IAMJ

INTERNATIONAL
AYURVEDIC
MEDICAL JOURNAL

Research Article ISSN: 2320-5091 Impact Factor: 6.719

CLINICAL EVALUATION OF BHUMYAMALAKI GHANA VATI IN THE MANAGEMENT OF KAMALA WITH SPECIAL REFERENCE TO HEPATITIS B

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https://doi.org/10.46607/iamj0209052021

(Published Online: May 2021)

Open Access

Article Received: 08/04/2021 - **Peer Reviewed:** 05/05/2021 - **Accepted for Publication:** 12/05/2021

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ABSTRACT

Kamala is *a Pittaja Nanatmaja Vyadi* and *Rakta Pradoshaja Vyadi*. The main *Dusya* is *Rakta*, at the same time it is *Pitta* predominant disease. In the present era, *Rakta Dhatu* (blood) is given utmost importance as the diseases pertaining to *Rakta* is more in incidence. *Ayurveda,* an ancient system of medicine has historically been highly proficient and has been treating liver disorders for centuries and drug toxicity tends to be lower than the conventional medicine. The drug *Bhumyamalaki* (Phyllanthus Niruri) is explained in *Bhava Prakash Nighantu* under *Guduchyaidi Varga* for the treatment of *Kamala. Bhumyamalaki* (Phyllanthus Niruri) is a well-known drug in *Ayurveda* for *Kamala* (Hepatitis B). The need for this research is to find out safer, potent, cost-effective treatment and also to inhibit potential long-term effects like Cirrhosis, Hepatocellular Carcinoma, transplantation and death. **Aims:** To access the efficacy of Phyllanthus Niruri herb through clinical and biochemical parameters; to provide quality of life to patients of Hepatitis B and to access side effect profile. **Materials/ Methods:** Selection of Cases: All the patients are selected from the OPD of GMC, Department of Gastroenterology. **Study Design:** Total No. of patients selected for the study are 40 and are divided into 2 groups (20 patients each): I & II. Group I received Tablet Entecavir 0.5 mg/day alone whereas other group II received Tablet Phyllanthus Niruri 3gm/day in divided doses as an add on therapy along with Tablet Entecavir 0.5mg/day. Duration of study: **60 days. Results**: It is suggested that Phyllanthus Niruri possess hepato protective, anti–viral and antioxidant properties due to novel bioactive compounds. It also has the ability to reduce viral load in HBV infection. **Conclusion**: This study suggests that there

is strong pharmacological potential in developing Phyllanthus Niruri as a drug to be used in liver disorders and as an anti-viral drug. The subjective and objective observations were evaluated statistically using "t test". The results that both these drugs are effective in HBV but Phyllanthus Niruri was a little more effective statistically.

Keywords: *Kamala*, Hepatitis B, Phyllanthus Niruri, Hepato protective activity.

INTRODUCTION

Hepatitis B is caused by Hepatitis B virus (HBV), an enveloped virus containing a partially double stranded, circular DNA genome & classified with the family Hepadna virus[1]. It is estimated that 2 billion people worldwide have been infected by HBV. Of these, approximately 360 million individuals are chronically infected & at risk of serious illness & death, mainly from liver cirrhosis & hepatocellular carcinoma[2]. At least 15 to 20 % of chronically HBV infected people will die due to liver disease caused by HBV and this constitutes nearly one million people each year[3]. The WHO estimates that about 90% of HBV –related deaths are associated with chronic HBV infection (70% from hepatocellular carcinoma with or without cirrhosis & 20% from cirrhosis). While less than 10% are associated with acute infection[4].

It is the most common cause of chronic liver disease, including cirrhosis of the liver & hepatocellular carcinoma worldwide. More than 780000 people die every year due to complications of Hepatitis B, including cirrhosis and liver cancer[5].

HBV infection is transmitted by blood, blood products, sexual intercourse, etc. Incubation period is 30-180 days. The presentation of chronic HBV infection has become a high priority in the global community.

Immunization with Hepatitis B vaccine is the single most effective means of preventing HBV infection and its consequences.

Ayurveda, an ancient system of medicine is still very popular in treating majority of chronic diseases with great efficacy and low or negligible side effects. *Bhumyamalaki Ghan Vati (Phyllanthus Niruri*) has shown to block DNA polymerase, which is the enzyme needed for the Hepatitis B virus to reproduce.

Phyllanthus is having *Tikta, Kashaya* and *Madhura Rasa*. It is also having the qualities like *Sheeta Virya*, *Madhura Vipaka*, *Laghu* and *Ruksha Guna*. Due to these qualities it pacifies the *Kamala Roga*[6].

Chemical Constituents

Phyllanthus Niruri [7]

Phyllanthin:- C24H34O6 Mol. Wt. 418.53 ,Hypophyllanthin:- C24H30O7 Mol. Wt. 430.49 Niranthin, Nirtetralin, Phyltetralin, Lintetratin, Phyllnirurin, Hirphyllin.

Phytochemistry:-

The major lignans Phyllanthin and Hypophyllanthin has been reported to exhibit antihepatotoxic activity.

Major: Lignans - a diarylbutane, Phyllanthin (~0.5%) and an aryl tetra hydronaphthalene, hypophyllanthin[8] (~0.2%).

Minor: Hydrolysable tannins viz., phyllanthusiin D3, amariin4, amarulone5 and amarinic acid6; alkaloids viz., norsecurinine7 sobubbialine, epibubbialine8; diarylbutane, nyrphyllin6 and a neolignan, phyllnirurin [9].

Ayurvedic Pharmacodynamic Properties [10]:-

Rasa –Tikta, *Kashaya* and *Madhura*
Guna –Laghu, ruksha
Virya –Shita
Vipaka –Madhura
Doshakarma – KaphaPitta Shamaka

Aim and Objectives

1. To assess the efficacy of Phyllanthus Niruri herb through Clinical parameters.
2. To assess the efficacy of the herb through biochemical parameters.
3. To provide quality of life to patients of Hepatitis B.
4. To assess the side effect profile of this herb.

Ethical Clearance: -

The proposed clinical study was approved by Institutional Ethical Committee of Government Medical College, Jammu before beginning the clinical trial.

Ethical Clearance Certificate ref. no. IEC/2016/241.

Material and Method

- **Selection of Case: -**
- All the patients were selected from the OPD of Government Medical, College [GMC], Department of Gastroenterology.
- Blood pressure, Pulse, Temperature, Weight of a patient was measured at the time of examination.
- A voluntarily consent form duly signed by a patient was taken before beginning treatment.

Inclusion Criteria: -

- All patients eligible for Hepatitis B treatment are considered for the study.

Exclusion Criteria: -

- Patients having Hepatitis A, C, D, E.
- Immunocompromised patients.
- Patient having Left ventricle failure.
- Patient having diabetes mellitus/ associated with complications.
- In pregnancy or lactating mother.

Laboratory parameters:-

a]. HBsAg., ALT,

b]. Serum bilirubin ALP.

c]. HBeAg d].HBV DNA

Study Methodology

Trial Group: Total 40 patients were selected for the present study that fulfilled the criteria of inclusion and gave consent for the trial. All the selected patients were studied randomly under two groups and the drug was given to all the patients in the dose and formulation stated ahead.

Table 1: Dosage of drugs in 2 different groups.

Group-I: *Tab. Entecavir - 0.5 mg/day*
Group-II: *Tab. Entecavir -0.5 mg/day**;** Phyllanthus Niruri -2 Tablets TDS after meals*.

Duration of trial:- 60 Days

Follow up

- 1 follow up after 30 days interval during trial.
- 1 follow up after 15 days after completion of trial.

Criteria of Assessment

Subjective Criteria:

***Haridra Netra* (Yellowish discolouration of eyes)**

***Haridra Twacha* (Yellowish skin)**

***Haridra Nakha* (Yellowish nails)**

***Haridra Mukha*: (Yellow discoloration of face and mucous membrane)**

***Haridra* Mutra (Yellow discoloration of urine)**

***Daha* (Burning sensation)**

***Avipaka* (Indigestion)**

***Daurbalya* (Weakness)**

- *Sadana* (Lethargy)
- *Aruchi* (Loss of appetite)
- *Jwara* (Pyrexia)

Objective Criteria

Feature	Grade 0	Grade 1	Grade 2	Grade 3
ALT	<35U/lt	36-100U/lt	101-500U/lt.	>500U/lt.
AST	<35U/lt.	36-90U/lt	91-350U/lt	>350U/lt.
ALP	<150IU/lt.	151-230IU/lt.	231-900IU/lt.	>900IU/lt
Bilirubin	<1.0mg/dl	1-1.5mg/dl	1.5-2.5mg/dl	>2.5mg/dl

Final assessment of Results:

The obtained data was analysed statistically and expressed in terms of mean score before treatment (BT), after treatment (AT), difference of mean (BT-AT), Standard deviation (SD) and Standard error (SE). Students paired 't' test was applied at $p>0.05$, $p< 0.05$, $p<0.01$ and $p<0.001$, to observe significance of results obtained after treatment. The results were considered significant or insignificant depending upon the value of p.

- Insignificant - $p > 0.05$
- Significant - $p < 0.05$ and $p < 0.01$
- Highly significant - $p < 0.001$

Overall percentage improvement of each patient was calculated by the following formula:

Total BT-Total AT Total BT

The result thus obtained from individual patient was categorized according to the following grades:

Assessment of Improvement: -

a. Complete relief -

- Complete relief in the initial chief complaints of the patient.
- Normalization of the Liver function tests.
- 76-100% decrease in the viral load assessed by measuring HBV- DNA.

B.	**Moderate Relief -** Moderate Relief In Initial Chief Complaints. Moderate Improvement In The Liver Function Tests.
	51-75% Decrease In Hbv- Dna.
C.	**Mild Relief -**
	Mild Relief In Initial Chief Complaints. Mild Improvement In The Liver Function Tests.
	26-50% Decrease In The Hbv -Dna .
D.	**No Relief -**
	No Relief In Initial Chief Complaints.
	No Improvement In The Liver Function Tests.
	0-25% Decrease In The Viral Hbv-Dna.

Statistical Analysis: The obtained data was analyzed statistically and expressed in terms of Mean, Standard deviation (±SD) and Standard error (±SE). Appropriate 't' test was applied to observe the significance of results obtained after treatment.

Table 2: Associated Symptoms Wise Distribution.

Symptoms	No. of patients		Total	Percentage
	Group- I	Group-II		
Haridra Netra	4	5	9	22.5%
Haridra Twacha	2	3	5	12.5%
Haridra Nakha	0	1	1	2.5%
Haridra Mukha	0	1	1	2.5%
Urine	5	8	13	32.5%
Avipaka	11	13	24	60%
Daurbalya	9	12	21	52.5%
Sadana	6	9	15	37.5%
Aruchi	6	5	11	27.5%
Jwara	2	3	5	12.5%

Table 3: Statistical Analysis Showing Effect of Therapy on Clinical features in Group-I

Sign Symptom	Mean Score		Mean Diff.	S.D	S.E±	't'	P
	BT	AT					
Haridra Netra	0.75	0	0.75	0.8506	0.1902	3.943	<.001
Haridra Twacha	0.4	0	0.4	0.882	0.197	2.028	<.05
Haridra Nakha	0.15	0	0.15	0.923	0.206	1.453	>.05
Haridra Mukha	0	0	0.3	0.8013	0.179	1.674	>.05
Urine	0.8	0	0.8	1.019	0.227	3.291	<.01
Daha	0.5	0	0.5	1.450	0.324	1.542	>.05
Avipaka	0.6	0.5	0.1	0.3077	0.0688	1.453	>.05
Daurbalya	0.5	0	0.5	0.229	0.051	9.764	<.001
Sadana	0.35	0	0.35	0.488	0.109	3.202	<0.001
Aruchi	0.75	0	0.75	0.966	0.216	3.472	<.001
Jwara	0.35	0	0.35	0.744	0.166	2.103	<.005

Table 4: Statistical Analysis Showing Effect of Therapy on Clinical features in Group-II

Sign Symptom	Mean Score		Mean Diff.	S.D	S.E±	't'	p
	BT	A					
Haridra Netra	0.95	0	0.95	0.614	0.137	5.82	<0.001
Haridra Twacha	0.4	0	0.4	0.8012	0.179	1.67	>.05
Haridra Nakha	0.1	0	0.1	0.447	0.100	1.0004	>0.1
Haridra Mukha	0.45	0	0.45	0.825	0.184	2.439	<0.05
Urine	0.95	0	0.95	0.825	0.184	5.149	<0.001
Daha	0.55	0	0.55	0.251	0.0561	10.690	<0.001
Avipaka	0.55	0	0.55	0.5103	0.114	4.819	<0.001
Daurbalya	0.7	0	0.7	0.801	0.179	3.908	<0.001
Sadana	0.55	0	0.55	0.886	0.198	2.77	<0.01
Aruchi	0.8	0	0.8	0.695	0.155	5.147	<0.001
Jwara	0.25	0	0.25	0.550	0.123	2.032	<0.05

Table 5: Comparison of Overall Effect of Therapy in Both Groups (40patients)

Results	Group I (n=20)		Group II(n=20)	
	No. of Patients	% age	No. of Patients	% age
Cured	15	75%	20	100
Moderately Improved	4	20%	0	0%
Mildly Improved	1	5%	0	0%
Not Improved	0	0%	0	0%

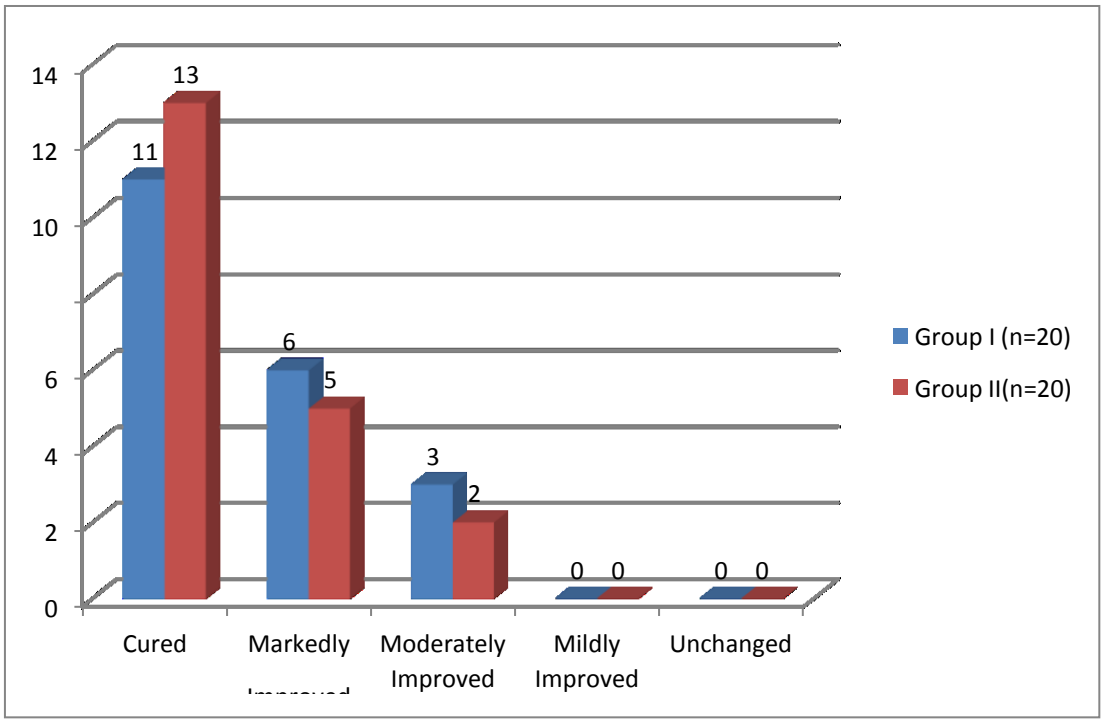

Figure 1: Comparison of Overall Effect of Therapy in Both Groups (40 patients).

Table 6: Comparison of Overall Effect of Therapy on HBV DNA in Both Groups (40 patients)

Group 1	DNA			Group 2			
BT	AT	Reduce	% Reduction	BT	AT	Reduce	% Reduction
110	0	110	100.00	6	0	6	100.00000
1200	0	1200	100.00	23444	0	23444	100.00000
12000	69	11931	99.43	6	0	6	100.00000
14000	219	13781	98.44	170000000	1269	169998731	99.99925
16000	400	15600	97.50	750000	12	749988	99.99840
12000	500	11500	95.83	230000000	5000	229995000	99.99783
17000	839	16161	95.06	109000	5	108995	99.99541
15362	1220	14142	92.06	4500000	679	4499321	99.98491
35000	2900	32100	91.71	8900000	1347	8898653	99.98487
12000	1500	10500	87.50	3700000	775	3699225	99.97905
15000	2000	13000	86.67	9000000	2350	8997650	99.97389
17000	2500	14500	85.29	1500000	869	1499131	99.94207
290000	51000	239000	82.41	12000000	9000	11991000	99.92500
13000	2500	10500	80.77	8500000	6450	8493550	99.92412
35000	7000	28000	80.00	3600000	2950	3597050	99.91806
45000	12000	33000	73.33	350000	470	349530	99.86571
45000	13569	31431	69.85	9600000	14960	9585040	99.84417
985000	412500	572500	58.12	14000	41	13959	99.70714
900000	400000	500000	55.56	5000000	15291	4984709	99.69418
135000	90000	45000	33.33	6000000	30000	5970000	99.50000
Out of 20 pts				Out of 20 pts			

Adverse Effect

No adverse effect of *Bhumyamalaki Ghana Vati* was reported during the entire period of research trial and at the same time there was not any increase in the levels of liver enzymes. The drug had shown dramatic decline in the levels of liver enzymes as well as on HBV-DNA.

DISCUSSION

In this study most of the patients belong to the age group of 20-45 years of age. Maximum number of patients belong to *Vata-Pittaja Prakriti* followed by *Pitta Kaphaja*. It is seen that people who are having low or poor educational qualification suffer from this disease more. *Daurbalya* (weakness) is a most important symptom that is seen independently or associated with abdominal pain or arthralgia. It is usually seen in all those patients who are not showing acute signs and symptoms of Hepatitis B and are rather asymptomatic. *Sadana* (lethargy) is found in moderate number of patients as it is associated with *Daurbalya* (weakness) in patients having high viral load. Fever is seen in acute stage only and is associated with yellowish discolouration of sclera and yellow coloured urine.

In the Controlled group or Group I, among the total number of patients there was 100% relief in *Haridra Netra*, *Haridra Twaka*, *Haridra Nakha* and *Mukha Laxanas*. At the same time there was also 100% relief in yellow coloured urine and *Daha*. But there was 16% relief in *Avipaka* (indigestion). On the other hand, Group II had shown 100% relief in all the above said *Laxanas*. Objective criteria of Controlled group show the following results-

There was 60.73% relief in serum bilirubin, 72.2% relief in AST, 64.4% relief in ALT, 24.9% relief in ALP, 62.2% relief in HBsAG, and 61.5% relief in HBV DNA. Objective Criteria of Add on Treatment Group shows-

There was 72.66% relief in serum bilirubin levels,54.4% relief in AST, 59.2% relief in ALT, 39.6% relief in ALP, 95.5% relief in HBsAG, 45.2% relief in HBeAG, 99.99% relief in HBV DNA.

CONCLUSION

From the above data it can be analysed that *Bhumyamalaki* carries the ability to decrease the viral load, mildly decreases HBeAG levels and to large extent helps in the normalisation of liver enzymes. Moreover, in the above trail period it is noted that the non-specific symptoms like dull right upper abdominal pain, athralgias respond well to *Bhumyamalaki*. The drug remained nontoxic during the entire period of duration of course. All the patients tolerated it well. To analyse the exact role of ***Bhumyamalaki Vati*** on the various parameters like HBsAG, HBeAG, HBV DNA we still need a further and multiple studies of having 200 - 300 patients using the different Phyllanthus species so that we can compare the efficacy of this herb on various bio chemical parameters and can also report undesirable side effects. As per as this study is concerned it is strongly believed that *Bhumyamalaki* is the future drug for Hepatitis B infection as it is hepato protective, reduces the HBV DNA and also reduces the oxidative stress on liver due to various toxins.

REFERENCES

1. a).Ganem D, Schneider RJ. Hepadnaviridae: The viruses and Their replication.In:Knipe DM et al, eds. Field virology,4th ed. Philadelpia, Lippincott Williams and wilkins, 2001:2923-2969.
   b). Hollinger FB, Liang TJ, Hepatitis B virus. In. Knipe DM et al, eds. Field virology,4th ed. Philadelpia, Lippincott Williams and wilkins, 2001: 2971- 3036.
2. Goldstein ST et al. A mathematical model to estimate global Hepatitis B disease burden and vaccination impact. International Journal of Epidemiology, 2005,34:1329-1339.
3. Hepatitis B Foundation. Doylestown, PA. Available from http://www.hepb.org/.
4. WHO. Western Pacific Regional Plan for Hepatitis B control through immunization; December 2007.Manila, Philippines.
5. Lazano R, Naghavi M, Foreman K, Lim S, Shibuya K, Aboyans V, Abhraham J, et al. Global and regional mortality from 235 causes of death for 20 age groups in 1990 & 2010: a systemic analysis for the global burden of Disease study 2010. Lancet 2012; 380:2095-2128.
6. Bhava Misra, Bhava Prakash Nighantu, commentary by Prof. K.C. Chunekar, edited by G. S. Pandey, Pub. By

Chaukhambha Bharti Academy, Varanasi, Edition 2010, Guduchyadi Varga, Sloka 278, p.no. 460.
7. Dravya Guna Vigyana volume II by Prof. P.V. Sharma, Edition: Reprint 2009, Chaukhamba Visvabharthi, Varanasi page no: 640
8. Dravya Guna Vigyana volume II by Prof. P.V. Sharma, Edition: Reprint 2009, Chaukhamba Visvabharthi, Varanasi page no: 640
9. Dravya Guna Vigyana volume II by Prof. P.V. Sharma, Edition: Reprint 2009, Chaukhamba Visvabharthi, Varanasi page no: 640
10. Bhava Misra, Bhava Prakash Nighantu, commentary by Prof. K.C. Chunekar, edited by G. S. Pandey, Pub. By Chaukhambha Bharti Academy, Varanasi, edition 2010, Guduchyadi Varga, Sloka 278, p.no. 460.

Source of Support: Nil
Conflict of Interest: None Declared

How to cite this URL: Raman Sharma et al: Clinical Evaluation Of Bhumyamalaki Ghana Vati In The Management Of Kamala With Special Reference To Hepatitis B. International Ayurvedic Medical Journal {online} 2021 {cited May, 2021} Available from: http://www.iamj.in/posts/images/upload/952_959.pdf