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A CLINICAL EVALUATION OF HEPATOPROTECTIVE EFFECTS OF KALMEGH (*Andrographis paniculata* WALL. EX NEES) IN PATIENTS OF ACUTE VIRAL HEPATITIS

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Abstract: Hepatitis is becoming a great problem for the medical world due to its variable etiology and clinical presentations. It is creating dangerous life threatening conditions and becoming a burden on the society. It may be a silent killer or continue as a benign disease leading to cirrhosis, hepatocellular carcinoma (HCC) and hepatorenal syndrome etc., if it is not treated properly. Acute viral infection is the most common cause of all forms of hepatitis. The viral hepatitis have been thought to be self limiting in nature but sometimes majority of patients of viral hepatitis have been observed ending up with a serious complications like hepatic failure etc. So, the present clinical study was planned to evaluate the hepatoprotective effect of Kalmegh (*Andrographis paniculata* Wall. ex Nees) on scientific parameters. In the present clinical trial, two groups of patients of viral hepatitis have been studied to evaluate the hepatoprotective effects of Kalmegh (*Andrographis paniculata* Wall. ex Nees) The first group of 35 patients, was given 50 ml of freshly prepared Kalmegh (*Andrographis paniculata* Wall. ex Nees) decoction with 50 gm of glucose powder, made from 10 gm of crude drug, twice daily. The second group of 10 patients, was given 100 gm of glucose powder daily. The trial was conducted for one month and liver functions test and subjective parameters were periodically evaluated to assess the hepatoprotective effect of drug under trial. At the end of the trial, trial group exhibited its hepatoprotective efficiency over the control.

Keywords: Ayurveda, Hepatoprotective, Kalmegh, *Andrographis paniculata.*

Introduction

Acute viral hepatitis infection continues to be an important cause of morbidity, mortality and source of potential new infections in many parts of the world. Patients of acute viral hepatitis present with almost similar clinical features to that of *Shakhashrita Kamala* of *swatantra* variety, mentioned in Ayurvedic treaties. Acute viral hepatitis is considered to be a self limiting disease, caused by the infected virus, but sometimes majority of hepatic viral diseases are ending up with serious complications. So, a faster restoration is desirable for every patient, even though they suffer from a self limiting disease. Definite treatment for acute viral hepatitis and its complications is not available in modern medicine and it is therefore always tempting to explore alternative systems of medicine for effective treatment of viral hepatitis. Ayurveda enumerated a lot of herbal drugs to posses hepatoprotective effects which can fill up this gap. Hepatoprotective herbal drugs like Amrita *(Tinospora cordifolia* Wild. Miers ex Hook.F & Thoms), Bhumyamalki *(Phyllanthus fraternus* Webster*)*, Kutki *(Picrorhiza kurroa* Royle ex Benth.*)*, Daruharidra (*Berberis aristata* DC.), Kalmegh (*Andrographis paniculata* Wall. ex Nees) and Bhringraja *(Eclipta alba* Linn.*)* etc. have been suggested to be useful in hepatitis. A lot of preliminary work has already been done on hepatoprotective effects of these drugs, with these leads, there is a need of more conclusive studies on these drugs including scientific clinical trial so that their hepatoprotective effect may be

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defined more precisely and these drugs may be brought to the level of public use. The present trial is exploration of ancient Ayurvedic literature to screen and dose standardization of the decoction of Kalmegh (*Andrographis paniculata* Wall. ex Nees) in protecting the hepatic damage caused by viral infection. Kalmegh (*Andrographis paniculata* Wall. ex Nees) is a well-known hepatoprotective herb. In Ayurvedic pharmacopoeia, Kalmegh (*Andrographis paniculata* Wall. ex Nees) is considered as *Tikta Rasa* predominant drug and as *Pitta, Kaphahara, Yakrituttejaka, Deepan, Kamalarogahara* and *Yakrit Vikarahara* and thus protect liver damage caused by viruses.

Materials and Methods

Selection of Patients

The present clinical research work was undertaken at Department of Kayachikitsa, Desh Bhagat Ayurvedic College & Hospital, Mandi Gobindgarh, Punjab (India). A total 58 patients of viral hepatitis were selected for the present study from OPD of the Kayachikitsa Department, irrespective of their sex, religion, and socio-economic status. Only those patients were selected for clinical trial, who presented themselves with anorexia, nausea, vomiting, low grade fever, weakness, dark urine, jaundice and tender hepatomegaly with abnormal liver function test (LFT). They were confirmed to have abnormal serum bilirubin, ALT, AST, serum alkaline phosphatase, and were not on any other hepatoprotective or hepatotoxic drug at the initiation of trial.

Assessment of Result

Assessment of result therapy was made in different parameters, subjective parameters (chief complaints, associated symptoms and signs) and biochemical parameters (objective parameters). Each patient was subjected to the series of laboratory tests such as serum bilirubin, AST, ALT, serum alkaline phosphatase, IgM anti-HAV, HbSAg, Anti-HCV and liver ultrasound before treatment, after 15 days of treatment and after one month of treatment to know the extent of liver damage as well as the rate of response to the trial drug. The trial was conducted for one month.


A twig of Kalmegh

Trial Drug: Kalmegh (*Andrographis paniculata* Wall. ex Nees) has been used over many centuries as a household remedy specifically for liver disorders and jaundice. It is a component of over 50% of the multi- ingredients herbal formulations available in India for the treatment of hepatic disorders. Recently acclaimed for its ability to protect the liver and help the liver regeneration itself, it has the added benefit of hindering the replication of viruses, by altering cell-to-cell transmissions. The ingredient *andrographolide* is suspected in destroying the virus communication mechanism, preventing the transmission of virus to other cells by modifying cellular signal transmission. *Andrographis* acts by blocking an enzyme known as reverse transcriptase, which is used by the virus to translate its genetic information in order to replicate. The ingredient *andrographolide* is suspected of destroying the virus communication mechanism by modifying cellular signal transmission. *Andrographolides* are thought to enhance immune system functions **(Puri A *et al.*, 1993)** such as production of WBCs, release of interferon and activity of the lymph system, stimulates scavengers of bacteria and other foreign matter, phagocytosis, inhibits hepatitis B & C, HIV-1, influenza virus replication, and improves CD4+ and T lymphocyte counts. It supports, alters and stimulates the properties and flow of bile **(Chaudhuri SK, 1978; Tripathi GS and Tripathi YB, 1991).** The herb is also reported to possess astringent, anodyne, tonic and alexipharmic properties and is helped in arresting dysentery, cholera, diabetes, consumption, influenza, bronchitis, swellings and

itching, piles and gonorrhea. A decoction of the herb is a blood- purifier. It is used as a cure for torpid liver and jaundice (**Chaturvedi GN** *et al*.**, 1983; Handa SS and Sharma A, 1990; Visen PK** *et al*.**, 1993).**

It forms, the major constituents of the Ayurvedic drug SG-I *Switradilepa*, which is effective in treating vitiligo. The macerated leaves and juice together with certain spices, such as cardamom, clove and cinnamon, are made into pills and prescribed for relief from gripe and other stomach ailments in infants. A decoction or infusion of the leaves is useful in general debility and dyspepsia **(Bhalla** *et al.***, 1982).**

The leaves and roots are also used as febrifuge **(Kanniappan M** *et al*.**, 1991),** tonic, stomachic **(Choudhury & Poddar, 1995),** cholagogue **(Chaudhuri SK, 1978; Tripathi GS** *et al*.**, 1991)** and anthelmintic (**Raj RK, 1975).** A tincture of the root is tonic, stimulant and aperient.

Method of preparation of trial drug

The freshly prepared 10 gm powder of crude drug was boiled with 16 times the volume of water by weight on mild fire till the contents of liquid were reduced to 1/8 of pre-boiling volume and liquid part was filtered. The filtrate was mixed with 50 gm of glucose and administrated to patients while still warm. OPD patients were explained the procedure thoroughly and told about the importance of therapy. Fresh raw drug was procured from the herbal garden of Desh Bhagat Ayurvedic College & Hospital Mandi Gobindgarh (Punjab).

After botanical identification from the Department of Pharmacognosy (Dravyaguna), decoction of drug was got prepared from hospital pharmacy. The standard of purify, quality and packing was maintained as per good manufacturing practice. In this group 43 patients were registered, of which 35 completed full course of trial of one month. The group was given 50 ml of freshly prepared Kalmegh decoction with 50 gm of glucose powder, made from 10 gm of crude drug, twice daily.

Control group (Glucose powder)

The patients of this group were given a 100 gm of glucose powder per day. In this group (control group), 15 patients were registered, of which 10 patients completed full duration of trial.

Results

For evaluation of hepatoprotective effect of Kalmegh (*Andrographis paniculata* Wall. ex Nees) decoction after use of one month in patients of acute viral hepatitis, both subjective and objective evaluation criteria were applied. The reliable amongst them was liver function test including serum bilirubin, ALT, AST and alkaline phosphatase. The trial patients were randomly scattered over two groups, but administration of trial drug and results were monitored from time to time. The observation regarding subjective evaluation of the patients over the trial are given in **Tables 1 and 2.** The observation regarding liver function tests of the patients over the trial are given in **Tables 3 and 6.**

Effects of Kalmegh (*Andrographis paniculata*) on clinical features in patients of acute viral hepatitis are given in **Table 1.**

After one month treatment with trial drug Kalmegh (*Andrographis paniculata* Wall. ex Nees)) decoction, 90-100% improvement was observed in clinical features such as nausea (*harillasa*) , vomiting (*chhardi*), anorexia (*aruchi*), headache (*shiroshoola*), clay coloured stool (*tilpista sannibha varchas*), fever (*jvara*) and pain abdomen (*udara shoola*). 81- 90% improvement was observed in signs and symptoms such as yellow sclera (*haridra netra*), yellow urination (*peetmutra*), fatigue (*klama*), malaise (*daurbalya*), pruritis (*kandu*), arthralgia (parvabheda) and hepatomegaly (*yakritavridhi*) 60-80 % improvement was observed in weight loss (*bharhani*), constipation (*malabadhta*), diarrhoea (*atisara*) and splenomegaly (*pleehavridhi*) **(Table 1).**

Effects of glucose powder (control) on clinical features in patients of acute viral hepatitis are given in **Table 2.**

After one month treatment with glucose powder, 60% improvement was observed in fever

Table 1. Showing incidence of clinical features of viral hepatitis and effect of Kalmegh decoction on clinical features (N=35)

Clinical Feature of Hepatitis/ *Kamala*	Before Treatment			After Treatment			Nil	Impv. in %
	Mild	Mod.	Sev.	Mild	Mod.	Sev.		
Yellow Sclera (*Haridra Netra)*	8	12	15	2	2	-	31	88.57
Yellow Urination (*Peet Mutra)*	8	12	15	2	2	-	31	88.57
Anorexia (*Aruchi)*	9	10	16	1	2	-	32	91.47
Nausea (*Hrillasa)*	9	12	14	2	-	-	33	94.28
Vomiting (*Chhardi)*	12	7	-	-	-	-	19	100
Fatigue (*Klama)*	10	12	13	3	2	-	30	85.71
Malaise (*Daurbalya)*	13	11	9	2	2	-	29	87.78
Arthralgia *(Parvabheda)*	6	4	1	1	1	-	09	81.81
Headache (*Shiroshoola)*	5	9	7	-	-	-	21	100
Fever (*Jvara)*	12	8	3	-	-	-	23	100
Clay Coloured Stool (*Tilpishtasannibha varchas)*	8	10	7	1	-	-	24	96.00
Diarrhoea (*Atisara)*	8	7	2	2	2	-	13	76.47
Pruritus *(Kandu)*	13	6	3	2	1	-	19	86.31
Weight Loss (*Bharhani)*	10	7	5	3	2	-	17	77.21
Hepatomegaly *(Yakritavridhi)*	9	8	6	2	2	-	19	82.60
Splenomegaly *(Pleehavridhi)*	3	2	-	1	1	-	03	60.00
Constipation (*Malabadhta)*	5	4	-	2	-	-	07	77.77
Pain Abdomen *(Udar shoola)*	10	8	2	2	-	-	18	90.00

Note: Mild = Mild; Mod. = Moderate; Sev. = Severe; Impv. = Improvement

(*jvara)* and 50 % improvement in clinical features such as anorexia (*aruchi),* nausea *(hrillasa),* arthralgia *(parvbheda*), splenomegaly (*pleehavridhi)* and pain abdomen *(udara shoola)* and 42% improvement was observed in both clay coloured stool (*tilpishtasannibha varchas*) and hepatomegaly (*yakritavridhi*). 40 % improvement was observed in yellow sclera (*haridra netra),* yellow urination (*peeta mutra*), fatigue (*klama*), malaise (*daurbalya*), headache (*shiroshoola*) and constipation (*malabadhta*). 33.33% improvement was observed in clinical features such vomiting (*chhardi*), diarrhoea (*atisara*) and weight loss (*bharhani*) while 37 % improvement was observed in pruritus (*kandu*) **(Table 2).**

Effects of Kalmegh (*Andrographis paniculata)* and glucose powder on total serum bilirubin in patients of acute viral hepatitis are given in **Table 3.**

Significant decrease in serum total bilirubin was observed after trial period of one month in both groups. It was found to have a mean of 8.55mg/dl and 7.24mg/dl before trial and reduced to 1.63mg/dl and 4.83mg/dl after trial period of one month in trial group and control group, respectively. Percentage of improvement was 80.81% in trial group, statistically, it was significant (t=17), ($p<0.001$). Percentage of improvement was 33.46% in control group, it was significant (t=3.5), ($p<0.05$). At the end of trial of one month, trial group exhibited its hepatoprotective efficiency over the control group **(Table 3).**

Effects of Kalmegh (*Andrographis paniculata*) and glucose powder on AST (SGOT) in patients of acute viral hepatitis are given in **(Table 4).**

It was found to have a mean AST (SGOT) of 328.28 IU/L and 319.3IU/L before trial and reduced to 52.45 IU/L and 204.3 IU/L after trial period of one month in trial group and control group respectively. Percentage of improvement was 83% in trial group, statistically it was significant (t=8.6, $p<0.001$). Percentage of improvement was 36% in control group, statistically it was significant (t=4.3, $p<0.01$). At

Table 2. Showing incidence of clinical features of viral hepatitis and effect of glucose powder on clinical features (N=10)

Clinical Feature of Hepatitis / *Kamala*	Before Treatment			After Treatment			Nil	Impv. in %
	Mild	Mod.	Sev.	Mild	Mod.	Sev.		
Yellow Sclera(*Haridra Netra)*	4	3	3	3	2	1	4	40.00
Yellow Urination *(Peet Mutra)*	4	3	3	3	2	1	4	40.00
Anorexia *(Aruchi)*	2	5	3	1	3	1	5	50.00
Nausea *(Hrillasa)*	2	2	2	2	1	-	3	50.00
Vomiting *(Chhardi)*	3	2	1	1	2	1	2	33.33
Fatigue (*Klama)*	2	4	4	2	1	3	4	40.00
Malaise (*Daurbalya)*	2	4	4	2	1	3	4	40.00
Arthralgia (*Parvabheda)*	2	1	1	1	1	-	2	50.00
Headache (*Shiroshoola)*	2	2	1	1	2	-	2	40.00
Fever (*Jvara)*	3	2	-	1	1	-	3	60.00
Clay Coloured Stool (*Tilpishtasannibha varchas)*	3	3	1	2	1	1	3	42.85
Diarrhoea (*Atisara)*	2	1	-	1	1	-	1	33.33
Pruritus (*Kandu*)	4	2	2	3	1	1	3	37.50
Weight Loss (*Bharhani)*	3	2	1	2	1	1	2	33.33
Hepatomegaly (*Yakritavridhi)*	3	2	2	2	1	1	3	42.00
Splenomegaly (*Pleehavridhi)*	1	1	-	1	-	-	1	50.00
Constipation (*Malabadhta)*	2	2	1	1	2	-	2	40.00
Pain Abdomen (*Udar shoola)*	3	2	1	1	2	0	3	50.00

Note: Mild = Mild ; Mod. = Moderate; Sev. = Severe; Impv. = Improvement

Table 3. Effects of Kalmegh on total serum bilirubin in the patients of viral hepatitis

Groups	S. Bilirubin (Mean Score) in mg/dl		Mean Diff.	SD ±	SE	%age Relief	t	p
	BT	AT						
Trial Group	8.55	1.63	- 6.91	2.39	0.40	80.81	17	<0.001
Control Group	7.24	4.87	- 2.37	2.10	0.66	33.46	3.5	<0.05

the end of trial of one month, trial group exhibited its hepatoprotective efficiency over the control group **(Table 4).** Effects of Kalmegh (*Andrographis paniculata*) and glucose powder on ALT (SGPT) in patients of acute viral hepatitis are given in **(Table 5).**

It was found to have a mean ALT (SGPT) of 333.28 IU/L and 347.7 IU/L before trial and reduced to 49.48 IU/L and 214.6IU/L after trial period of one month in trial group and control group respectively.

Percentage of improvement was 85% in trial group, statistically it was significant (t=8.7, p<0.001). Percentage of improvement was 38.28% in control group, statistically it was significant (t=7.3, p<0.001). At the end of trial

Table 4. Effects of Kalmegh on AST (SGOT) in the patients of viral hepatitis

Groups	AST (SGOT) Mean Score in IU/L		Mean Diff.	SD ±	SE	%age Relief	t	p
	BT	AT						
Trial Group	328.28	52.45	- 275.82	187.84	31.75	83.00	8.6	<0.001
Control Group	319.3	204.3	- 115	82.78	26.17	36.00	4.3	<0.01

Table 5. Effects of Kalmegh on ALT (SGPT) in the patients of viral hepatitis

Groups	ALT (SGPT) Mean Score in IU/L		Mean Diff.	SD ±	SE	%age Relief	t	p
	BT	AT						
Trial Group	333.28	49.48	2.83.85	192.95	32.61	85.00	8.7	<0.001
Control Group	347.7	214.6	133.1	57.47	18.17	38.28	7.3	<0.001

Table 6. Effects of Kalmegh on alkaline phosphatase in the patients of viral hepatitis

Groups	Serum Alkaline Phosphatase Mean Score in IU/L		Mean Diff.	SD ±	SE	%age Relief	t	p
	BT	AT						
Trial Group	488.94	163.91	325.03	99.31	16.78	66.47	19	<0.001
Control Group	416.6	339.6	77	56.17	17.76	18.48	4.3	<0.01

of one month, trial group exhibited its hepatoprotective efficiency over the control group **(Table 5).**

Effects of Kalmegh (*Andrographis paniculata*) and glucose powder on serum alkaline phosphtase (ALP) in patients of acute viral hepatitis are given in **Table 6.**

It was found to have a mean serum alkaline phosphatase 488.94 IU/L and 416 IU/L before trial and reduced to 163.91IU/L and 339.6IU/L after trial period of one month in trial group I and control group respectively. Percentage of improvement was 66.47% in trial group, statistically it was significant (t=19, p<0.001). Percentage of improvement was 18.48% in control group, statistically it was significant (t=4.3, p<0.01). At the end of trial of one month, trial group exhibited its hepatoprotective efficiency over the control group **(Table 6).**

Discussion

Acute viral hepatitis is a systemic viral infection in which hepatic cell necrosis and hepatic inflammation lead to a characteristic constellation of clinical, biochemical, immunoserological and morphological features. Almost all cases of acute viral hepatitis are caused by one of five viral agents- hepatitis A virus (HAV), hepatitis B virus (HBV), hepatitis C virus (HCV), hepatitis D virus (HDV) and hepatitis E virus (HEV). These agents can be distinguished by their molecular and antigenic properties; all types of viral hepatitis produce clinically similar illness. Acute viral hepatitis is clinically characterized by malaise, nausea, vomiting, diarrhoea and low- grade fever followed by dark urine, jaundice and tender hepatomegaly; may be sub clinical and detected on basis of elevated aspartate and alanine aminotransferase (AST and ALT) levels. Hepatitis B may be associated with immune complex phenomena, including arthritis, serum-sickness like illness, glomerulonephritis, and polyarteritis nodosa. In acute viral hepatitis, the particular virus damages the hepatocytes and produces the symptoms and signs. The earliest biochemical evidence of hepatocellular injury in

viral hepatitis is the elevation of transaminases (AST and ALT). These two enzymes which are normally present in the cell are leaked into plasma, due to the damage of hepatocyte causing the infecting virus. Very high levels of AST and ALT are seen in acute viral hepatitis. Transaminase estimations are useful in early diagnosis of viral hepatitis, to assess the severity of damage, to judge the prognosis and to evaluate the therapy. In the next phase of development, the serum bilirubin content goes up. This symptom is caused due to the pressure of swollen liver cells on the finer ducts of bile, present within the liver (intrahepatic cholestasis). Mild to moderate elevation in serum alkaline phosphatase (ALP) is also observed in viral hepatitis. The present trial is exploration of ancient Ayurvedic literature to screen and dose standardization of the decoction of Kalmegh in protecting the hepatic damage caused by viral infection. The trial drug Kalmegh showed definitive hepatoprotective effect over the trial period of one month. The drug Kalmegh is having potent hepatoprotective **(Chaturvedi GN *et al*., 1983; Handa SS and Sharma A, 1990; Visen PK *et al*., 1993)**, immunostimulating **(Puri *et al*., 1993),** anti- inflammatory, antiviral **(Change RS *et al*., 1991; Otake T *et al*., 1995),** antioxidant, cholagogue **(Chaudhuri SK, 1978; Tripathi GS and Tripathi YB, 1991)**, adaptogenic and membrane stabilizing effects on hepatocytes, which are constitutive qualities for any hepatoprotective drugs to act against viral hepatitis. These activities have been attributed to their anticholestatic action, reduction in free radicals and reduction in cell protein necrosis as well as immune suppression and glutathione depletion reduction potential. The patients of both groups showed statistically significant improvement in the clinical manifestations along with reduction in marker of enzymes of hepatotoxicity i.e. serum bilirubin, ALT, AST and serum alkaline phosphatase. But patients of trial group exhibited their hepatoprotective efficiency over the control group. In further post trial analysis, it was observed that in efficiency to protect liver during acute viral hepatitis, the effect of fresh decoction of Kalmegh was better than glucose powder. There were no clinically significant adverse events, either reported or observed, during the entire study period.

Conclusion

Kalmegh *(Andrographis paniculata)* in dosage of 50ml, twice daily, a favoured drug for acute viral hepatitis because of its oral effectiveness, good safety profile, easily availability in India and most importantly at an affordable price. It has established effective hepatoprotective effects as this drug has produced statistically significant improvement in the clinical manifestations and also reduction in marker of enzymes of hepatotoxicity i.e. serum bilirubin, ALT, AST and serum alkaline phosphatase. Kalmegh decoction (50 ml twice daily) is more effective than glucose powder (control) as the results obtained in the patients treated with former are better than those treated with later.

Thus, it can be concluded that Kalmegh *(Andrographis paniculata)* decoction drug is effective in checking the progress of the acute viral hepatitis.

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