

## A CLINICAL STUDY TO EVALUATE AND COMPARE THE EFFICACY OF KAMALAHARA KASHAYA AND PHALATRIKADI KASHAYA IN KOSHTASHAKHASRITA KAMALA

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### ABSTRACT

**Background:** *Rakta Dhatu* is given utmost importance as the disease incidences pertaining to *Rakta* are more in number. *Kamala* is such a disease where in the *Rakta Dhatu* is vitiated primarily by *Pitta Dosha*. The clinical presentation of *Koshtashakhasrita Kamala* stands in parlance with Hepatic Jaundice, especially Infective Hepatitis. *Kamala* being a *Pitta Pradhana Vyadhi* should be treated with *Pitta Rechaka & Shamaka Aushadhi*, Most of the *Dravya* in *Kamalahara Kashaya* and *Phalatrikadi Kashaya* have *Tridoshahara* property and almost all drugs have *Pittahara* property. Hence a sincere effort is made to evaluate and compare the effect of *Kamalahara Kashaya* and *Phalatrikadi Kashaya* in *Koshtashakhasrita Kamala*. **Methods:** The study was a Single Blind Randomized Parallel Comparison Clinical Study. The study was conducted in 40 subjects for a period of 28 days. Clinical features and haematological parameters were documented at baseline, 7<sup>th</sup> day, 14<sup>th</sup> day and after treatment. Observations were analysed and findings were evaluated by using statistical methods. **Results:** This study shows that both *Kamalahara Kashaya* and *Phalatrikadi Kashaya* have significant effect in *Koshtashakhasrita Kamala*. **Conclusion:** The result obtained was both *Kamalahara Kashaya* and *Phalatrikadi Kashaya* have significant effect in *Koshtashakhasrita Kamala*. There is no significant difference in the effect of *Kamalahara Kashaya* and *Phalatrikadi Kashaya* in *Koshtashakhasrita Kamala*.

**Keywords:** *Kamalahara Kashaya*, *Phalatrikadi Kashaya*, *Koshtashakhasrita Kamala*, Viral Hepatitis

### INTRODUCTION

In Ayurveda *Rakta Dhatu* is given utmost importance as the disease incidences pertaining to *Rakta* are more in number<sup>1</sup>. *Kamala* is such a disease where in the *Rakta Dhatu* is vitiated primarily by *Pitta Dosha*<sup>2</sup>. Indulgence with *Pitta Prakopa Nidana* independently or after *Pitta Pradhana Vyadhi* such as *Pandu* is considered as *Nidana* for *Kamala*<sup>3</sup>. The clinical presentation of *Koshtashakhasrita Kamala* stands in parlance

with Hepatic Jaundice, especially Infective Hepatitis. Among the Infective Hepatitis, Viral Hepatitis causes an estimated 1.4 million deaths worldwide each year. WHO estimates that more than 300 million people are chronically infected with Hepatitis worldwide. However less than 5% of those people have been tested or are aware of their diagnosis<sup>4</sup>. The annual mortality

figure of Viral Hepatitis all over world has been placed at 2 million by WHO.

*Kamala* being a *Pitta Pradhana Vyadhi* should be treated with *Pitta Rechaka & Shamaka Aushadhi*. Even though there are innumerable recipes are available in Ayurvedic literature apart from the contemporary management *Kamalahara Kashaya* and *Phalatrikadi Kashaya* were selected for the study because of their economical and easy availability.

So an attempt is made to evaluate the efficacy of *Kamalahara Kashaya*<sup>5</sup> and *Phalatrikadi Kashaya*<sup>6</sup> in *Koshtashakhasrita Kamala* on scientific basis.

## MATERIALS AND METHODS

### OBJECTIVES OF THE STUDY

1. To evaluate the efficacy of *Kamalahara Kashaya* in *Koshtashakhasrita Kamala*.
2. To evaluate the efficacy of *Phalatrikadi Kashaya* in *Koshtashakhasrita Kamala*.
3. To compare the efficacy of *Kamalahara Kashaya* and *Phalatrikadi Kashaya* in *Koshtashakhasrita Kamala*.

### SOURCE OF DATA

**Sample Source:** Patients were selected from OPD and IPD of PG studies of Kayachikitsa, Alva's Ayurveda Medical College and Hospital, Moodbidri.

**Drug Source:** Raw drugs were collected from the source of procurement and identified by experts concerned.

**Method of Sampling:** Lottery Method. Patients diagnosed with *Koshtashakhasrita Kamala* were randomly allocated into two groups A and B.

### CRITERIA FOR SELECTION OF PATIENTS

#### Diagnostic criteria:

1. Yellowish discolouration of urine, sclera, mucous membrane of oral cavity, nails, and skin with or without other symptoms of *Koshtashakhasrita Kamala*.
2. Raised Serum Bilirubin levels, Raised SGOT and SGPT levels.

**Inclusion Criteria:** Patients having *Lakshana* of *Koshtashakhasrita Kamala* and Patients between 16 – 60 years of Age.

**Exclusion Criteria:** Patient who do not give written consent for clinical trial, *Koshtashakhasrita Kamala*

with *Upadrava*, *Koshtashakhasrita Kamala* occurring as *Upadrava* in other diseases and vulnerable group of patients.

**Study design:** Single Blind Randomized Parallel Comparison Clinical Study.

### Method of Preparation of Medicine

**Ingredients:** *Kamalahara Kashaya* - *Vasa, Guduchi, Yashtimadhu, Kathaka, Hribera, Nimba. Phalatrikadi Kashaya* - *Harithaki, Amalaki, Vibhithaki, Guduchi, Vasa, Katuki, Bhunimba, Nimba.*

**Method of Preparation of Kashaya:** The *Kashaya* was freshly prepared every day. All of the ingredients were taken in equal quantity and made into coarse powder. 12.5 gm of *Kwatha Churna* was subjected to *Mandagni* with 16 times of water and reduced to 1/4<sup>th</sup>. Thus obtained *Kashaya* was filtered through a clean cloth and collected in a clean sterile container.

**Intervention:** Group A - participants were given with *Kamalahara Kashaya* 25 ml with honey two times in a day before food for three week. Group B - participants were given with *Phalatrikadi Kashaya* 25 ml with honey two times in a day before food for three week.

**Observation Period:** Patients were assessed with clinical and laboratory parameters at baseline and on 7<sup>th</sup>, 14<sup>th</sup>, 21<sup>st</sup> day of treatment and the Follow Up was on 28<sup>th</sup> day. Total Study Duration was 28 days.

**Assessment Criteria:** Primary outcomes were Serum Bilirubin – Indirect, Serum Bilirubin – Direct, SGPT, SGOT, S.ALP and Secondary outcomes were Urine – Bile Salts, Urine – Bile Pigments, *Dourbalya, Avipaka, Daha, Hrullasa, Chardi, Jwara.*

## RESULTS

There were 42 patients of *Koshtashakhasrita Kamala* registered for the study and were randomly allocated into two groups A & B. Group A had 20 patients and Group B had 22 patients. But two patients were dropped out from Group B. Hence out of 42 registered patients 40 patients completed the clinical trial. In Group A, 20 patients were given *Kamalahara Kashaya* and in Group B, 20 patients were given *Phalatrikadi Kashaya*. Summary statistics have been interpreted for S.D, SE, MD, MEAN, t-value, p-value. Test

of significance applied for comparing the results within the group by using paired t-test and between groups by using unpaired t-test. The Clinical parameters that assessed for the study were *Chardi, Daha, Avipaka, Dourbalya, Hrullasa, and Jwara*. Lab parameters that taken for assessment were Bilirubin –

Direct, Bilirubin – Indirect, SGOT, SGPT, Alkaline Phosphate, Bile salt and Bile pigment. Both the individual effect of Lab parameters on baseline, 14<sup>th</sup> day, after treatment and follow up day in Group A and Group B were compared.

**Table 1:** Statistical Results For Individual Assessment Criteria

Parameters	Group	BT Mean	During Treatment	M.D	%	S.D	S.E	t-value	p-value
Bilirubin- Direct	A	1.965	D14	0.745	38	0.914	0.204	3.646	=0.002
			AT	1.270	65	0.777	0.174	7.312	<0.001
			AF	1.520	77	0.759	0.170	8.962	<0.001
	B	2.275	D14	1.010	44.3	2.444	0.546	1.848	=0.080
			AT	1.500	65	2.604	0.582	2.576	=0.019
			AF	1.755	77	2.670	0.597	2.940	=0.008
Bilirubin – Indirect	A		D14	1.275	43	1.223	0.273	4.662	<0.001
			AT	1.770	60.2	1.119	0.250	7.075	<0.001
			AF	2.235	76	1.094	0.245	9.139	<0.001
	B		D14	0.630	25.9	1.244	0.278	2.266	=0.035
			AT	1.325	54.4	0.834	0.187	7.104	<0.001
			AF	1.530	62.8	0.840	0.188	8.147	<0.001
SGOT	A		D14	670.40	82	758.50	169.60	3.953	<0.001
			AT	722.00	89	756.59	169.18	4.268	<0.001
			AF	760.60	93.8	748.14	167.29	4.547	<0.001
	B		D14	618.45	67.3	745.98	166.80	3.708	=0.001
			AT	676.70	82.7	761.69	170.32	3.973	<0.001
			AF	726.00	88.7	739.50	165.35	4.390	<0.001
SGPT	A		D14	553.70	66	479.59	107.24	5.163	<0.001
			AT	720.30	86.2	439.25	98.21	7.334	<0.001
			AF	767.60	92	453.71	101.45	7.566	<0.001
	B		D14	582.60	64.4	503.22	112.52	5.178	<0.001
			AT	709.05	78.5	545.10	121.89	5.817	<0.001
			AF	773.45	85.5	533.70	119.34	6.481	<0.001
ALP	A		D14	241.40	30	813.32	181.86	1.327	=0.200
			AT	323.70	40.5	888.70	198.72	1.629	= 0.120
			AF	421.35	47	880.17	196.81	2.141	= 0.045
	B		D14	38.30	6.19	383.07	85.657	0.447	= 0.66
			AT	52.50	8.5	392.746	87.821	0.598	= 0.557
			AF	208.75	33.7	337.689	75.509	2.765	=0.012

**Table 2:** Statistical Results While Comparing the Individual Assessment Criteria.

Parameter	Group	M.D			t- value			p- value		
		D14	AT	AF	D14	AT	AF	D14	AT	AF
Bilirubin – Direct	A	0.265	0.23	0.235	0.454	0.379	0.379	=0.652	=0.707	=0.707
	B									
Bilirubin	A	0.645	0.48	0.705	1.654	1.526	2.286	0.106	=0.135	=0.028

– Indirect	B									
SGOT	A	51.95	45.3	34.60	0.218	0.189	=0.147	= 0.828	= 0.851	= 0.884
	B									
SGPT	A	28.9	11.4	5.85	=0.186	=0.079	=0.038	=0.853	=0.942	= 0.970
	B									
ALP	A	279.7	249.8	212.6	=1.391	=1.140	=1.009	=0.172	=0.261	=0.320
	B									

## DISCUSSION ON OBSERVATIONS

**Age:** In present study, maximum number of patients (100%) in both the groups belonged to age group between 16-30 years. This reveals that most of the patients are in the age where *Pitta* is more predominant<sup>7</sup> i.e. *Madhyama Vaya*.

**Diet Habit:** Majority of the patients followed unhealthy dietic habits like *Vishamashana* (67.5%), since most of the patients were students.

**Rasa in Diet:** *Amla Pradhana Ahara* (42.5%) was taken more frequently; second most was *Katu Pradhana Ahara* (32.5%) then *Lavana Pradhana Ahara* (15%). *Rasa* like *Amla*, *Katu*, *Lavana* can cause *Pitta Prakopa* and *Dushana* of *Rakta*<sup>8</sup>.

**Agni:** It was observed that *Mandagni* was present in highest incidence (32.5%). *Tikshnagni* was present in about (27.5%), *Samagni* was present in about (22.5%) and *Vishamagni* was present in about (17.5%). Most people had *Mandagni*. It is said “*Rogah Sarve Api Mandagnou*” which means *Mandagni* is the root cause of all disease.

**Shareera Prakriti:** It was observed that most of the participants from the *Vata-Pitta Prakriti* (40%), second most incidence was seen in the group of *Tridosha Prakriti* (35%), and *Pitta-Kapha Prakriti* group of participants are present in about (25%). So along with the assessment of *Prakriti* consumption of *Nidana* as per literatures could have led to causation

## DISCUSSION ON RESULTS

In the clinical trial the given drug Group A and Group B had very good response in improving symptomatology and laboratory values, which were also statistically significant. Further it was accepted that there is no significant difference in the effect of *Kamalahara Kashaya* and *Phalatrikadi Kashaya* in *Koshta-*

*shakhasrita Kamala*. Subjective Parameters, *Chardi*, *Daha*, *Avipaka*, *Dourbalya*, *Hrullasa*, and *Jwara* manifest as *Poorvarupa* of *Kamala* and subside when the actual *Lakshana* occurs. During these clinical trial participants from both groups got good relief in these parameters in the initial stage and 100% relief was found. In case of Urine Bile Salts and Bile Pigments also 100 % effect was found. So no statistical tests were done for these parameters. **Effect of treatment in Laboratory Parameters:** The treatment showed significant result in parameters like Serum Bilirubin – Direct, Serum Bilirubin – Indirect, SGOT, SGPT, Alkaline Phosphate in both group and while comparing between the groups there was no significant difference in the effect was found.

## DISCUSSION ON MODE OF ACTION OF DRUG

### Probable mode of action of *Kamalahara Kashaya*

In *Kamalahara Kashaya* most of the drugs are having *Thikta-Kashaya Rasa* which helps to *Kapha-Pitta Shamaka* & *Rakta Prasadana*. *Thikta Rasa* and *Katu Vipaka* property of these drugs helps for *Amapachana*. *Laghu-Rooksha Guna* of these drugs helps to pacify *Pitta* & *Kapha Dosha*. *Sheeta Veerya* is again *Rakta Shamaka* and *Pittahara*. In *Kamalahara Kashaya*, *Guduchi* is best immune-modulator, so it helps to improving immunity against Viral Infection. The anti-hepatotoxic activity of *Guduchi* helps to normalising the liver function<sup>9</sup>. *Yashtimadhu* have pharmacological actions of anti-inflammatory, immune regulatory and anti-viral effects<sup>10</sup>. Hepato-protective action of *Kathaka* helps to reduce the elevated SGOT, SGPT, ALP and Bilirubin levels<sup>11</sup>. *Hribera* also have anti-oxidant and hepato-protective properties which help to control the altered SGOT, SGPT, ALP and Bilirubin levels<sup>12</sup>.

### Probable mode of action of Phalatrikadi Kashaya

In *Phalatrikadi Kashaya* most of the drugs are predominantly *Thikta-Kashaya Rasa, Laghu- Ruksha Guna*. These drugs are having *Kapha-Pittahara* property. *Madhura & Katu Vipaka* helps in *Pitta Shamana*. In *Phalatrikadi Kashaya, Katuki*<sup>13</sup> have the Choleric and Cholegogue action which helps to reduce the Serum Bilirubin level constantly due to clearance of bile passage. All the drugs have anti-oxidant properties, which helps to protect the liver from getting disease due to free radical over load. *Katuki, Bhunimba, Amrita* has the capacity to suppress the kupffer cells, which are major determinant of outcome of liver injury. As *Kamala* is one of the *Pittaja Nanatmaja Vyadhi*, with the help of these *Pittahara Dravya*, both *Kashaya* acted well on it.

### CONCLUSION

*Pitta* is the *Pradhana Dosha* in *Koshtashakhasrita Kamala*. Indulgence with *Pitta Prakopa Nidana* independently or after *Pitta Pradhana Vyadhi* such as *Pandu* is considered as *Nidana* for *Kamala*.

In the present clinical trial, Group A and Group B result shows that; the effect of both treatment produced significant results for the secondary outcomes like *Daha, Avipaka, Aruchi, Jwara, Chardi* and *Dourbalya* as well as primary outcomes like Bilirubin-Direct, Bilirubin-Indirect, SGOT, SGPT, and Alkaline Phosphate. *Kamalahara Kashaya* and *Phalatrikadi Kashaya* were effective in reducing the symptoms and disease progression of *Koshtashakhasrita Kamala*. While comparing the effect of *Kamalahara Kashaya* and *Phalatrikadi Kashaya* between group A and B, there was no statistical difference obtained which means both have equal effect.

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