads to vitiation of Vata Dosha, mainly Udana and Prana Vayu, takes an upward course expelling other Doshas (Kapha and Pitta) abruptly through throat and produce dry, paroxysmal cough with sound like broken bronze vessel. **Objectives:** The trial was designed to evaluate the effect of chitrakadi leha in Vataja Kasa and to compare the efficacy with Agastaya Hareetaki. **Material and Methods:** On the basis of subjective and objective parameters 44 patients were enrolled and randomly allotted in two groups, A and B. Group A received 12gm Q.I.D of Chitrakadi leha with Warm water for 30 days and group B received Agastaya Hareetaki 12gm Q.I.D for 30 days. The study was comparative clinical and respiratory parameters were graded and assessed before and after the treatment (31st day). **Results:** The subjective parameters in both the groups showed statistically significant results from 10th day of intervention which was sustained till end of intervention on 31st day. Highly significant result was found on AEC in trial group and significant result in than control group. **Conclusion:** Chitrakadi leha showed better improvement in the symptoms like Shushka Kasa, Swarabheda, Shirashoola, Parshwashoola and in objective parameters viz. AEC were seen.

KEYWORDS

Vataja Kasa, Chitrakadi Leha, Agastaya Hareetaki, Parshwashoola, and AEC.

INTRODUCTION

Kasa is a disease of Pranavaha Srotas. Cough is the most common complaint encountered in general practice. It is named after its cardinal symptom which can hinder the normal life style. Cough is a resultant action to clear the airways from mucous phlegm and irritants like dust, smoke. It can also occur due to irritation and inflammation of the upper respiratory tract which includes throat and wind pipe¹. The irritation may be caused due to infection, which cold, laryngitis and bronchitis. Coughing is caused by respiratory tract infection but can be triggered by choking, smoking, air pollution, chronic bronchitis, heart failure and such as ACE Inhibitors, Sulphonamides etc². Kasa may develop as an independent disease or may be a symptom of other diseases & sometimes might develop as Upadrava (complication) of a particular disease. Untreated Kasa Roga can lead to life threatening illnesses and long-term sequelae like Shwasa (Dyspnea), Shosha (Consumption), Rajyakshama (Tuberculosis), Ura Kshata (Traumatic chest disorders), Raktapitta (Bleeding disorders), Granthi (Benign tumours), Arbuda (Carcinoma) etc. of the respiratory tract. Kasa is broadly classified in Ayurveda as Shushka (non-productive) and Sakapha (productive) apart from Doshaja classification for diagnostic point of view. India being a tropical country, the prevalence of cough is remarked. There is need to analyze Vataja Kasa in a scientific background for its effective management. The cough manifesting primarily due to vitiation of Vata Dosha is called as "Vataja Kasa". It presents as a dry, non-productive cough with no phlegm production. While small amounts of phlegm may occasionally accompany cough, the condition is for the most part dry. The cough may be accompanied by a loss or change of voice, chest pain, headache, flank pain etc. The frequency of the cough may be episodic or continuous (Prasakta). Vataja Kasa is provoked by exposure to pollution, dust, smoke and other toxic gases. Vataja Kasa may not be life threatening but increasingly annoying and irritating to the individual in carrying out routine activities due to its nature. Many research studies have been carried out on Vataja Kasa with multiple herbs/herbo-mineral formulations but Chitrakadi Leha has not been subjected to clinical trial yet. As per the ingredients of Chitrakadi Leha cited in Charaka Sahmita, the ingredients are easily available and can be formulated easily and the ingredients possess Guru, Snigdha and Madhura Vipaka. The formulation is Vata Kapha pacifying, Anulomaka and holds promising result in the management of Vataja Kasa.³ It is primarily indicated in the treatment of Vataja Kasa and other ailments associated with Vataja Kasa viz., Hridroga, Shwasa and Gulma.⁴ Owing to the context, ingredients and indications of the

formulation and the lacuna in subjecting it to the clinical trial the present study is being undertaken to evaluate its effect in the management of Vataja Kasa.

Objective of the Study

1. To Evaluate the effect of Chitrakadi Leha in management of Vataja Kasa.
2. To compare the effect of Chitrakadi Leha over Agastya Hareetaki in management of Vataja Kasa.

MATERIALS & METHODS

Selection of Patients: A total of 44 patients, with age between 30-80 years, irrespective of their sex, religion, occupation, fulfilling the inclusion criteria were taken for the present study, from OPD of Department of Kayachikitsa of KLE University's Ayurveda Hospital, Shahapur, Belagavi. Ethical Clearance obtained from Institutional Ethical Committee via BMK/16/PG/KC/05. This clinical trial was registered with the Clinical Trials Registry of India (CTRI) prior to participant enrolment. The registration number is CTRI/2018/11/016482. Informed written consent in language suitable to the patients was obtained from all enrolled participants. A detailed history regarding family history, past illness, and clinical findings pertaining to Ashtavidha and Dashvidha Pariksha.

Sample Size: 44 subjects were enrolled and randomly, placed into two groups A and B, respectively. 41 subjects completed the treatment. 20 subjects were placed in trial Group A and 21 Subjects placed in trial group B on other side. Two patients in Group A whereas one patient in Group B discontinued the intervention prior to completion of the trial.

Inclusion Criteria

- Patients fulfilling the diagnostic criteria will be included in the trial.
- Patients with elevated AEC.
- Patients between age group of 30 to 80 years, of both genders.
- Patients willing to participate with written consent.

Exclusion Criteria

- Patients with multisystem disease or those seriously ill
- Known cases of Tuberculosis, Interstitial Lung Disease, Loeffler's Syndrome, Acute & chronic Eosinophilia, Pneumonia, Hyper-eosinophilic syndrome, Allergic bronchopulmonary Aspergillosis, Pulmonary Vasculitis.
- Pregnant woman, Lactating mothers.

- Patients with known history of hypersensitivity to trial drug or any of its ingredients were excluded from the study.

Follow up

- Assessment was done on 10th, 20th and 31st days.

Assessment Criteria

- Assessment of the patient was done on the basis of signs and symptoms related to Vataja Kasa.
- Investigations were done before and after the treatment.

Table No. 1: Showing the Parametric and Non-parametric Assessment Criteria for Vataja Kasa

Non-Parametric Assessment	Parametric Assessment
• Shushka kasa (Dry cough) • Swarbheda (Hoarseness in voice) • Shirshoola (Headache) • Parshwashoola (Pain in flanks)	CBC ESR AEC
Patient Having Any One of the Following in Addition to the Above Clinical Features • Kantha Ura, Vaktra Shushkta (Dryness of throat, chest and mouth) • Nirghosha (Rattling sound) • Stanana (The sound of a hollow cough, hard breathing) • Daurbalya (Weakness)	

Intervention

Total of out of 44, total 41 patients completed the study who were assigned into two groups, 20 patients in Trial group & 21 patient in control group. Group A patients received Chitrakadi Leha and Group B received Agastaya Hareetaki 12gm Q.I.D for 30 days.

Do's and Don'ts: Patients were instructed to avoid oily, cold food and milk products during the course of the treatment.

Collection and Preparation of Test Drug: Raw materials were collected from Kaher Khasbag pharmacy. These drugs were identified and authenticated by the experts. Drug preparation as per the SOP mentioned in AFI and analytical studies of each drug was done in the CRF of KAHER Shri B.M.K. Ayurveda Mahavidyalaya, Shahapur, Belagavi, Karnataka, 590003

Outcome Measures

1. Cough-Shushka Kasa (Dry cough) was assessed on the basis of Leicester Cough Questionnaire⁵
2. Swarabheda (GRBAS Scale.)⁶

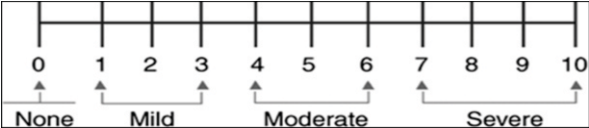
Table No. 2: Showing the GRBAS Scale for Swarabheda Assessment.

Grade	Parameter	Day 0	Day 10	Day 20	Day 31
1	Normal Voice				
2	Mild Dysphonia				
3	Moderate Dysphonia				
4	Severe Dysphonia				
5	Aphonic				

3. Shira, Parshwa shoola and Ura Shoola - (Visual Analogue Scale)

Diag. No.1: Showing the Visual Analogue Scale for Shira, Parshwa Shoola and Ura Shoola Assessment.

Before Treatment



After Treatment

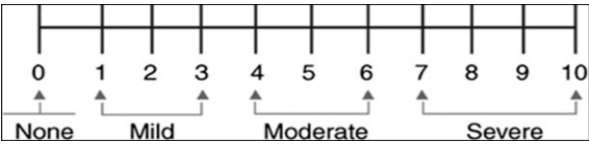


Table No. 3: Showing the VAS (Visual Assessment Scale) on Follow up Days for Shoola (pain) Assessment.

Shira Parshwa & Ura Shoola	Day 0	Day 10	Day 20	Day 31
Grading				

4. Kantha/Vaktra Shushkata (Clinical Oral Dryness Scale⁷)

Table No. 4: Showing the Kantha /Vaktra Shushkata on the Basis of Clinical Oral Dryness Scale on Follow up Days.

Grade	Observation	0th Day	10th Day	20th Day	31st Day
1.	Mirror stick to buccal mucosa				
2.	Mirror sticks to Tongue				
3.	Frothy saliva				
4.	No saliva pooling in floor of mouth				
5.	Tongue show loss of papillae				
6.	Smooth gingival architecture				
7.	Glassy appearance to other oral mucosa especially palate				

5. Nirgosha (Rattling Sound in Chest)

Table No. 5: Showing the Nirgosha (Rattling Sound in Chest) on Follow up Days.

Observation	Day 0th	Day 10th	Day 20th	Day 31st
Present / Absent				

6. Daurbalya (Fatigue Scale⁸)

Table No. 6: Showing the Daurbalya Assessment on the Basis of Fatigue Scale.

Grade	Observation	0th	10th	20th	31st
1.	I am bothered by fatigue				
2.	I get tired very quickly				
3.	I do not do much during the day				
4.	I Have enough energy for everyday life				
5.	Physically, I feel exhausted				
6.	I have problem to start thing				
7.	I have problem to think clearly.				
8.	I feel no desire to do anything				
9.	Mentally, I feel exhausted				
10.	When I am doing something, I can concentrate quite well				

Other Laboratory Investigations:

Absolute Eosinophil Count: It is well known that Eosinophils and neutrophils play major roles in the pathogenesis of allergy. Erythrocyte Sedimentation Rate: There are many studies which had proved that ESR values are higher in patients of Vataja Kasa. Complete Blood Picture: - For inflammatory mediators like Hb, Eosinophils, and Neutrophils.

RESULT

Table 7. Overall Results on Group A (Chitrakadi Leha) and Group B (Agastaya Hareetaki).

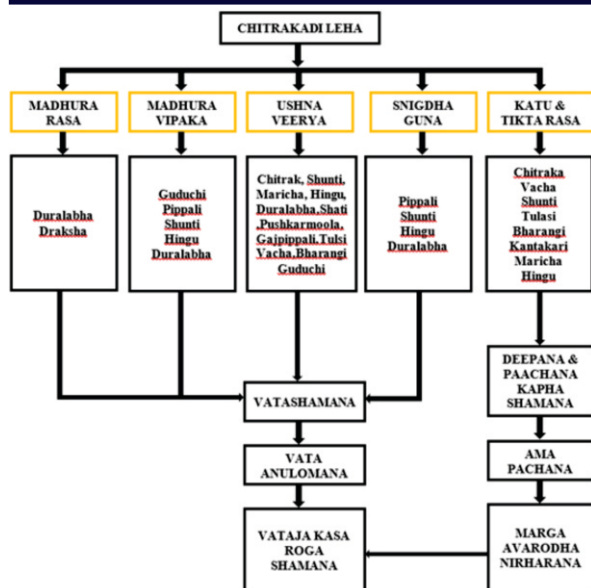
Parameters	Group A			Group B			B/W Groups
	0-10	0-20	0-30	0-10	0-20	0-30	
Kasa	**	***	***	***	***	***	NS
Swarabheda	**	***	***	**	***	***	NS
Shira Shoola	**	***	***	***	***	***	NS
Parshwa Shoola	**	***	***	***	***	***	NS
Ura shola	*	*	*	**	**	**	*
Kantha shushkata	**	***	***	***	***	***	NS
Dourbalyata	**	**	**	NS	**	**	NS
AEC	-	-	***	-	-	***	NS
ESR	-	-	NS	-	-	NS	NS
Eosinophils	-	-	**	-	-	NS	NS
Monocytes	-	-	NS	-	-	***	***

p<0.05*, p<0.001 ** and p<0.0001 ***

Overall result was calculated with the help of statistical Test i.e. Wilcoxon Signed Rank Test, Man–Whitney, paired t-test, Independent Sample t-Test and respectively mentioned in table no. 7 with comparison within and between the group A and group B.

DISCUSSION

In Chitrakadi Leha (CL), statistically significant results were obtained on subjective parameters viz., Shushka Kasa, Swarabheda, Shirashoola and Parshwashoola as well as objective parameters viz., AEC, and Eosinophils. subjective parameters such as Shushka Kasa, Swarabheda, Shirashoola, Parshwashoola, Kantha Shushkata, Urashoola as well as objective parameters viz., AEC, Eosinophil's and Monocytes.



Diag. No.2: Showing the Combined Effect of Chitrakadi Leha on Vataja Kasa.

In Agastya Hareetaki (AG) group, statistically significant result was obtained in subjective parameters such as Shushka Kasa, Swarabheda, Shirashoola, Parshwashoola, Kantha Sushkata, Urashoola as well as objective parameters viz., AEC, Eosinophil's and Monocytes.

Shushka Kasa (Dry cough) – Significant results were observed in both the groups from 10th day of intervention and there on with slightly better results in group A in terms of difference in percentage. This reflects the improvement in quality-of-life w.r.t Physical, Psychological and Social domains of LCQ score. The herbs in both formulations possess kasahara property and are Anulomaka. These might have acted in reducing the cough reflex. herbs like Chitraka, Shati, Kantakari, Bharangi and Pushkaramoola in both the formulations possess vatakapah pacifying properties by virtue of Ushna veerya and Katu rasa respectively and are indicated in Kasa. Kantakari is ushna veerya pacifies vata dosha causing Kasa. The plant powder is antitussive & beneficial in bronchial asthma and nonspecific cough due to the depletion of histamine from lung & expectorant action to nitrate⁷. Shunti in by virtue of its snigdha guna, ushna veerya and madhura vipaka pacifies Vata and is indicated in Kasa. Gingerols - 6- Shogaol administered intravenously showed the strong antitussive effect when compared to dihydrocodeine phosphate¹⁰.

Swarabheda- Statistically significant results were obtained within both the groups on 10th day of intervention itself. The outcome was probably because of soothing effect of herbs in the formulations which are kanthya and act as anti-inflammatory and antiallergic and relieve swarabheda.

Shira Shoola- Statistically significant results were obtained within both the groups from 10th day of intervention itself. The formulations contain ingredients that are Vedanahara. Shoola is a symptom of abnormal Vata that manifests with aggravation of Ruksha and Sheeta quality counteracted by Snigdha guna and Ushna veerya of herbs thereby reducing the shira shoola.

Ura Shoola- Significant results were attained in both the groups on 10th day of intervention. There was statistically significant difference in results between the groups from baseline to 10th Day, baseline to 20th day and from before to after treatment on 31st day. The herbs of Agastya Rasayana are vedanahara and shothaghna which reduce shoola. The effect could be due to the anti-inflammatory activity of herbs like dashamoola in Agastya Rasayana.

Parshwa Shoola- Statistically significant results were obtained on the parameter parshwa shoola within both the groups on 10th day of intervention onwards. The outcome may be due the vedanahara herbs in both the formulations like Pushkaramoola and Dashamoola in Chitraka hareetaki and Agastya Rasayana respectively. The herbs possess ushna veerya by which the aggravated vata causing shoola is pacified. The herbs also possess anti-inflammatory activity by which the pain is relieved.

Kantha Shushkata- Statistically significant results were obtained within both the groups from 10th day of intervention onwards. No significant difference in results was observed between the groups statistically, though Group B fared better than Group A in terms of difference in percentage. The outcome was probably due to the Snigdha quality and madhura vipaka of herbs in both the formulations. Also, the form of formulations being in leha act as demulcent due to honey in both the formulations reducing the dryness of throat.

Vaktra Sushkata - Statistically non-significant results were obtained in control group. However, in Trial group, there were no subjects who reported to have Vaktra Sushkata at base line visit and during trial period. The dryness of mouth is the result of aggravated vata dosha and kapha kshaya. The maximum herbs in both the formulations are vatakapahara and possess ushna veerya which might not be sufficient enough to tackle severely aggravated vata. Very few herbs possess snigdha quality and madhura vipaka that is essential in reducing the vaktrasushkata.

Nirghosha - Nirghosha is rattling sound in the chest. There was 100% relief with Nirghosha in both the groups on two subjects each in both groups. There was no significant difference in results between the groups on Nirghosha.

Stanana - Stanana is the sound of the hollow cough. No subjects reported with stanana among both the groups before and during the trial period.

Dourbalya - Statistically significant results were obtained within both the groups on 10th day of intervention onwards. There was no statistically significant difference in results in between the groups though Group A fared better than Group B in terms of difference in percentage. The outcome could be because of ingredients in both formulations with santarpana, brumhana, vrushya effect.

Objective Parameters

AEC - Statistically significant results were obtained on parameter AEC within both the groups. There was no significant difference in results between the groups on AEC statistically though Group A fared better than Group B in terms of difference in percentage. This may be due to the ant-allergic and anti-inflammatory herbs like Guduchi, Haridrā, Bhārangi, Kanthakāri, and Shunti etc in both the formulations. Results from pilot showed that S. xanthocarpum (kantakari) relieved the bronchial asthma have Bronchodilatory effect, reducing in the secretions within the airway lumen, and also reducing the bronchial mucosal edema which patient having allergy¹¹

Eosinophils - There was significant change in the values of Eosinophils in Group A as compared to Group B with mean 7.35 BT to 5.90 AT and p value 0.0063. Eosinophils are the inflammatory mediator cells which in response to allergens cause excess secretion from the respiratory tract. The outcome may be due to the anti-allergic activity of ingredients in Chitrakadi Leha.

ESR - No significant difference was observed between group A and group B from the pre- test to post-test. The mean ESR difference from pre-test to post-test are similar in both the group i.e., around 19%. This result could be because of anti-inflammatory activity of herbs in both the groups like Karkatashringi, Bharangi, Guduchi and Tulasi.

The other blood parameters like Hb%, Neutrophils were non-significant within and between groups.

Blood Parameters

Eosinophils are the inflammatory mediator cells which in response to allergens cause excess secretion from the respiratory tract. Significant results were found on eosinophils count in both the groups. This might be due to reduction in bio active lipid mediators and oxygen radicals, toxic basic proteins and correction of airway epithelium.

Significant result was found on Absolute Eosinophil count (AEC) in control group and highly significant result in trial group. This might be because of more anti allergic herbs in trial group reducing inflammatory mediators and micro-vascular leakage. This result in reduction in plasma exudation into lumen airway contributing to mucous plugging improves mucociliary clearance and reduces oedema of airway. This may be due to anti-allergic, anti-inflammatory properties of Guduchi, Haridrā, Bhārangi, Dhānyaka, Kanthakāri, and Sunthi.

During the trial there were no adverse effects noted in any subjects. Results are made on 41 patients who completed the treatment protocol i.e. 20 patients in trial group & 21 patients in Control group.

CONCLUSION

The Chitrakadi Leha is effective in the management of Vataja Kasa and significant Improvement was observed on parameters like Shushka Kasa, Swarabheda, Shirashoola and Parshwashoola symptoms as well as objective parameters viz., AEC, Lymphocytes and Eosinophils. Chitrakadi Leha and Agastya Rasayana are comparable in the management of Vataja Kasa. Both Drugs help in early reduction of symptoms and reduce disease course.

Conflict of Interest- It's declaring that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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