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## Research Article

### A CONTROLLED CLINICAL STUDY ON THE EFFECT OF CERTAIN INDIGENOUS DRUGS IN SHAKHASHRITA KAMALA WITH SPECIAL REFERENCE TO VIRAL HEPATITIS-B

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#### ABSTRACT

Hepatitis-B is an infective disease predominantly affecting liver. Along with AIDS, which has been a major concern since 90's. Many of the Ayurvedic herbal medicines have been tried and have been proved to be effective in treating *Shakhashrita kamala*. The objective of the study was to see the effect of tablet Nirocil and indigenous drugs *Kashaya* in *Shakhashrita kamala* (Hepatitis-B) and to compare both of them. A Total of 26 patients, after considering the inclusion and exclusion criteria, having signs and symptoms of *Shakhashrita kamala* were included in the study and after diagnosing Hepatitis-B by elevated liver function tests and HBsAg (Elisa). Patients were assessed and scores were given with regards to the subjective parameters like *Peetata* of *netra*, *Peetata* of *Mootra*, *Peetata* of *Jihwa jala*, *Swethavarchas*, *Kandu* and objective parameters like total bilirubin, and HBsAg. All the subjective parameters are recorded and assessed on initial day, during and after treatment. Objective parameters are assessed before and after treatment. Out of 26 patients, 10 patients got completely cured, 8 patients got improvement and 8 patients got slight improvement. Overall assessment of the study revealed that, after treatment of 26 patients, there were 8 patients having HBsAg positive result and 18 patients were having HBsAg negative result which was highly significant. Both the groups showed significant positive in subjective parameters. Thus study revealed that indigenous drugs *Kashaya* has significant role to play in the management of *Shaksahashrita kamala*. To conclude, the study emphasized that indigenous drugs *Kashaya* has significant role to play in the management of *Shaksahashrita kamala*.

**KEYWORDS:** *Shaksahashrita kamala*, Hepatitis-B, Indigenous drugs, Nirocil.

#### INTRODUCTION

Acute Hepatitis-B infection is a generalized disease predominantly affecting liver. Along with AIDS, which has been a major concern since 90's, Hepatitis-B is the cause of global health hazard in the post 2000 era. Because of high HBV related morbidity and mortality, the global disease burden of HBV is substantial. Despite the invention of latest drugs and vaccines, the infectious stage, carrier stage and the complications arising due to HBV has not been controlled up to the desired expectation<sup>[1]</sup>. Hence the need for alternative system of medicine has now been recognized worldwide. Hepatitis-B is claimed to be 100-200 times more infectious than AIDS. It is estimated that around 2 billion people have serological evidence of past

or present HBV infection by WHO. At the same time about 350 million people have been infected by Hepatitis-B, roughly making around 5% of world population. In India, 34 million people are reactive to HBV, constituting 10% of entire HBV pool of the world. It is reported that 15-40% of HBV infected patients would develop cirrhosis, liver failure or Hepatocellular carcinoma. It is also estimated that about 5-12 lakh people die of HBV infection annually. Because of high HBV related morbidity and mortality, the global disease burden of HBV is substantial. Despite the invention of latest drugs and vaccines, the infectious stage, carrier stage and the complications arising due to HBV has not been controlled upto the desired expectation.

Hence the need for alternative system of medicine has now been recognized world wide.<sup>[2]</sup>

## MATERIALS AND METHODS

### Research Design

Total number of 26 patients excluding dropouts was divided into 2 groups, Group A and Group B, consisting of 13 patients in each group. The study was conducted at JSS Ayurveda college and Hospital. The study was conducted as a part of research and academic activity.

### Inclusion Criteria

- Patients of either sex , age group between 15-50 years
- Patients diagnosed as *Shakhashrita kamala* <sup>[3]</sup>/ Hepatocellular jaundice, confirmed by serological test for HBsAg (Elisa) and Liver function tests were included after obtaining informed consent.

### Exclusion Criteria

- HBsAg carrier (asymptomatic)
- Hepatitis B with complications , Drug induced hepatitis , Alcoholic hepatitis
- Patients with other systemic disorders were excluded, other variants of viral hepatitis were excluded.

### Diagnostic Criteria

- With clinical features of *shakhashrita kamala* with reference to Hepatitis-B.
- Elevated liver function test values and urine examinations.
- Laboratory evidence of HBsAg by Elisa method.

### Investigations

Urine - Bile salt, Bile pigment.

Haematological - Liver function test - HBsAg (Elisa Method)

### Study Design – Comparative Study

#### Intervention (Plan of Treatment)

#### Group A – Controlled Group

- *Amapachana* by *Trikatu choorna* 3 gm thrice daily with honey and lemon juice for 3 days before food
- After *Mala Ranjana, Sadhyosneha* by *Haridradi Gritha*, <sup>[3]</sup> according to *Kostha*
- *Mrudu Virechana* by *Trivruth lehya* with *Triphala Kwata*<sup>[3]</sup>, according to *Kostha*.
- *Shamanoushadhi* by Tab Nirocil – 1 gm – 2 thrice daily for 30 days

#### Group B – Test Group

- *Amapachana* by *Trikatu choorna* 3 gm thrice daily with honey and lemon juice for 3 days before food
- After *Mala Ranjana, Sadhyosneha* by *Haridradi Gritha*, according to *Kostha*
- *Mrudu Virechana* by *Trivruth Lehya* with *Triphala Kwata*, according to *Kostha*.
- *Shamanoushadhi* by *Kashaya* of indigenous drugs 15ml with hot water before food thrice daily for 30 day

#### Assessment Criteria

For the assessment of treatment, the following parameters were considered. They were graded and scores were given as follows.

**Table 1: Subjective Parameter**

Subject	Scales			
<i>Peetavarnata of Netra</i> (yellowishness of eye)	PN <sub>0</sub> (Nil) Normal	PN <sub>1</sub> Mild Lemon Yellow	PN <sub>2</sub> (Moderate) Turmeric Yellow	PN <sub>3</sub> (Severe) Dark Yellow
<i>Peetavarnata of mootra</i> (yellowishness of urine)	PM <sub>0</sub> (Nil) Normal	PM <sub>1</sub> Mild Lemon Yellow	PM <sub>2</sub> (Moderate) Turmeric Yellow	PM <sub>3</sub> (Severe) Dark Yellow
<i>Peetavarnata of jihwa tala</i> (yellowishness of tongue)	PJ <sub>0</sub> (Nil) Normal	PJ <sub>1</sub> Mild Lemon Yellow	PJ <sub>2</sub> (Moderate) Turmeric Yellow	PJ <sub>3</sub> (Severe) Dark Yellow
<i>Swethavarchas</i> (pale stool)	SW <sub>0</sub> (Present)		SW <sub>1</sub> (Absent)	
<i>Kandu</i> (itching)	Ka <sub>0</sub> (Present)		Ka <sub>1</sub> (Absent)	

#### Objective Parameters

- Liver function test
- HBsAg (Elisa)

#### Overall Assessment

##### Cure

HBsAg - Negative  
LFT value - Normal

Signs & symptoms completely - Relieved

### Improvement

HBsAg - Negative  
LFT value - nearly normal  
Signs & symptoms completely - Relieved

### Slight

### Improvement

HBsAg - Positive  
LFT value - nearly normal to normal  
Signs & symptoms completely - Relieved

### No Improvement

HBsAg - Positive  
LFT values - Unchanged

Persistent signs and symptoms

Assessment of the patients was made in the following intervals.

**For subjective parameters:** From 1<sup>st</sup> day followed by weekly assessment.

**For Objective parameters:** on 1<sup>st</sup> day and after 45 days of administration of *Shamanoushadhi*.

The data was collected and analysed the total score of before treatment, during treatment and after treatment was assessed by contingency co-efficient, descriptive statistics, Repeated measures ANOVA test. Analysis was considered by SPSS for windows (Statistical Presentation System Software) version 14.0 developed by SPSS, New York.

## Observation and results

### Observation

In majority of cases, 24 patients (92.5%) route of transmission was unknown and 1 patient (3.8%) transmission was by blood transfusion and by sexual contact. Among 26 patients, 46.2% had chronicity between 11-20 days, followed by 23.1% having chronicity between 21-30 days. All 26 patients had a complaint of *Peetata* of *netra*, *Mootra* and *Jihwa tala*. Followed by 14 patients (53.8%) having complaints of *Kandu* all over the body. 8 patients(30.1%) had complaint of *Swethavarchas*, 7 patients(26.9%) had signs of enlarged liver. It is observed that 11 patients had a bilirubin level ranging from 10-15 mg/dl, followed by 5 patients having range between 0-5 mg/dl, 4 patients having range between 15-20 mg/dl and 2 patients having range between 35-40 mg/dl

## Results

### Subjective Parameter

**Table 2: Showing the Results on *Peetavarnata* of *Netra* Group A**

	BT	1 <sup>st</sup>	2 <sup>nd</sup>	3 <sup>rd</sup>	4 <sup>th</sup>	5 <sup>th</sup>	6 <sup>th</sup>
Nil	0	0	4 (30.8%)	8 (61.5%)	10(76.9%)	13 (100%)	13 (100%)
Mild	2 (15.4%)	5 (38.5%)	6 (46.2%)	5 (38.5%)	3 (21.1%)	0	0
Moderate	6 (46.2%)	6 (46.2%)	3 (23.1%)	0	0	0	0
Severe	5 (38.5%)	2 (15.4%)	0	0	0	0	0

**Table 3: Showing the Results on *Peetavarnata* of *Netra* Group B**

	BT	1 <sup>st</sup>	2 <sup>nd</sup>	3 <sup>rd</sup>	4 <sup>th</sup>	5 <sup>th</sup>	6 <sup>th</sup>
Nil	0	1 (7.7%)	1 (7.7%)	3 (23.1%)	12(92.3%)	13(100%)	13(100%)
Mild	0	3(23.1%)	8(61.5%)	10(76.9%)	1(7.7%)	0	0
Moderate	7(53.8%)	7(53.8%)	4(30.8%)	0	0	0	0
Severe	6(46.2%)	2(15.4%)	0	0	0	0	0

Group A = P value - i.e., 0.000 HS; Group B = P value - i.e., 0.000 HS

**Table 4: Showing the Results on *Peetavarnata* of *Mootra* in Group A**

	BT	1 <sup>st</sup>	2 <sup>nd</sup>	3 <sup>rd</sup>	4 <sup>th</sup>	5 <sup>th</sup>	6 <sup>th</sup>
Nil	0	3(23.1%)	9(69.2%)	12(92.3%)	13(100%)	13(100%)	13(100%)
Mild	2(15.4%)	6(46.2%)	3(23.1%)	1(7.7%)	0	0	0
Moderate	4(30.8%)	2(15.4%)	1(7.7%)	0	0	0	0
Severe	7(53.8%)	2(15.4%)	0	0	0	0	0

**Table 5: Showing the Results on Peetavarnata of Mootra in Group B**

	BT	1 <sup>st</sup>	2 <sup>nd</sup>	3 <sup>rd</sup>	4 <sup>th</sup>	5 <sup>th</sup>	6 <sup>th</sup>
Nil	0	1(7.7%)	10(76.9%)	13(100%)	13(100%)	13(100%)	13(100%)
Mild	0	8(61.5%)	2(15.4%)	0	0	0	0
Moderate	2(15.4%)	3(23.1%)	1(7.7%)	0	0	0	0
Severe	11(84.6%)	1(7.7%)	0	0	0	0	0

Group A = P value – i.e., 0.000 HS; Group B = P value – i.e., 0.000 HS

**Table 6: Showing the Results on Peetavarnata of Swetha varchas Group A**

	BT	1 <sup>st</sup>	2 <sup>nd</sup>	3 <sup>rd</sup>	4 <sup>th</sup>	5 <sup>th</sup>	6 <sup>th</sup>
Absent	10(76.9%)	10(76.9%)	13(100%)	13(100%)	13(100%)	13(100%)	13(100%)
Present	3(23.1%)	3(23.1%)	0	0	0	0	0

**Table 7: Showing the Results on Peetavarnata of Swetha varchas Group B**

	BT	1 <sup>st</sup>	2 <sup>nd</sup>	3 <sup>rd</sup>	4 <sup>th</sup>	5 <sup>th</sup>	6 <sup>th</sup>
Absent	8(61.5%)	11(84.6%)	13(100%)	13(100%)	13(100%)	13(100%)	13(100%)
Present	5(38.5%)	2(15.4%)	0	0	0	0	0

Group A = P value – ie., 0.015 HS; Group B = P value – i.e., 0.001 HS

**OBJECTIVE PARAMETER**

**In Group A**

There was a decrease of 11.36 mg/dl of total bilirubin after the treatment and which showed statistically significant, was a decrease of 411.5 iu/dl of SGOT after the treatment, there was a decrease of 383.81 iu/dl of SGPT after treatment, out of 13 patients, 6 patients were having HBsAg positive result and 7 patients were having HBsAg negative result after treatment.

There was a decrease of 15.22 mg/dl of total bilirubin after the treatment and which showed highly significant result, there was a decrease of 701.71 iu/dl of SGOT after treatment, in Group B there was a decrease of 672.11 iu/dl of SGPT values after treatment. Out of 13 patients 2 patients were having HBsAg positive result and 11 patients were having HBsAg negative result after treatment. The results showed highly significance result.

**Table 8: Showing the result on HBsAg in Group B**

	Pre		Post	
	Positive	Negative	Positive	Negative
Group A	13	0	6	7
Group B	13	0	2	11

P values – Group A = 0.002-HS P value – Group B =0.000 – HS

**Table 9: Showing the Overall Assessment**

	Group A	Group B	Total
Cured	4 (30.8%)	6 (46.2%)	10 (38.5%)
Improvement	3 (23.1%)	5 (38.5%)	8 (30.8%)
Slight improvement	6 (46.2%)	2 (15.4%)	8 (30.8%)
No improvement	0	0	0
P value = 0.235, NS			

In Group A, 4 patients got completely cured, 3 patients got improvement, 6 patients got slight improvement. In Group B, 6 patients got completely cured, 5 patients got improvement and 2 patients got slight improvement.

**DISCUSSION ON RESULTS**

Statistically, results showed significant difference between Groups A & Group B. But they were highly significant result within the groups. When comparison was done before and after treatment, there were few insignificant and statistically significant results between the groups. There was also a difference in overall improvement which was not significant

statistically. Group A and Group B showed significant results in both subjective and objective parameters.

#### On subjective parameters

During assessment of *Peetata* of *Netra* reduction was found after 5<sup>th</sup> week of treatment in both group A and B which showed highly significant results. Because the drugs used were hepatoprotective, and choleric effect which helped in normal bilirubin metabolism. Similarly in assessment of *Peetata* of *Mootra* reduction was noted during 4<sup>th</sup> week of treatment in both the groups A and B. Because the drugs had *Mutrala* property significant results was achieved. At the same time *Peetata* of *Jihwa tala* showed reduction during 4<sup>th</sup> week of treatment. *Swethavarchas* showed a decrease during 2<sup>nd</sup> week of treatment in both groups A and B. Due to the action of the *Dravyas*, obstruction was relieved and highly significant results were observed.

#### On Objective Parameters

The levels of total bilirubin, SGOT and SGPT showing raised values changed to border line to normal levels after the study period of 45 days. The result indicated highly significant P value < 0.001 was observed within the groups. But N P > 0.005 changes was observed in between the groups. The results of HBsAg, group B showed highly significant result compared to group A. The reason of which can be positively interpreted that Group B had a combination of 5 indigenous drugs where as in Group A it was a single drug. So positive result was observed and also all the indigenous drugs were having antiviral and immunomodulator activity which helped in fast relief of signs and symptoms and even LFT values. Overall a highly significant result was observed because of the multi action of the indigenous drugs on hepatic cells. In persistent positive cases a total of 30.1% remained seropositive for HBsAg even after the completion of 45 days of treatment. Only for these patients medicines were continued even after the treatment period, out of which 26.9% became seronegative within 15-30 days.

#### Criteria for Selection of Indigenous Drug *Kwath*

The ingredients are *Daruharidra*, *Katuki*, *Kasani*, *Erandas*, *Rohitaka*, *Sharapunkha*<sup>[4],[5],[6]</sup> These drugs were selected on the basis of their indication in *kamala* and *Yakrit vikara*<sup>[3],[4]</sup> The

majority of drugs have properties of *Shothahara*, *Yakrith uttejaka* hepatoprotective, immunomodular, and hepatic cell regenerator.<sup>[3],[7]</sup> However, the drugs were tried once on laboratory animals. At the same time it was found out that these drugs are hepatoprotective in general but not specifically on Hepatitis-B. Majority of these 6 drugs were formulations advised in *Kamala*.<sup>[3],[6]</sup> Hence, keeping all these points in mind, this study is undertaken to evaluate the efficacy of 6 drugs in combination.

#### CONCLUSION

Many of the Ayurvedic herbal medicines have been tried and have been proved to be effective in treating *Shakhashrita kamala*. Still there was no effective and specific medicine for treating Hepatitis-B. The objective of the study was to see the effect of tablet Nirocil and indigenous drugs *Kashaya* in *Shakhashrita kamala* viz., Hepatitis-B, and to compare both of them. Total of 26 patients, after considering the inclusion and exclusion criteria, having signs and symptoms of *Shakhashrita kamala* viz., Hepatitis-B were included in the study and after diagnosing Hepatitis-B by elevated liver function test and HBsAg (Elisa). Patients were assessed and scores were given with regards to the subjective parameters like *Peetata* of *Netra*, *Peetata* of *Mootra*, *Peetata* of *Jihwa jala*, *Swethavarchas*, *Kandu*. Objective parameters like total bilirubin, SGOT, SGPT and HBsAg. All these subjective parameters were recorded and assessed on initial day, during and after treatment. objective parameters are assessed before and after treatment. Overall assessment showed symptomatic cure and improvement in most of the cases of both the groups. Out of 26 patients, 38.5% got completely cured and 30.8% got improvement and 30.8% got slight improvement. Both the groups showed significant result in subjective parameters. Group B showed highly significant result in sero conversion of HBsAg when compared to group A. There was no difference in the results between two groups. In comparison, general observation and individual results of indigenous drugs *Kashaya* proved it to be more beneficial in reducing the symptoms and in sero conversion of HBsAg. A elaborative scrutiny is needed in finding out HBsAg positively in patients coming with symptoms of jaundice / hepato cellular. Laboratory investigations played a major role in diagnosing and treating the disease with clinical findings playing a secondary role. The probable

mode of action of indigenous drugs can be inferred as hepatoprotective, immunomodulator, choleric effect and antiviral agent. In the present study patients of group B showed a highly significant results compared to group A. Thus *Kashaya* prepared out of indigenous drugs proved to be beneficial. Thus study revealed that indigenous drugs *Kashaya* has significant role to play in the management of *Shakhashrita kamala* viz Viral Hepatitis-B.

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