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CLINICAL EVALUATION OF PHALATRIKĀDI KWĀTHA IN THE MANAGEMENT OF KOSHTHAŚĀKHĀŚRITA KĀMALĀ VIS-A-VIS HEPATOCELLULAR JAUNDICE

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ABSTRACT

The present study aims to evaluate the effect of *Phalatrikādi kwātha* in the management of *KoshthaśākhāśritaKāmalā* (hepatocellular jaundice) on the basis of various clinical and laboratorial parameters.

The clinical manifestations of *Koshthaśākhāśrita Kāmalā* are very much similar to that of hepatocellular jaundice. There are several causes of hepatocellular jaundice but viral hepatitis, alcoholic liver disease, drug-induced hepatitis are the common among them.

The trial drug *Phalatrikādi Kwātha*, consisting of eight herbal drugs (*āmalakī, harītakī, vibhītaka, guduci, kutakī, nimba, kirātatikta and vāsā*) is a very useful preparation indicated by *Śārangdhara* for the management of *Kāmalā Roga*.

All the 50 registered patients were assessed on clinical and laboratorial parameters to evaluate the effect of *Phalatrikādi kwātha* in the management of *Koshthaśākhāśrita Kāmalā.* Initially there was slow but steady clinical recovery but later on patients showed very fast recovery in clinical symptoms. Significant reduction in serum bilirubin, S.G.O.T, S.G.P.T, ALP and significant increase in Hb%, total serum protein, serum albumin justifies the curative effect of *phalatrikādi kwātha* in *Koshthaśākhāśrita Kāmalā.*

KEY WORDS: *Phalatrikādi Kwātha, Koshthaśākhāśrita Kāmalā, Hepatocellular Jaundice.*

INTRODUCTION

There are many diseases that can affect the liver, common among them are hepatitis, cirrhosis and alcohol induced liver diseases [1-3]. A common sign of impaired liver function is jaundice, a yellowness of the eyes and skin arise from excessive bilirubin in the blood.

The Ayurvedic texts give vivid description of disorders of the liver. The detailed description of Hetu, Samprāpti etc. is seen in samhita period where Kāmalā (jaundice)is described with Pāndu roga (anaemia). The very detailed description of Kāmalā is present in CharakaSamhita, SushrutaSamhita, AshtangHridya, Ashtang Samgraha etc [4-6].

Kāmalā, according to Ayurveda may be defined as a disease in which the color of the netra (eyes) and twak (skin) changes to deep yellow (hāridra-varna) along with the symptoms of aruci (loss of appetite) and daurbalya (weakness). In this disease, the patient passes hāridra (deep yellow) or rakta-pīta (reddish yellow) coloured urine. It is classified into two types, viz. koshthahāśrita kāmalā and śākhāśrita kāmalā [7]

Incidences of hepatocellular jaundice are increasing very rapidly. Twenty years ago, hepatitis A virus (HAV) and hepatitis B virus (HBV) were the only known etiological agents of viral hepatitis. Today, in addition to HAV and HBV, hepatitis C, D, E and G have also been identified and recognized as etiological agents of viral hepatitis, in which the infection is prolonged and sometimes lifelong. Alcoholism, which is a worldwide social and medical problem, is a leading cause of morbidity and mortality throughout the world8. Alcohol affects many organ systems of the body, but perhaps most notably affected are the central nervous system and liver. Almost all the ingested alcohol is metabolized in the liver and excessive alcohol use can lead to acute and chronic liver diseases.

As the treatment of jaundice is concerned, it is still a challenge before the modern medical science to treat this disease despite all the development and advancement in this system. There is no such curative and satisfactory treatment but only the symptomatic which has various hazardous side effects.

In Ayurvedic texts various preparations have been advocated for the treatment of kāmalā. In recent years also, researchers have confirmed that Ayurvedic preparation improve the liver function and treat the liver diseases. Many allopathic practitioners are also advocating Ayurvedic formulations since long for treatment of liver disorders.

The present research work has been undertaken with the following two main objectives.

1. Conceptual study on Kāmalā Roga vis-à-vis hepatocellular jaundice.
2. To evaluate the effect of Phalatrikādi Kwātha in the management of Koshthaśākhāśrita Kāmalā vis-à-vis hepatocellular jaundice.

MATERIALS AND METHODS

Following materials and methods were employed for this research work:

1. SELECTION OF PATIENT

Patients attending the OPD or admitted in the ward of Kayachikitsa Department of Ayurvedic and Unani Tibbia College and Hospital, were selected during 2004-2006, irrespective of sex, caste, and religion. The selection was made on the basis of proforma specially prepared according to the modern system of medicine for diagnosis of hepatocellular jaundice and signs and symptoms of Kāmalā described in various Ayurvedic texts.

(A) CRITERIA OF DIAGNOSIS: Koshthaśākhāśrita Kāmalāwas diagnosed on the basis of the presence of clinical features described in Ayurvedic texts mainly Charaka Samhita9. Hepatocellular jaundice was diagnosed on the basis of detailed history, clinical examination and laboratory investigations.

(B) CRITERIA OF EXCLUSION: Following patients of Kāmalā Roga were excluded from study:

1. Patients with haemolytic jaundice
2. Patients with obstructive jaundice.
3. Patients suffering from any other disease such as tuberculosis, leprosy, heart disease, epilepsy.
4. Patients of age less than 12 years.

5. Patients with cirrhosis of liver and ascites.

(C) CRITERIA OF DISCONTINUATION:

Those patients who did not report for regular follow-up were discontinued from the clinical trial. During the trial period if any other emergency developed in any patient, he/she was discontinued from the clinical trial.

2. SELECTION OF DRUG

Herbal preparation 'Phalatrikādi Kwātha' was selected for this clinical trial in the patients of Kāmalā. The drug Phalatrikādi Kwātha is a compound preparation of herbs, available in different Ayurvedic texts. The same drug selected for this clinical trial is mentioned by 'Śārangadhara', indicated for the treatment of 'pāndu and kāmalā Roga'[10],

1. Āmalakī (Emblica Officinalis)
2. Harītakī (Terminalia Chebula)
3. Vibhītaka(Terminalia belerica)
4. Amritā (Tinospora Cordifolia)
5. Kutakī (Picrorhiza Kurroa)
6. Nimba(Azadirachta indica)
7. Kirātatikta(Swertia Chirayita)
8. Vāsā(Adhatoda vasica)

PREPARATION OF PHALATRIKĀDI KWATHA

Dry Yavakuta (coarse) powder of 'Phalatrikādi Kwātha', supplied by the Hospital was given to the kāmalā patients and directed to prepare the kwātha as follows:

10 gm Yavakuta (coarse) powder was to be drenched in 160 ml of water for 2 to 3 hrs. This mixture was gradually boiled under medium heat till ¼th was left behind. Then this extract was filtered out through a clean cotton cloth and allowed to cool. Patients were directed to take freshly prepared Kwātha after meal twice daily in the dose of 40 ml with 1 TSF (approx. 5 ml) honey for consecutive 45 days.

3. CRITERIA OF ASSESSMENT

All the patients registered for clinical trial were screened for their demographic profile such as age, sex, religion, marital status, educational status, occupation, socio-economic status, etc.

During the clinical trial the patients were assessed on the following parameters:

(a) Clinical parameters
(b) Laboratory parameters

4. DURATION OF CLINICAL TRIAL

All the patients of Kāmalā were administered Phalatrikādi Kwātha for a period of 45 days. After every 15 days interval, all the patients were clinically examined and improvements in different symptoms were noted. The patients were asked to undergo laboratory investigation before and after the treatment.

Table No. 01: Showing the frequency distribution of patients according to their sign and symptoms before, during and at the end of clinical trial

S.No.	Symptom	Initial	After 15 days	After30 days	After 45 days
1.	Yellowish discoloration of eyes, skin nails and face	50	42	17	6
2.	Yellowish discoloration of urine	50	42	18	8
3.	Dāha (Burning sensation)	20	12	2	0
4.	Avipāka (Indigestion)	50	46	25	5
5.	Daurbalya (Weakness)	50	42	15	7
6.	Sadana (Malaise)	50	30	10	3
7.	Aruci (Anorexia)	50	40	12	2
8.	Trishnā (Thirst)	27	12	0	0
9.	Jvara (Fever)	34	18	2	0
10.	Śvāsa (Breathlessness)	40	32	8	3

11.	Yakrit Vriddhi (Hepatomegaly)	28	25	15	6
12.	Śveta-vacha (Clay-Coloured stool)	12	2	0	0
13.	Vishtambha (Constipation)	50	32	7	4
14.	Kandu (Itching)	16	4	0	0
15.	Chardi (Vomiting)	12	2	0	0
16.	Bhrama (Vertigo)	24	10	4	0
17.	Ātopa (Flatulance)	50	35	15	3
18.	Parva-śūla (Arthralgia)	22	15	8	4

Table No. 02: Showing the frequency distribution of patients according the grades of various signs and symptoms of Kāmalā

S. No.	Symtoms	Initially				After 15 days				After 30 days				After 45 days			
		Grade				Grade				Grade				Grade			
		3	2	1	0	3	2	1	0	3	2	1	0	3	2	1	0
1.	Yellowish discoloration of eyes, skin, nails, and face	32	15	3	0	12	16	14	8	0	5	12	33	0	0	6	44
2.	Yellowish discoloration of urine	30	16	4	0	7	15	20	8	0	6	12	32	0	0	8	42
3.	Dāha (Burning sensation)	3	9	8	30	0	5	7	38	0	0	2	48	0	0	0	50
4.	Avipāka (Indigestion)	25	15	10	0	10	26	10	4	0	10	15	25	0	1	4	45
5.	Daurbalya (Weakness)	18	22	10	0	13	17	12	8	0	5	10	35	0	3	4	43
6.	Sadana (Malaise)	32	18	0	0	15	7	8	20	0	2	8	40	0	0	3	47
7.	Aruci (Anorexia)	18	24	8	0	8	19	13	10	0	3	9	38	0	0	2	48
8.	Trishnā (Thirst)	0	9	18	23	0	3	9	38	0	0	0	50	0	0	0	50
9.	Jvara (Fever)	0	8	26	16	0	3	15	32	0	0	2	48	0	0	0	50
10.	Śvāsa (Breathlessness)	3	20	17	10	2	15	15	18	0	2	6	42	0	0	3	47
11.	Yakrit Vriddhi (Hepatomegaly)	3	9	16	22	2	8	15	25	0	5	10	35	0	2	4	44

12.	Śveta-vacha (Clay-Coloured stool)	2	6	4	38	0	2	0	48	0	0	0	50	0	0	0	50
13.	Vishtambha (Constipation)	10	26	14	0	0	7	25	18	0	2	5	43	0	2	2	46
14.	Kandu (Itching)	0	9	7	34	0	2	2	46	0	0	0	50	0	0	0	50
15.	Chardi (Vomiting)	0	4	8	38	0	0	2	48	0	0	0	50	0	0	0	50
16.	Bhrama (Vertigo)	0	9	15	26	0	3	7	40	0	0	4	46	0	0	0	50
17.	Ātopa (Flatulance)	24	18	8	0	8	10	17	15	1	6	8	35	0	2	1	47
18.	Parva-śūla (Arthralgia)	0	5	17	28	0	2	13	35	0	1	7	42	0	0	4	46

B. LABORATORIAL OBSERVATION

Table No. 03: Showing the statistical analysis of laboratorial observation

S.No.	Parameter	BT	AT	% Change	S.D.	t-Value	P-Value	Result
1.	Hemoglobin (gm%)	10.40	10.92	5.00	0.64	5.78	<0.001	H.S
2	TLC	7538	7708	2.25	430.7	2.78	<0.01	S
3.	ESR	22.62	19.74	12.73	7.22	2.82	<0.01	S
4.	Total Bilirubin	7.88	1.48	81.22	2.84	15.93	<0.001	H.S
5.	Direct Bilirubin	4.72	0.64	86.44	1.80	15.97	<0.001	H.S
6.	Indirect Bilirubin	3.16	0.84	73.41	1.54	10.64	<0.001	H.S
7.	SGOT	461.0	42.16	90.85	401.7	7.37	<0.001	H.S
8.	SGPT	457.8	40.38	91.18	408.4	7.22	<0.001	H.S
9.	ALP	341.3	171.5	49.75	197.2	6.07	<0.001	H.S
10.	Serum Albumin	3.63	4.09	12.67	0.65	5.05	<0.001	H.S
11.	Serum Globulin	2.68	2.83	5.59	0.46	2.46	<0.05	S

12.	Total Serum Protein	6.31	6.92	9.66	0.78	5.54	<0.001	H.S

S=Significant H.S= Highly Significant

OBSERVATIONS:

As described earlier all the 50 registered patients of Kāmalā were observed on three parameters:

1. Demographic Observations
2. Clinical observations
3. Laboratorial Observations

1. Demographic Observations: The demographic observation of 50 registered patients had shown more incidence of kāmalā in third decade (40%) and second decade (32%) of life. The incidence of kāmalā was more common in males (72%). According to religion, incidence of kāmalā was more common in Hindu religion (84%). This might be due to location of our hospital in Hindu dominated area. Incidence of kāmalā was more common urban areas (90%). This might be due to location of our hospital (located in urban area). Incidence of education did not reveal any significant pattern. According to occupation, most of them were labourers (30%). According to socio-economic status most of them belong to lower–middle class (56%). According to marital status, most of them were married (56%), according to dietary habits most of them were vegetarian (58%). In present series of patients 52% were addicted to smoking, 12% were addicted to pan (betel), 32% were addicted to alcohol, and 44% were addicted to tobacco. Majority of patients had mandāgni (70%) and krūra kostha (62%). Majority of patients had samyaka nidra (54%). Vāta-Pittaja Prakrati patients (56%) dominated the series. Madhyama sanhanan patients (56%) and madhyama satva patients (50%) and madhyama sātmya (52%) dominated the series. Avara type of āhāra-śakti (64%) and avara type of vyāyāma–śakti (58%) dominated the series.

2. Clinical Observations: Clinical observations of the 50 registered patients of Kāmalā Roga showed 100% presence of symptoms like yellow colour of eyes, skin, nails and face; yellow colour of urine, avipāka, daurbalya, sadana, aruci, vistambha, and ātopa. Śwāsa was present in 80% of patients. Yakrit-vriddhi was present in 56%, trishnā was present in 54%, jvara was present in 68% of patients. Other symptoms like dāha (40%), śveta-varcha (24%) kandu (32%), chardi (24%), bhrama (48%), parva śūla (44%) were also presents. Mostly the symptoms were related to the gastrointestinal involvement, specifically pertaining to Koshthaśākhāśrita Kāmalā, in association with the other generalized symptoms like jvara, kandu, sadana, daurbalya etc.

At every 15 days, assessment was made upto 45 days to observe the improvement in the signs and symptoms of kāmalā roga. It was observed that the action of the drug was slow during the initial phase of clinical trial but highly significant during the later phase. Symptoms like dāha, trishnā, jvara, śveta-varcha, kandu, chardi, bhrama showed 100% improvement. Symptoms like yellowish discolouration of eyes, skin, nails and face; yellowish discoloration of urine, avipāka, daurbalya, sadana, aruci, śwāsa, vishtambha and ātopa showed improvement from 90-98% while relief in yakrit-vridhi was 81.39% and relief in parvaśūla was 85.18%. Statistically the improvement in all the symptoms at the end of clinical trial was highly significant showing the effectiveness of the drug.

3. Laboratorial Observations:

Besides clinical observation, all the 50 registered patients were also observed on the basis of laboratorial parameters before and after clinical trial. Increase in hemoglobin level was highly significant. But change in ESR and TLC level was only significant. Changes in total serum bilirubin, direct serum bilirubin, indirect serum bilirubin, S.G.O.T, S.G.P.T. serum alkaline phosphates were highly significant. Change in serum globulin was only significant but changes in serum albumin and total serum protein were highly significant. Statistically overall change in the laboratorial parameters shows the effectiveness of the Phalatrikādi Kwatha.

CONCLUSION

On the basis of above data and results, it is proved that phalatrikādi Kwatha is very effective for the management of

Koshthaśākhāśritakāmalā. Phalatrikādi Kwātha not only causes the symptomatic improvement but also restores the normal liver function.

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