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A Comparative Clinical Study on *Phalatrikadi Kwata* and *Darvyadi Kwatha* in the management of *Kamala* w.s.r. to Jaundice

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A B S T R A C T

Background: Jaundice (*Kamala*) is a yellowish pigmentation of the skin, the conjunctival membranes over the sclera (whitish of the eyes), and other mucous membranes caused by hyperbilirubinemia (increased levels of bilirubin in the blood). Today's lifestyle with unhygienic and poor dietary habits and alcoholic habits etc. are responsible factors to promote hepatic damage which clinically reflects as *Kamala Roga*. The incidence of such causes resulting in Jaundice. In India it is 2.37-3.15 per 1000 population. The effect of Ayurvedic treatment was assessed in relation to improvement in overall clinical signs and symptoms. **Objectives:** To evaluate the effect of *Phalatrikaadi Kwatha* and *Darvyadi Kwatha* in *Kamala Roga*. **Methodology:** A comparative clinical study was conducted on *Kamala* for period of 15 days. The patients were divided into 2 groups. In Group A 20 patients were administered with *Phalatrikadi Kwatha* internally and in Group B 20 patients were administered with *Darvyadi Kwatha* internally. **Results:** Group A and Group B have shown statistically significant result. Group B treated with *Darvyadi Kwatha* showed better result compared with Group B treated with *Phalatrikadi Kwatha*.

Key words: Kamala, Jaundice, Phalatrikadi Kwatha, Darvyadi Kwatha.

INTRODUCTION

Ayurveda is a Science it deals with the study of knowledge of life. The aim of this science is to protect the Human being from various diseases, which acquire by not following the Swasthavritha, The prevention of the disease and curative aspect of disease knowledge and explanation is available in the ancient period. Ayurveda is the Upaveda of Atharvaveda.[1] In Vedas there is a vivid description of a *Vyadhi*, which has been characterized by yellowish pigmentation of sclera, tongue, nails, urine and skin etc. and with suitable treatment is also explained.[2]

Ayurvedic health care system has perfected efficient methods and herbal preparations to keep the physical, mental and emotional health of a person in its prime through out life. It is contrary to current practice of seeking treatment when disease strikes, or waiting to get medical help till the symptoms manifest. It is a mind; body medicare system evolved to help human beings and get maximum benefit out of their lives in a perfectly natural healthy way.

Ayurveda instills in you a view of life that is holistic and congenial to enjoy the pleasures of life in a sustainable way. This can be achieved without disturbing the rhythm of your life.

Ayurveda favours administration of natural health care products (of plant, animal, mineral origin) and

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their preparations. Generally, Ayurvedic products cause no toxic or side effects, and hence are totally safe. These are time tested preparations, which have been used by many generations. There is no question of tolerance, resistance or addiction with Ayurvedic health care products.

Day today practice receives number of patients suffering from *Kamala* (Jaundice) and its complications as the negligence of *Kamala* management. Even though there are innumerable recipes in Ayurvedic literature apart from the contemporary management, *Phalatrikadi Kwatha*[3] and *Dharvyadi Kwatha*[4] was selected for the study as it seems as classical, authentic, economical and easily available mentioned in Bhaishajya Ratnavali. Attempt is made in this study to evaluate comparative study of *Phalatrikadi Kwatha* and *Darvyadi Kwatha* in the management of *Kamala*.

The contents of *Phalatrikadi Yoga* are *Triphala, Katuki, Nimba, Guduchi, Vasa* and *Chirayata*.[5] The *Darvyadi Kwatha Yoga* contents are *Triphala, Trikatu, Daruharidra, Vayuvidanga, Loha Bhasma*.[6] Some of these are very frequently used drugs in *Kamala*. In contemporary medical system jaundice is the word analogous with *Kamala*.

MATERIALS AND METHODS

Selection of patients

The patients with the conformed diagnosis of *Kamala* clinically as well as laboratory investigations were selected for the study. Patients were selected from the RGE Ayurvedic Medical College and Hospital, Ron.

Inclusion criteria

The patients of both sexes presenting with the following *Lakshanas* were selected.

- The patients between the age group of 20-50 years, irrespective of sex and occupation, both fresh and treated individuals, presenting with the symptoms of *Kamala* were selected.

- Patients presenting with the lakshanas like *Peetanetrata, Peetamutrata, Peetavarchas, Peetanakha, Peetatvak.*

Exclusion criteria

- Patients with other systemic diseases like DM, HTN, IHD, HIV, TB, HbsAg, etc. or conditions which interfere with the course of the treatment.

- The patients below age of 20 and above age of 50

- Pregnant women

- Lactating mother

- Obstructive jaundice

- Cirrhosis of liver due to alcohol

Severe Jaundice patients, complications of Jaundice, who will not agree for the study were also excluded.

Investigation

The laboratory investigations are very important for the diagnosis of the diseases. For the Kamala disease diagnostic purpose

1. Hb%[7]

2. Urine bile salts and bile pigments[8]

3. Serum bilirubin - direct, indirect, total[9]

Trial drug

*Phalatrikadi Kwatha***:** *Harithaki, Vibhitaki, Amalaki, Vasa, Guduchi, Katuki, Kiratatikta* and *Nimba*.

Dharvadi Kwatha: *Harithaki, Vibhitaki, Amalaki, Shunti, Pippali, Maricha, Daruharidra, Lohabhasma, Jala.*

Phalatrikadi Kwatha and *Darvyadi Kwatha* will be prepared according to the classical references.

Study design: Prospective comparative clinical study

Sample size

- Total number of patients taken for the study will be 40.

- Two groups including 20 patients in each.

- Group A: 20 patients will receive *Phalatrikadi Kwatha.*

- Group B: 20 patients will receive *Darvyadi Kwatha.*

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Posology

- *Phalatrikadi Kwatha* 15ml dvivaaram, pragbhakta with *Anupana* as *Madhu*.

- DarvyadiKwatha 15ml dvivaaram,pragbhakta With Anupana as Madhu.

Duration of treatment: 30 days.

Assessment criteria

- Changes in clinical signs and symptoms of *Kamala Roga*.

- Serum bilirubin - Direct, Indirect, Total.

- Urine Bile salt and bile pigments.

PARAMETERS

Subjective Parameters[10]

Clinical signs and Symptoms of *Kamala Roga* mentioned in Ayurveda.

- *Peetanetrata,*

- *Peetatwak,*

- *Peetamutrata,*

- *Peetavarchas,*

- *Peetanakha.*

Objective parameters

- Haemoglobin.

- Serum bilirubin - Direct, Indirect, Total.

- Urine - Bile salt and Bile pigments

Subjective parameters

Symptoms	No	Mild	Moderate	Severe
Peetanetrata	0	1	2	3
Peetatvak	0	1	2	3
Peetamutrata	0	1	2	3
Peetavarchas	0	1	2	3
Peetanakha	0	1	2	3

1. *Peetanetrata*

- Normal *Varna* of *Netra* - 0

- *Paanduharitha Varna* of *Netra* - 1

- *Peetaharitha Varna* of *Netra* - 2

- *Raktapeeta Varna* of *Netra* - 3

2. *Peetatvaka*

- Normal *Varna* of *Tvaka* - 0

- *Paanduharitha Varna* - 1

- *Peetaharitha Varna* of *Tvaka* - 2

- *Raktapeeta Varna* of *Tvaka* - 3

3. *Peetamutrata*

- Normal *Varna* of *Mutra* - 0

- *Paanduharitha Varna* of *Mutra* - 1

- *Peetaharitha Varna* of *Mutra* - 2

- *Raktapeeta Varna* of *Mutra* - 3

4. *Peetavarchasa*

- Normal *Varna* of *Varchasa* - 0

- *Paanduharitha Varna* of *Varchasa* - 1

- *Peetaharitha Varna* of *Varchasa* - 2

- *Raktapeeta Varna* of *Varchasa* - 3

5. *Peetanakha*

- Normal *Varna* of *Nakha* - 0

- *Paanduharitha Varna* of *Nakha* - 1

- *Peetaharitha Varna* of *Nakha* - 2

- *Raktapeeta Varna* of *Nakha* - 3

Objective parameters

Investigations	Normal	Mild	Moderate	Severe
Haemoglobin	0	1	2	3
S.B. Total	0	1	2	3
S. B. Direct	0	1	2	3
S.B. Indirect	0	1	2	3

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Haemoglobin

0 - Normal >12 mg/dl

1 - Mild 10-12 mg/dl

2 - Moderate 8-10 mg/dl

3 - Severe <8 mg/dl

Serum Bilirubin Total

0 - Normal 0.3-1.4 mg/dl

1 - Mild 1.4-2.5 mg/dl

2 - Moderate2.5-3.5

3 - Severe >3.5 mg/dl

Serum Bilirubin Direct

0 - Normal 0.0-0.3mg/dl

1 - Mild 1.2-2 mg/dl

2 - Moderate 2-3mg/dl

3 - Severe <1.5mg/dl

Serum Bilirubin Indirect

0 - Normal 0.2-1.2 mg/dl

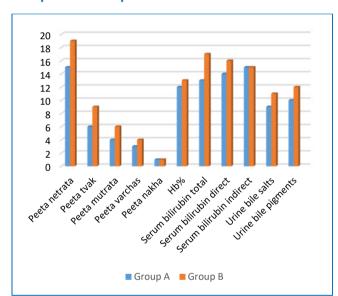1 - Mild 0.3-1 mg/dl

2 - Moderate 1-1.5mg/dl

3 - Severe >3

Investigations	Absent	Present
Urine Bile salt	0	1
Urine Bile pigments.	0	1

OBSERVATIONS

Demographic data have been presented for 40 patients while clinical data and observation were made on 40 patients (i.e. 20 in Group A and 20 in Group B) who completed the trail. In the present study, maximum patients were in age group of 20-30 years 15 (37.5%), were males 26 (65%), hindu 30 (75%), residence of rural area 30 (75%), belonged to middle class 22 (55%), and enjoyed mixed diet 27 (67.5%), tobacco addiction 21 (52.5%), majority of patients were farmer 11 (27.5%), *Madhyamasatva* 22

(55%), 21 (52.5%) were *Madhyamavyayamashakti*. Maximum number of patients were suffering from *Peetanetrata* 34 (85%), followed by *Peetatvak* 15 (37.5%), 10 (25%) patients having *Peetamutrata*, *Peetavarchas* 7 (17.5%) patients, and *Peeta Nakha* were 2 (95%). Hb% was found abnormal in 25 (62.5%) of the patients, followed by serum bilirubin total 30 (75%), serum bilirubin direct 30 (75%), and serum bilirubin indirect 30 (75%), urine bile salts 20 (50%), and urine bile pigments was abnormal in 22 (55%). The incidence of clinical signs and symptoms are depicted in chart no.1.

Chart 1: Incidence of clinical features of Kamalain Group A and Group B.

RESULTS

Effect of therapy in Group A

In *Peetanetrata*, *Peetatvak,* *Peetamutrata, Peetavarchas* and *Peetanakha* the relief percentages observed were 48.3%, 46.66%, 41.66%, 46.66%, 42.37% in that order. In Hb% improved by 48.33%, serum bilirubin total subsided by 60%, the effect was statistically significant (P <0.01). In serum bilirubin direct, the percentage of relief was 60%, which was significant statistically (P< 0.004). In serum bilirubin indirect the relief observed was 56.33%, which were statistically significant (P<0.01). In the urine bile salts and urine bile pigments the relief percentage observed were 45% and 45% in that order (Table 1 & 2).

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Table 1: Showing Individual study of the Subjective parameters in Group A.

Parameter		Mean		%	S.D	S.E	df	t value	p value	Remarks
Peeta Netrata	BT	3.00	1.45	48.33	0.00	0.10	19	3.198	0.004	H. S
	AT	1.55			0.49					
Peeta Tvak	BT	3.00	1.4	46.66	0.00	0.11	19	3.559	0.002	H. S
	AT	1.60			0.50					
Peeta Mutrata	BT	3.00	1.25	41.66	0.00	0.10	19	2.853	0.01	S. S
	AT	1.75			0.47					
Peeta Varchas	BT	3.00	1.4	46.66	0.00	0.10	19	3.198	0.004	H. S
	AT	1.60			0.49					
Peeta Nakha	BT	2.95	1.25	42.37	0.22	0.10	19	2.853	0.01	S. S
	AT	1.70			0.49					

Table 2: Showing Individual study of the Objective parameters in Group A.

Parameter		Mean		%	S.D	S.E	df	t value	p value	Remarks
Hb%	BT	3.00	0.55	18.33	0.00	0.10	19	2.858	0.01	S. S
	AT	2.45			0.47					
Serum bilirubin in total	BT	3.00	1.8	60	0.00	0.10	19	2.858	0.004	H. S
	AT	1.20			0.47					
Serum bilirubin in direct	BT	3.00	1.8	60	0.00	0.10	19	3.198	0.004	H. S
	AT	1.20			0.49					
Serum bilirubin in indirect	BT	3.00	1.7	56.33	0.00	0.10	19	2.858	0.01	S. S
	AT	1.30			0.47					
Urine bile salts	BT	1.00	0.45	45	0.00	0.10	19	2.858	0.01	S. S
	AT	0.55			0.47					
Urine bile pigments	BT	1.00	0.45	45	0.00	0.10	19	2.858	0.01	S. S
	AT	0.55			0.47					

Effect of therapy in Group B

In *Peetanetrata, Peetatvak, Peetamutrata, Peetavarchas* and *Peetanakha* the relief percentages observed were 63.33%, 54.23%, 60%, 56.89%, 41.66% in that order. In Hb% improved by 48.33%, serum bilirubin total subsided by 61.66%, the effect was statistically significant (P <0.002). In serum bilirubin direct, the percentage of relief was 86.66%, which was significant statistically (P< 0.004). In serum bilirubin indirect the relief observed was 60%, which were statistically significant (P<0.02). In the urine bile salts and urine bile pigments the relief percentage observed were 90% and 90% in that order (Table 3 & 4).

Table 3: Showing Individual study of the Subjective parameters in Group B.

Parameter		Mean		%	S.D	S.E	df	t value	p value	Remarks
Peeta Netrata	BT	3.00	1.9	63.33	0.00	0.09	19	2.853	0.007	H. S
	AT	1.10			0.47					
Peeta Tvak	BT	2.95	1.6	54.23	0.22	0.12	19	2.348	0.02	S. S
	AT	1.35			0.49					
Peeta Mutrata	BT	3.00	1.8	60	0.00	0.10	19	2.853	0.01	S. S
	AT	1.10			0.47					

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				%	S.D	S.E	df	t value	p value	Remarks
Peeta Varchas	BT	2.90	1.65	56.89	0.31	0.10	19	2.853	0.01	S. S
	AT	1.25			0.50					
Peeta Nakha	BT	3.00	1.25	41.66	0.00	0.11	19	3.948	0.009	H. S
	AT	1.75			0.51					

Table 4: Showing Individual study of the Objective parameters in Group B.

Parameter	Mean		%	S.D	S.E	df	t value	p value	Remarks
Hb%	BT	3.00	1.45	48.33	0.00	0.11	19	4.358	0.003	H. S
	AT	1.55			0.51					
Serum bilirubin in total	BT	3.00	1.85	61.66	0.00	0.11	19	3.559	0.002	H. S
	AT	1.15			0.50					
Serum bilirubin in direct	BT	3.00	1.7	56.66	0.00	0.10	19	3.198	0.004	H. S
	AT	1.30			0.49					
Serum bilirubin in indirect	BT	3.00	1.8	60	0.00	0.09	19	2.516	0.021	S. S
	AT	1.20			0.44					
Urine bile salts	BT	1.00	0.9	90	0.00	0.09	19	2.179	0.004	H. S
	AT	0.10			0.41					
Urine bile pigments	BT	1.00	0.9	90	0.00	0.09	19	2.516	0.004	H. S
	AT	0.10			0.44					

Inter group comparison

In a comparative study over criteria of assessment, statistically insignificant differences (P>0.05) was observed between the two drugs except in *Peetanakha* (P<0.01) on which the standard group showed 42.37% more relief than the trail group (Table no. 5). The effect of Ayurvedic treatment was found to be equivalent to the standard group of *Peetanetrata* in terms of statistically significance,

although the trail drug provided more relief in *Peetatvak* (54.23%), *Peetamutrata* (60%), *Peetavarchas* (56.89%), *Peetanakha* (41.66%), and In Hb% improved (48.33%), serum bilirubin total subsided by (61.66%), serum bilirubin direct (86.66%), serum bilirubin indirect (60%), urine bile salts and urine bile pigments the relief percentage observed were 90% and 90% in terms of relief percentages. The trail drugs provided more relief than standard drug.

After completion of the trail also, the results were sustained for a long time in trail group patients who came for follow up. No adverse effects of both the therapies came into light during or after the course of the trail.

Table 5: Comparative effect of treatment between the Group A & B after follow-up in Subjective parameters.

Parameter	Group	Mean	S.D	S.E	PSE	t-value	p-value	Remarks
Peeta Netrata	A	1.55	0.47	0.11	0.152	0.329	>0.05	NSS
	B	1.10	0.49	0.11				
Peeta Tvak	A	1.60	0.49	0.11	0.157	0.318	>0.05	NSS
	B	1.35	0.50	0.11				
Peeta Mutrata	A	1.75	0.47	0.11	0.149	0.000	>0.05	NSS
	B	1.20	0.47	0.11				
Peeta Varchas	A	1.60	0.49	0.11	0.157	0.318	>0.05	NSS
	B	1.25	0.50	0.11				
Peeta Nakha	A	1.70	0.49	0.11	0.158	0.632	>0.05	NSS
	B	1.75	0.51	0.11				

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Table 6: Comparative effect of treatment between the Group A & B after follow-up in Objective parameters.

Parameter	Group	Mean	S.D	S.E	PSE	t-value	p-value	Remarks
Hb%	A	2.45	0.47	0.11	0.156	1.285	>0.05	NSS
	B	1.55	0.51	0.11				
Serum Bilirubin Total	A	1.20	0.47	0.11	0.154	0.649	>0.05	NSS
	B	1.15	0.50	0.11				
Serum Bilirubin Direct	A	1.25	0.49	0.11	0.155	0.000	>0.05	NSS
	B	1.30	0.49	0.11				
Serum Bilirubin Indirect	A	1.30	0.47	0.11	0.145	0.345	>0.05	NSS
	B	1.20	0.44	0.11				
Urine Bile Salts	A	0.55	0.47	0.11	0.140	0.716	>0.05	NSS
	B	0.10	0.44	0.11				
Urine Bile Pigments	A	0.55	0.47	0.10	0.345	0.731	>0.05	NSS
	B	0.10	0.44	0.11				

DISCUSSION

In Ayurveda it was clearly mentioned that *Agnimandya* and *Pitta Vikruti* are the main causative factor for the *Kamala*, in this clinical study it was observed that patients showed *Agnivikruti*, in terms of *Pitta Vikruti.* Major literatures of Ayurveda explain the disease *Kamala* and its management. In *Charaka Samhita*, *Kamala* is mentioned as *Nidanarthakara Roga* of *Pandu*. The later author *Vagbhata* explained about *Swatantra Kamala* apart from the *Paratantra Kamala*,[11] which was explained by the *Charaka* and *Susruta*. However, the predominant *Dosha* in both *Swatantra* and *Paratantra Kamala* is the *Pitta Dosha*.

Dalhana, Susruta Samhita commentator, in his ideology on *Kamala* enrolled the term *Panaki* as a variety of *Kamala*.

The fundamental treatment method of *Samsodhana, Samshamana* and *Nidanaparivarjana* mentioned in Ayurvedic classics, if administered judiciously, the desired results can be achieved. In the present context, the re-validation of ancient Ayurvedic or traditional compound preparations Various *Shamana Yogas* are explained for *Kamala*; among them *Phalatrikadi Kwatha* and *Darvyadi Kwatha* was selected for the study to evaluate its action

Probable mode of action of *Phalatrikadi Kwatha* in *Kamala*

The pharmaco-dynamics in Ayurveda is mainly based on the fundamental doctrine of *Phanchamahabuta* and *Tridosha* theory, which govern the physico-chemical and biological phenomena respectively.

Phalatrikadi Yoga can reduce the symptoms as well as disease process due to the various actions of the individual drugs, in the mechanism and action is confined in the *Rasa, Guna, Veerya, Vipaka* and *Prabhava* of the individual drugs.

The *Veerya* as the potency of drug by which the action is carried out commentator *Chakrapani* explain that the *Veerya* is two types, *Chintyam* and *Achintyam*, *Chintayam*[12] which can be inferred and understood, *Achintyam* which is beyond the inference of human imagination. *Achintya Veerya* is known as the *Prabhava*, this special property which produces action in different forms ascribed audits of *Rasa, Guna, Veerya, Vipaka* and *Prabhava*.

All the drugs of *Phalatrikadi Yoga* have some similarities with respect to their *Rasa, Guna, Veerya* and *Vipaka*. All have *Katu, Tikta Rasa* and *Katu Vipaka* with respect to *Guna* it can observe that *Rooksha* and *Laghu* are common in these ingredients of the formulation.

Statement gives clear idea about *Karmukata* of the drugs which have a specific role to play in this disease.

The *Kamala* is one of the *Pitta* and *Raktaprodushaja Vyadhi* here *Pitta* is vitiated and the help of *Kashaya, Tikta* and *Madhura Rasa Pradhandravya* normalizes it,

and *Phalatrikadi Yoga* is best *Deepana, Amapachan, Pitta Prasaman* and *Srotovishodhan*. For management of *Kamala*, more single drug therapy and compound drugs have been explained in our classics, about the supremacy and relevancy of *Phalatrikadi Yoga* explained in text. These drugs are *Kamalahara* properties, and individual drugs *Katuki, Nimba, Guduchi* are also studied for their hepato protective properties and the result are encouraging.

Considering the above fact, the combination of the drugs given desired effect. *Kamala* was successfully, treated as *Phalatrikadi Yoga*. The medicine combination also showed the hepato-protective property.

Probable mode of action of *Darvyadi Kwatha* in *Kamala*

Darvyadi Kwatha can reduce the symptoms as well as disease process due to the various actions of the individual drugs, in the mechanism and action is confined in the *Rasa, Guna, Veerya, Vipaka* and *Prabhava* of the individual drugs. All the drugs of *Darvyadi Kwatha* have some similarities with respect to their *Rasa, Guna, Veerya* and *Vipaka*. All have *Katu, Tikta Rasa* and *Katuvipaka* with respect to *Guna* it can observed that *Rooksha* and *Laghu* are common in these ingredients of the formulation.

Statement gives clear idea about *Karmukata* of the drugs which have a specific role to play in this disease.

The *Kamala* is one of the *Pitta* and *Raktaprodushajavyadhi* here *Pitta* is vitiated and the help of *Kashaya, Tikta* and *Madhura Rasa Pradhandravya* normalizes it, and *Darvyadi Kwatha* is best *Deepana, Amapachan, Pitta Prasaman* and *Srotovishodhan*.

Considering the above fact, the combination of the drugs given desired effect. *Kamala* was successfully, treated by *Darvyadi Kwatha*. The medicine combination is also showed the hepato-protective property.

CONCLUSION

Kamala is characterised by the yellowish discoloration of sclera, skin, nails, and urine. It is a disease in which

Pitta Dosha effect over *Rakta* and *Mamsa Dhatu* leads to *Kamala*. *Kostashakhashrita Kamala* is manifested as a sequel *Pandu* and *Shakhastrita Kamala Vata* and *Kapha Dosha* and *Dushya Rasa, Rakta*, which obstructs the passage of *Pitta Varga*. The *Phalatrikadi Yoga* and *Darvyadi Kwatha* repairs the *Agnivikruti* and restores the *Agnivyapara*. The probable mode of action of *Phalatrikadi Yoga* and *Darvyadi Kwatha* acts as a *Deepaka, Pachaka* and *Pitta Shamaka, Anulomaka* along with *Kaphahara* quality.

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