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A CLINICAL EVALUATION OF GOMUTRA HARITAKI IN THE MANAGEMENT OF BAHUPITTA KAMALA

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ABSTRACT

Introduction: *Bahupitta Kamala* is an independent disease mentioned in *Ayurveda*, showing conditions like jaundice or hyperbilirubinemia. Changes in food habits, obesity, alcohol and viral infection are the causes for *kamala*. A clinical trial was planned for the treatment of *Bahupitta kamala* using *Gomutra Haritaki vati* to evaluate the efficacy of *vati*. **Aim and Objective**: To evaluate efficacy of *Gomutra Haritaki vati* in the management of *Bahupitta kamala.* **Materials and Methodology**: A single blind randomized study was carried out on 30 patients of either sex of alcoholic and patients showing history viral hepatitis. *Gomutra Haritaki Vati* 250mg was given orally twice daily to the patients for 45 days and asked to take these between their meals. Strict necessary instructions regarding diet and activities were given. **Observations**: Marked improvement was observed in sign and symptoms of patients. **Conclusion**: The *Gomutra Haritaki vati* effectively managed the *Bahupitta kamala*.

Keywords: *Bahupitta kamala*, Jaundice, *Gomutra Haritaki Vati*

INTRODUCTION

Ayurveda (science of life) is one of the branches of *Vedas*. In *samhitas* it has been said that *tridosha- vata, pitta* and *kapha* are the main constituents of the body and when they get vitiated they cause the disease in our body. According to that one of the disease

described in the *samhitas* is *kamala* which is caused by vitiated *pitta dosha*. *Kamala* has been described along with *panduroga* (anemia) as a disease of *raktavah strotasa*[1] but has also described that *kamala* may occur without *panduroga*[2].

There are two types of kamala

1. *Rudhapatha/shakhashrita kamala*
2. *Bahupitta/koshtashakhashrita kamala*

Bahupitta kamala is caused by liver dysfunction. The main symptoms of *Bahupitta kamala* are yellowish color of eyes, skin, mucous, feces and urine. *Kamala* can be correlated with jaundice or hyperbilirubinemia in modern concepts. Hyperbilirubinemia is the condition where there is yellow appearance of skin resulting from an increased bilirubin concentration in the body fluids. The etiology behind the condition is over production of bilirubin and the causes are as following-

1. Increased bilirubin production e.g. heamolysis
2. Impaired excretion
3. Hepatocellular jaundice e.g. viral infection, alcohol, obesity, drug toxicity and pregnancy
4. Cholestasis

Amongst these viral and alcohol induced hepatocellular jaundice are the main problem in India hence these two are focused in the study. Bahupitta *Kamala* has various causes which have particular features and the causes cannot be distinguished only on the basis of the pathology. Ayurvedic medicines seems to be more effective for treating such conditions as they show less side effects, synergism and are easily available. In this study *Gomutra* and *Haritaki* was chosen for treatment[3]. Treatment is based upon basic principles like *rasa, virya, vipaka* and *guna* of the drugs. In the preparation of *gomutra haritaki, Terminalia chebula* fruits were main constituent along with *gomutra* (Cow's urine).

In Ayurvedic medicaments, *T. chebula* is an important plant, the fruits of plant are extensively used as an adjuvant to other medicines in various diseases. *T. chebula* shows prominent hepatoprotective activity which could be attributed to its anti oxidant and membrane stabilizing activity[4]. Chebulic acid is one of the major constituent of *T. chebula* which shows hepatoprotective activity. *T. chebula* fruit extract has high phenolic content and strong biological activities, including anticancer, anti-lipid peroxidation and anti-diabetic activities[5]. It has *lavanavarjit pancharasa, virya ushna, vipak madhur, guna laghu* and *ruksha, doshaghnata tridosha*[6].

Gomutra has been suggested for the treatment of various immunological, metabolic and other diseases. G*omutra* has *katu rasa, guna tikshaushna*[7]. It has various vitamins and minerals. Hence in accordance with this, *gomutra haritaki* was selected for the management of the *bahupitta kamala* condition.

MATERIALS AND METHODS:

Source of data: Patients were selected from OPD of Kayachikitsa dept., S.V.N.H. ayurveda college, Shrishivajinagar Dist. A. Nagar. The patients were registered and treated on OPD basis.

Study type: A single blind randomized study was carried out on patients of alcoholic and

viral hepatitis, which were selected after clinical and objective examination. Follow up assessment of every patient was done by specially prepared case record form. At each follow up signs and symptoms were recorded. The study was entirely based on clinical observation and lab investigation.

Sample size: Patients were selected who full filled the inclusion criteria. Only legally mature (i.e. age only above 18 years) patients were selected. Every patient was asked to sign the written voluntary consent in presence of doctor and local witness. 30 patients were accepted for the study and were observed and treated. On the 1st day all patients were given strict and necessary instructions regarding the diet and activity. All the patients were asked to stop all types of drug therapy and at fixed interval of period they were observed for a response.

Before conducting the clinical study, approval from the Institutional ethics committee was taken.

Diagnostic criterion: The diagnosis was based on the serological investigation i.e. serum bilirubin level > 2mg/dl

Inclusion criteria: The patients of either sex, within age group of 18-60 years with serum bilirubin level > 2mg/dl and <20mg/dl were included.

Exclusion criteria: Age below 18 and above 60 years, patients having malignancy, suffering from AIDS, patients with acute alcohol withdrawal state, intoxication, hepatic encephalopathy, serum bilirubin more than 20mg/dl, pregnant and lactating mother, psychotic patients, hyperbilirubinemia due to congenital causes, obstructive pathology, liver abscess, liver cirrhosis and HBsAg positive patients.

Drug material: *Gomutra Haritaki vati* was made from *haritaki churna* which was collected and authenticated. The main content of *haritaki churna* is *Terminalia chebula.* *Gomutra* was also collected and both the material were mixed together to be converted into *vati* by the process as described in classics[8]. 250mg of *haritaki churna* and 500 ml of *gomutra* were mixed together to form *vati* weighing 250mg.

Intervention: Patients were given *gomutra haritaki vati* of 250mg orally twice daily between their lunch and dinner (*madhyabhukta*) with water for duration of 45days. These patients were advised strict diet and activity i.e. *nidan parivarjana & pathya palana*.

Investigation: Specific investigations were done - Liver function test (LFTs) which includes serum bilirubin, SGOT (AST), SGPT (ALT). Urine analysis was done for bile salt and bile pigment. Serum alkaline phosphate was done at the start and at the end of the study. Other investigation like CBC, ESR was also done at the start and at the end of the study and HBsAg and HIV was done at the start of study. Stool examination was carried out.

Assessment Criteria: The patients of *kamala* were Assessed for the effect of *gomutra haritaki*, on the basis of lab methods such as LFTs Serum bilirubin, and urine & stool analysis for the presence or absence of bilirubin, on 0,21,45[th] day of the trial. Hemoglobin, W.B.C., ESR and alkaline

phosphate were performed and other symptoms were visually examined.

Statistical Methods: The data was collected on 0, 21 and 45th day and was assessed and interpreted by using paired 't' test.

OBSERVATION AND RESULT

Table 1: Table showing Age wise distribution of 30 patients

Sr. No.	Age Group	Total no. of patients	Percentage
1.	20-35yrs	15	50%
2.	36-45yrs	10	33.33%
3.	Above 46 yrs	5	16.67%

Table 2: Table showing Sex wise distribution of 30 patients

Sr. No.	Sex Group	Total no. of patients	Percentage
1.	Male	21	70%
2.	Female	9	30%

Table 3: Table showing Doshaja prakriti of 30 patients kamala

Sr. No.	Doshaja Prakriti	Total no. of patients	Percentage
1.	Vata Pittaja	18	60%
2.	Pitta Kaphaja	7	23.33%
3.	Kapha Vataja	5	16.67%

Table 4: Table showing Agni parikshan of 30 patients

Sr. No.	Agni	Total no. of patients	Percentage
1.	Tikshna	16	53.33%
2.	Vishamagni	7	23.33%
3.	Mandagni	7	23.33%

Table 5: Table showing Koshtha Parikshan of 30 patients of Kamala

Sr. No.	Koshtha	Total no. of patients	Percentage
1.	Krura Koshtha	10	33.33%
2.	Mridu koshtha	12	40%
3.	Madhyama	8	26.67%

Table 6: Table showing Vyasana of 30 patients

Sr. No.	Type of Vyasana	Total no. of patients	Percentage
1.	Alcohol+smoking+tobacco	17	56.67%
2.	Tobacco/Smoking	5	16.67%
3.	Tea/Coffee	4	13.33%
4.	Non-addict	4	13.33%

Table 7: Table showing Dominant rasa in Aahar of 30 patients

Sr. No.	Dominant Rasa in Aahar	Total no. of patients	Percentage
1.	Madhura	6	20%
2.	Amla	4	13.33%
3.	Lavan	4	13.33%
4.	Katu	15	50%
5.	Tikta	1	3.33%
6.	Kashaya	0	00%

Table 8: Table showing Economical status wise distribution of 30 patients

Sr. No.	Economical Status	Total no. of patients	Percentage
1.	Lower class	18	60%
2.	Middle class	12	40%
3.	High class	-	00%

Result: Subjective assessment-

Table 9: Effect of symptoms of *kamala* by paired't' test (Before Treatment-After Treatment)

No.	Symptoms		Mean	t value	p value
1	*Haridra netra*	B.T.	2.9	35.22	
		A.T.	0.1333		<0.0001
2	*Peeta twaka*	B.T.	2.233	13.57	
		A.T.	0.0667		<0.0001
3	*Peeta mutra*	B.T.	2.7667	22.91	
		A.T.	0.1667		<0.0001
4	*Avipaka*	B.T.	1.867	10.17	
		A.T.	0.1667		<0.0001
5	*Aruchi*	B.T.	2	10.91	
		A.T.	0.133		<0.0001
6	*Sadanam*	B.T.	1.7	9.898	
		A.T.	0.033		<0.0001
7	*Chhardi*	B.T.	1.3	6.9659	
		A.T.	0		<0.0001
8	*Jwar*	B.T.	1.7333	9.6849	
		A.T.	0.9609		<0.0001
9	*Udarshul*	B.T.	1.2667	7.346	
		A.T.	0.8919		<0.0001
10	*Daurbalya*	B.T.	1.633	12.33	
		A.T.	0.516		<0.0001
11	*Daha*	B.T.	0.5667	3.789	<0.005
		A.T.	0.6678		
12	*Yakritvriddhi*	B.T.	1.0667	4.86	
		A.T.	1.4436		<0.0001

Follow up of 45 days showed that there was significant relief in symptoms such as *haridra netra, peeta tvak, peeta mutrata, avipaka, aruchi, sadanam, Chhardi, jvara, udarshul, dourbalya, daha, and yakritvriddhi* which was checked on 7th, 14th 21th, 30th, 45th day[9].

From Table9, it was shown that t value for *haridra netra* was found to be 35.22 and also t value is much significant i.e. more than 10 were found for *peeta tvak, peeta mutrata, avipaka, aruchi and daurbalya* also for other symptoms it was more than 3. p value for *haridra netra, peeta tvak, peeta mutrata, avipaka, aruchi, sadanam, Chhardi, jvara, udarshul, dourbalya, and yakritvriddhi* was found to be $p<0.0001$ and for *daha* it was found to be $p<0.005$.
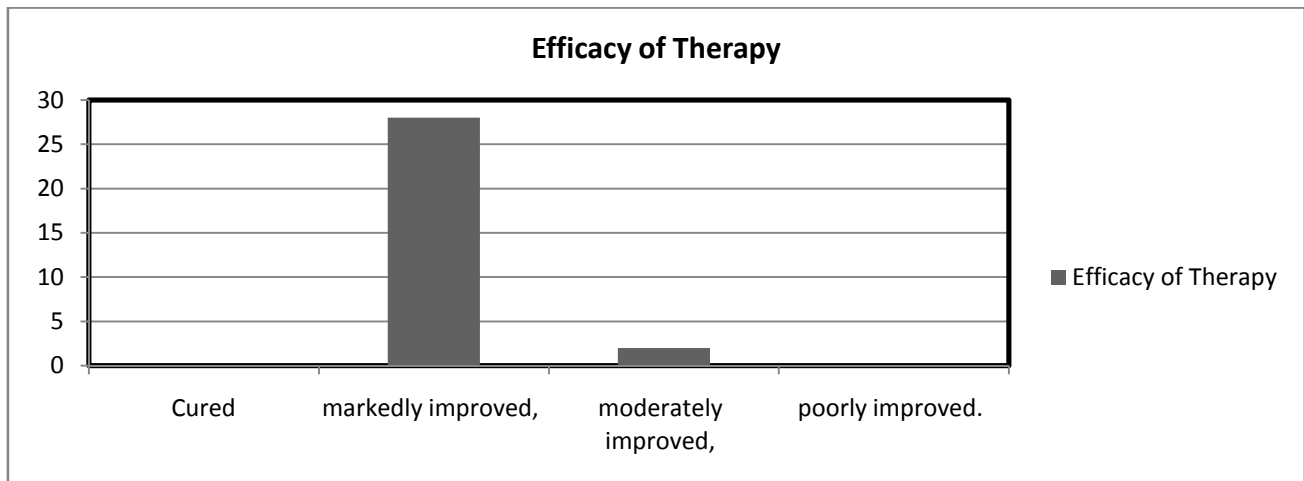
Objective Assessment-

Table10: Effect of therapy on investigatory parameters of *kamala* by paired 't' test

No.	Biochemical Test		Mean	t value	p value
1	Serum bilirubin (mg/dl)	B.T.	6.0433	16.37	<0.0001
		A.T.	0.9366		
2	SGOT (IU/L)	B.T.	192.26	4.8939	<0.0001
		A.T.	32.866		
3	SGPT (IU/L)	B.T.	209.23	5.1368	<0.0001
		A.T.	30.3		
4	Alkaline phosphate (IU/L)	B.T.	89.7	6.0759	<0.0001
		A.T.	84.3		
5	Hemoglobin (gm/dl)	B.T.	12.233	1.8645	<0.05
		A.T.	12.143		
6	WBC (cells/mcl)	B.T.	6495	0.9599	<0.05
		A.T.	6461.6		
7	ESR (mm/hr)	B.T.	16.3	0.4683	<0.05
		A.T.	16.133		

From Table10 it can be concluded that the treatment was effective in order to control effect of the condition. At the end of the therapy, level of serum bilirubin was significantly reduced. Also the results for SGOT, SGPT and alkaline phosphate were statistically very highly significant ($p<0.0001$). The changes in hemoglobin, WBC and ESR values were statistically insignificant ($p<0.05$) which can lead to say that the therapy primarily acted on the liver.

Percentage of the relief in subjective and objective assessment was observed statistically. According to that individual effect of therapy was also observed thus patients after 45 days of trial were divided into four groups- cured, markedly improved, moderately improved and poorly improved. Out of 30 patients, 28 were markedly improved and 2 were moderately improved.

DISCUSSION

Effect on clinical feature was shown by relief in symptoms by taking follow up of every 0,7,14,21,30,45 days. The drug therapy showed significant management of the disease condition. Relief in symptoms was due to *gomutra haritaki* which acted on *dushta pitta*, and helps in eradication of *rakta mansa dushti*. It also acted on *yakrita dushti* (Liver dysfunction) as *gomutra haritaki* having action on liver it regulates liver functioning thus helps in *samprapti bhanga* of *Bahupitta kamala*. As the *gomutra haritaki* having *mridu virechan* property it flushes *dushit pitta* through purgation.

Various biochemical markers which reflect the disease condition were measured. The therapy showed marked improvement in those markers which were also statistically significant.

Gomutra is having property *kashay, katu and tikta rasa and ushna virya* which helps in regulation of liver [10] From above trial it can be concluded that both *haritaki and gomutra*, hence act synergistically. *Gomutra haritaki* is of *tikta rasa. tikta rasa* is *agnideepak and aampachak* which improves *agni* status and hence *gomutra haritaki* helps into proper formation of *rasa dhatu*. *Gomutra haritaki* seems to regulate liver and helps it in normalizing bile secretion and also has hepatoprotective activity.

CONCLUSION

Bahupitta Kamala is one of the critical problem in the world because which trouble has been caused to patients and has to suffer a lot. This initial study is toddler step forward for further study to find satisfactory solution. Investigation using other drug therapy can be done as there are various hepatoprotective drugs mentioned in *ayurveda*. Also, other therapeutic uses of *gomutra haritaki* can be explored. Study concluded that the *gomutra haritaki* can play a vital role in the treatment of *Bahupitta kamala*.

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