A COMPARATIVE CLINICAL EVALUATION OF SOME *AYURVEDIC* DRUGS IN THE TREATMENT OF INFECTIVE HEPATITIS *(KAMALA)*

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ABSTRACT

Recent WHO data indicates hepatitis now along with malaria as the fourth most common cause of death from infectious diseases in the world. Among the infectious hepatitis most common are Hepatitis A, B, C, D, E & G are the most hazardous to mankind. Approximately 400 million people get infected with HBV, out of theses more than 50% persons are in south east asian countries. Among these 400 millions approximately 30% die due to complications such as cirrhosis of liver, hepatic encephalopathy & Hepato cellular carcinoma. Liver is concerned with synthetic, excretory as well as metabolic functions. So it is clear that liver has an indispensable and irreplaceable role in the human body. If due to any cause, liver parenchyma gets irreversible damage, all metabolic functions of the body cease and ultimately leads to death. The clinical presentation of *Koshtha shakhashrita Kamala* and infectious hepatitis (hepatocellular jaundice) seems to be one and the same. Different Ayurvedic preparations have been found to be effective for the treatment of liver disorders. The untiring efforts made by various previous Ayurvedic scholars inspired me to carry out a comparative study on the efficacy of Ayurvedic hepato-protective drugs i.e. *Phaltrikadi Kwath, Bhumyamlaki & Amrita swaras.*

KEYWORDS: Hepatitis, Hepatocellular jaundice, *Koshthashakhashrita Kamala, Phaltrikadi kwath, Bhumyamlaki, Amrita* &Hepatic encephalopathy.

INTRODUCTION

Kamala/jaundice is as old as our human civilization. Ancient texts *Rigveda & Atharvaveda* described its name as *Vilohita, Harima, & Halima.*

Nirukti/ **Etymology:** *"Kamam kanti lunatic cheti Kamala.*" The disease in which the *kama*/ desire of any physical activity & *Kanti*/lusture of our body decreased/ hampered.

"Kutsit malam karoti yasminna rog sa kamala" The meaning of this version that in which disease *kutsit/*dirty color & consistency of stool occurred the disease termed as *Kamala*. As in Koshthashakhashrita Kamala/Hepato cellular jaundice the stool is *raktapeet*/reddish yellow in color, in case of *Shakhaashrit Kamala*/obstructive jaundice the color of stool will be *tilpishtnibham*/clay & in the case of *Kumbh kamala/* incurable Hepato cellular failure the stool will be *krishnpeet*/ blackish yellow.

Nidan/ **Aetiology**- Excessive consumption of either *pattika ahar & vihar* by *Pandu rogi* or patient suffering from any chronic deabilating disease or use of *pattik ahar & vihar* disease free person i.e. person who have aggaravation of *pitta*. *Acharya* mentioned the *Kamala roga* as a sequel of *Pandu*/Anaemia *roga*.

Symptoms: The clinical features may manifest in different forms based on the types and different stages of *Kamala*. *Acharya Charak* has mentioned the common clinical features of Kamala and unique clinical features of *Koshtha Shrita Kamala* as well as *Shakha Shritha Kamala*. *Acharya Sushruta* and *Vagbhatta* explained the general clinical features of *Kamala*. General clinical features *(Roop)* of *Kamala* according to different *Ayurvedic* texts are as follows:

Table 1: Symptoms of Kamala.

Charak Samhita	*Haridra Netra* (yellow discoloration of eyes)
	Haridra Twak, Nakha and Mukha (yellow discoloration of skin, nails and face)
	Raktapeet, Sakrann Mutra (Reddish yellow discoloration of urine and stool)
	Bhekaverna (Appearance of colour of skin, like frog skin)
	Hatendriya (Abnromality in sensory systems)
	Daha (Burning sensation)
	Avipaka (Indigestion)
	Sadan / *Aruchi* (Anorexia)
	Karshita (Extreme body weakness)
Sushruta Samhita	*Arati* - Loss of interest
	Tandra – Drowsiness
	Bal Kashaya (Weakness)

Table 2: Properties of Phaltrikadi kwath.

S. No.	Ingredient	Rasa	Guna	Veerya	Vipaka	Dosa Karma
1.	Phalatrikadi	Pancharasa (Alavana – Tikta, Kashaya, Pradhan)	Laghu, Ruksha, Guru, Snigdha	Anushnasheet	Madhura/Katu	Tridoshahar

(Hareetaki, Vibheetaki, Amalaki, Guduchi, Vasa, Katuki, Kiratatikta, Nimbmool twak).

Table 3: Pharmacological properties of Bhumyamlaki.

S. No.	Rasa	Guna	Veerya	Vipaka	Dosa Karma	Action and Indications
1.	Kashaya	Laghu	Sheeta	Madhura	Pittashamak	Pipasa, Kasa, Pandu, Kapha

Table 4: Pharmacological properties of Amrita.

S. No.	Rasa	Guna	Veerya	Vipaka	Dosa Karma	Action and Indications
1.	Tikta, Kashaya	Guru, Snigdha	Ushna	Madhura	Tridoshahar	Rasayan, Jwarhar, Pittasarak

All the selected drugs possess the following properties. Cholegogue and Cholertic action, Hepato cellular regeneration, membrane stabilizing effect, antiviral, antioxidant (rejuvenator), enzymes and metabolic corrections, digestive and antipyretic action.

MATERIAL AND METHODS

Selection of Patients- Total 46 patients of Kamala attending OPD as well as IPD of Kayachikitsa Department were selected for the present clinical study from S.S. Hospital, Institute of Medical Sciences, B.H.U., Varanasi.

Inclusive Criteria: Age of patients were in between 10-70 yrs, History, clinical signs and symptoms & Biological parameters (LFTs) suggestive of acute as well as chronic infective hepatitis i.e. Kamala.

Exclusive Criteria: Patients who developed Cirrhosis, malignancy, hepatic failure, hepatic encephalopathy and other complications, Patients of obstructive jaundice due to any cause, Other diseases which confuses in the interpretation of LFTs, Patients suffering with other disease along with hepatitis like D.M., T.B. etc.

Symptomatological Grading of Infective Hepatitis (i.e. Kamala) Clinical assessment of symptoms were subjectively done in terms of gradation of symptoms according to the rating scale in each patient at the initial stage i.e. before starting the treatment and subsequent follow up. Improvement of symptom grading is supposed to be directly proportional to the improvement in the patient's conditions. clinical symptomatology was graded into four grades (0-3)scale on the basis of severity. Symptoms were Anorexia, Weakness, Nausea, Vomiting, Fever, Yellowness of sclera & urine, Pain in abdomen, Hepatomegaly, Liver tenderness & weight loss. Gradings were 0 = Absent (nil), 1 = Mild, 2 = Moderate, 3 = Severe

Diagnosis: History, Clinical Signs & Symptoms, LFTs, USG abdomen & HbSAg (Australian antigen).

Distribution of Cases: All registered patients of Hepatitis i.e. Kamala were divided into four groups.
Group- A: This group contain 10 patients which were given Phaltrikadi Kwatha + Amrita swaras.
Group- B: This group comprises 10 patients which were given Phaltrikadi Kwatha + Bhumyamlaki swaras.
Group- C: This control group comprises 10 patients and were advised for Specific diet, complete bed rest & Oral glucose.
Group- D: This group also contains 10 patients and were given Phaltrikadi Kwatha.

Dose of Drug Preparations

- ***Phaltrikadi Kwath*** *(Hareetaki, Vibheetaki, Amalaki, Guduchi, Vasa, Katuki, Kiratatikta, Nimbmool twak) 80-100ml/day.*
- ***Amrita Swaras*** *20-30 ml/day*
- ***Bhumyamlaki Swaras*** *20-30 ml/day*

Duration: Total duration of trial drug was one month with every 10 days follow-up.

Route of administration: Orally

Assesment Parameters

1. Biological- Liver Function Test LFTs on every 10 days
2. Subjective – according to grading 0-3 improvement was noted in each patient after every 10th day follow up.

OBSERVATION AND RESULT

FIG.-1: Effect of trial drugs on total serum bilirubin in the patients of infective hepatitis i.e. Kamala.
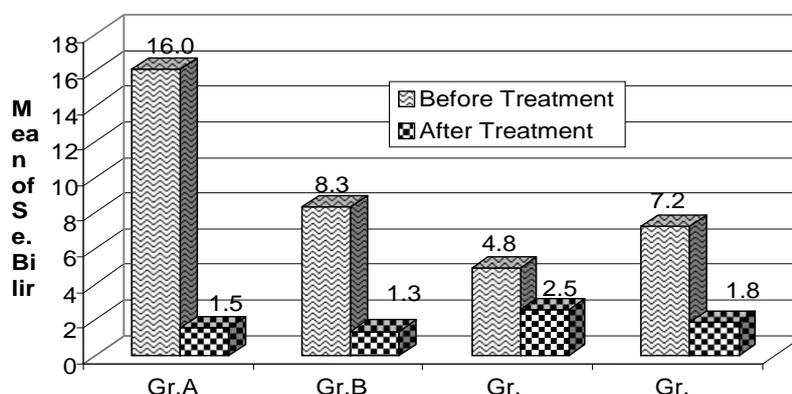

FIG-2: Effect of trial drugs on serum ALT (SGPT) in the patients of infective hepatitis i.e. Kamala.
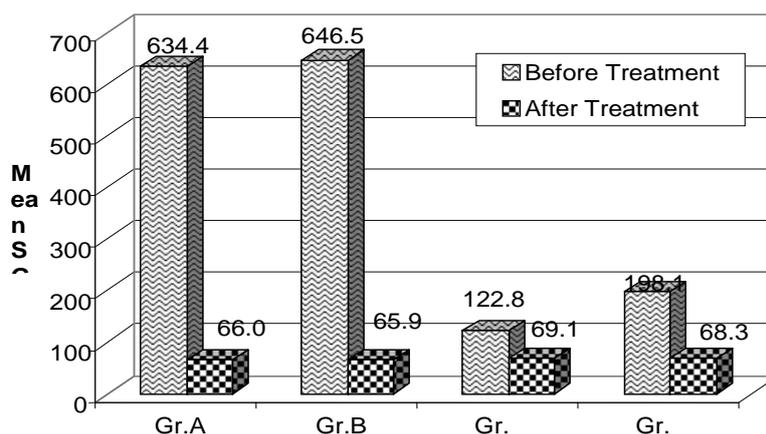
Table 5: Effect of trial drugs on serum AST (SGOT) in the patients of infective hepatitis i.e. Kamala.

Groups (n=10)	Total Serum AST (SGOT) (IU/L)			Intra group comparison		Inter group comparison	
	BT	AT	BT-AT				
	Mean ±SD	Mean ±SD	Mean ±SD	't' value	'p' value	't' value	'p' value
A	512.15 ±370.41	48.60 ±28.90	463.55 ±358.00	4.014	<0.01	3.79	A vs C <0.01[HS]
B	291.92 ±469.14	47.93 ±42.42	249.29 ±455.06	1.732	>0.05	1.49	B vs C >0.05[NS]
C	92.06 ±32.50	57.89 ±17.30	34.17 ±20.69	5.23	<0.001	--	--
D	188.44 ±102.34	52.09 ±23.77	136.35 ±140.34	3.04	<0.02	2.28	D vs C >0.05[S]

Table 6: Effect of trial drugs on serum alkaline phosphatase in the infective hepatitis i.e. Kamala.

Groups (n=10)	Serum Phosphatase (IU/L)			Intra group comparison		Inter group comparison	
	BT	AT	BT-AT	't' value	'p' value	't'value	'p' value
	Mean ±SD	Mean ±SD	Mean ±SD				
A	368.20 ±248.90	202.29 ± 76.21	170.21 ±229.02	2.34	>0.05	1.81	A vs C >0.05[NS]
B	320.98 ±139.53	200.98 ±119.2	120.04 ±113.35	3.35	<0.01	2.11	B vs C <0.05[S]
C	199.56 ± 54.55	163.50 ± 38.03	34.06 ±60.97	1.77	<0.01	--	--
D	212.95 ± 75.68	180.50 ± 47.33	32.42 ±93.80	1.09	>0.05	0.05	D vs C >0.05[NS]

Table 7: Effect of trial drugs on total serum protein in the infective hepatitis i.e. Kamala.

Groups (n=10)	Total Serum Protein (IU/L)			Intra group comparison		Inter group comparison	
	BT	AT	BT-AT	't' value	'p' value	't' value	'p' value
	Mean ±SD	Mean ±SD	Mean ±SD				
A	6.98±0.88	7.62±0.32	-0.84±1.94	-1.38	>0.05	-2.33	A vs C >0.05[S]
B	6.85±0.91	7.23±0.85	-0.48±0.91	-1.65	>0.05	-3.35	B vs C <0.01[HS]
C	7.32±0.63	6.69±0.68	0.63±0.51	3.94	<0.01	--	--
D	7.18±1.02	6.85±0.87	0.37±0.94	1.27	>0.05	0.78	D vs C >0.05[NS]

Table 8: Improvement in yellow sclera (Haridra Netra).

Gr. (n=10)	Improvement in Yellow Sclera					Intra group comparison		Inter group comparison	
	BT	FUI	FUII	AT	BT-AT	't' value	'p' value	't' value	'p' value
	Mean ±SD	Mean ±SD	Mean ±SD	Mean ±SD	Mean ±SD				
A	2.5 ±0.5	1.6 ±0.49	1.2 ±0.75	1.0 ±0.77	1.5 ±0.5	9.37	<0.001	2.20	A vs C <0.05[S]
B	2.1 ±0.7	1.7 ±0.46	1.5 ±0.5	1.1 ±0.3	1.0 ±0.63	5.0	<0.001	0.34	B vs C >0.005[NS]
C	1.6 ± 0.66	1.3 ±0.45	0.9 ±0.3	0.7 ±0.45	0.9 ±0.7	4.09	<0.01	--	--
D	2.0 ±0.6.3	1.6 ±0.66	1.1 ±0.83	0.6 ±0.66	1.4 ±0.49	9.0	<0.001	1.86	D vs C >0.05[NS]

Table 9: Improvement in Raktpeet Mutra (Reddish yellow urine).

Gr. (n=10)	Improvement in Raktapeet Mutra					Intra group comparison		Inter group comparison	
	BT	FUI	FUII	AT	BT-AT	't' value	'p' value	't' value	'p' value
	Mean ±SD	Mean ±SD	Mean ±SD	Mean ±SD	Mean ±SD				
A	2.2 ±0.75	1.7 ±0.78	1.0 ±0.77	0.5 ±0.67	1.7 ±0.6	8.5	<0.001	2.22	A vs C <0.01[HS]
B	1.6 ±0.49	1.1 ±0.54	0.8 ±0.4	0.6 ±0.44	1.0 ±0.77	4.17	<0.001	0.00	B vs C >0.05[NS]
C	1.4 ±0.49	1.0 ±0.0	0.8 ±0.4	0.4 ±0.49	1.0 ±0.77	4.1	<0.001	--	--
D	1.3 ±0.64	0.9 ±0.3	0.2 ±0.4	0.1 ±0.3	1.2 ±0.6	6.3	<0.001	0.65	D vs C >0.05-NS

Table 10: Improvement in Anorexia (Avipaka).

Gr. (n=10)	Improvement in Anorexia (Avipaka)					Intra group comparison		Inter group comparison	
	BT	FUI	FUII	AT	BT-AT	't' value	'p' value	't' value	'p' value
	Mean ±SD	Mean ±SD	Mean ±SD	Mean ±SD	Mean ±SD				
A	2.1 ±0.94	1.2 ±0.75	0.5 ±0.5	0.0 ±0.0	2.1 ±0.94	7.0	<0.001	4.11	A vs C <0.001[HS]
B	1.3 ±0.64	0.8 ±0.6	0.4 ±0.94	0.31 ±0.46	1.0 ±0.45	7.14	<0.001	1.59	B vs C >0.05[NS]
C	0.7 ±0.64	0.6 ±0.49	0.1 ±0.3	0.1 ±0.3	0.6 ±0.66	2.88	<0.02	--	--
D	1.0 ±0.63	0.6 ±0.49	0.3 ±0.46	0.2 ±0.4	0.8 ±0.6	4.2	<0.01	0.71	D v C >0.05[NS]

Table 11: Improvement in Nausea (Hrillasa).

Gr. (n=10)	Improvement in Nausea (Hrillasa)					Intra group comparison		Inter group comparison	
	BT	FUI	FUII	AT	BT-AT	't' value	'p' value	't' value	'p' value
	Mean±SD	Mean±SD	Mean±SD	Mean±SD	Mean±SD				
A	1.7 ±1.0	1.0 ±0.89	0.4 ±0.66	0.1 ±0.3	1.6 ±0.92	5.51	<0.001	2.80	A vs C <0.02[S]
B	0.4 ±0.49	0.3 ±0.46	0.1 ±0.3	0.1 ±0.3	0.3 ±0.46	2.06	>0.05	0.20	B vs C >0.05 [NS]
C	0.6 ±0.66	0.3 ±0.46	0.1 ±0.3	0±0	0.6 ±0.66	2.88	<0.02	--	--
D	1.1 ±0.7	0.6 ±0.66	0.3 ±0.64	0.2 ±0.4	0.9 ±0.53	5.38	<0.001	1.12	D vs C >0.05 [NS]

Table 12: Improvement in Vomiting (Vaman / Chardi).

Gr. (n=10)	Improvement in Vomiting (Vaman/Chardi)					Intra group comparison		Inter group comparison	
	BT	FUI	FUII	AT	BT-AT	't' value	'p' value	't' value	'p' value
	Mean±SD	Mean±SD	Mean±SD	Mean±SD	Mean±SD				
A	1.1± 0.83	0.7 ±0.64	0.3 ±0.46	0.1 ±0.3	1.1 ±0.72	4.17	<0.1	0.34	A vs C >0.05 [NS]
B	0.3± 0.46	0.3 ±0.46	0.1 ±0.3	0±0	0.3 ±0.46	2.06	>0.05	-2.71	B vs C <0.02[S]
C	0.9± 0.53	0.5 ±0.5	0.3 ±0.46	0±0	0.9 ±0.53	5.4	<0.001	--	--

Table 13: Improvement in pain in abdomen.

Gr. (n=10)	Improvement in pain in abdomen					Intra group comparison		Inter group comparison	
	BT	FUI	FUII	AT	BT-AT	't' value	'p' value	't' value	'p' value
	Mean ±SD	Mean ±SD	Mean ±SD	Mean ±SD	Mean ±SD				
A	0.9 ±0.83	0.5 ±0.67	0.2 ±0.4	0.2 ±0.4	0.7 ±0.64	3.5	<0.01	0.36	A vs C >0.05 [NS]
B	0.6 ±0.66	0.4 ±0.49	0.2 ±0.33	0±0	0.6 ±0.66	2.88	<0.02	-0.71	B vs C >0.05 [NS]
C	0.9 ±0.53	0.6 ±0.49	0.4 ±0.49	0±0	0.8 ±0.6	3.15	<0.02	--	--
D	0.6 ±0.49	0.3 ±0.46	0.2 ±0.4	0.1 ±0.3	0.5 ±0.5	3.16	<0.02	-1.21	D vs C >0.05 [NS]

Table 14: Improvement in Hepatomegaly.

Gr. (n=10)	Improvement in Hepatomegaly					Intra group comparison		Inter group comparison	
	BT	FUI	FUII	AT	BT-AT	't' value	'p' value	't' value	'p' value
	Mean±SD	Mean±SD	Mean±SD	Mean±SD	Mean±SD				
A	1.3 ±0.9	1.0 ±0.77	0.4 ±0.49	0.3 ±0.46	1.0 ±0.63	5.0	<0.001	1.58	A vs C <0.05 [NS]
B	1.0 ±0.44	1.0 ±0.44	0.3 ±0.46	0.3 ±0.46	0.7 ±0.45	4.9	<0.001	0.47	B vs C >0.05 [NS]
C	0.8 ±0.4	0.8 ±0.4	0.5 ±0.05	0.2 ±0.4	0.6 ±0.49	3.87	<0.01	--	--
D	1.0 ±0.63	0.9 ±0.54	0.7 ±0.46	0.4 ±0.48	0.6 ±0.66	3.0	<0.02	0.00	D vs C >0.05 [NS]

Table 15: Improvement in Liver tenderness.

Gr. (n=10)	Improvement in Liver tenderness					Intra group comparison		Inter group comparison	
	BT	FUI	FUII	AT	BT-AT	't' value	'p' value	't' value	'p' value
	Mean±SD	Mean±SD	Mean±SD	Mean±SD	Mean±SD				
A	0.5 ±0.67	0.3 ±0.46	0.1 ±0.3	0.1 ±0.3	0.4 ±0.49	2.67	<0.05	-0.46	A vs C >0.05 [NS]
B	0.7 ±0.45	0.6 ±0.49	0.2 ±0.4	0.2 ±0.4	0.5 ±0.5	3.16	<0.02	0.00	B vs C >0.05 [NS]
C	0.5 ±0.5	0.3 ±0.46	0.2 ±0.4	--	0.5 ±0.5	3.16	<0.02	--	--
D	0.3 ±0.46	0.2 ±0.4	0.1 ±0.3	--	0.3 ±0.46	2.0	<0.05	-0.93	D vs C >0.05 [NS]

Table 16: Improvement in Weight loss.

Gr. (n=10)	Improvement in Weight loss					Intra group comparison		Inter group comparison	
	BT	FUI	FUII	AT	BT-AT	't' value	'p' value	't' value	'p' value
	Mean±SD	Mean±SD	Mean±SD	Mean±SD	Mean±SD				
A	1.2 ±0.98	0.9 ±0.7	0.5 ±0.67	0.3 ±0.46	0.9 ±0.7	4.09	<0.01	0.39	A vs c >0.05 NS
B	0.9 ±0.53	0.7 ±0.64	0.4 ±0.66	0.2 ±0.4	0.7 ±0.45	4.9	<0.001	-0.53	B vs C >0.05 NS
C	1.1 ±0.5	1.0 ±0.63	0.6 ±0.49	0.3 ±0.46	0.8 ±0.4	3.17	<0.01	--	--
D	0.6 ±0.49	0.4 ±0.49	0.2 ±0.4	0±0	0.6 ±0.49	3.16	<0.02	1.0	D vs C >0.05 NS

Table 17: Improvement in Weakness (Daurbalya).

Gr. (n=10)	Improvement in Weakness (Daurbalya)					Intra group comparison		Inter group comparison	
	BT	FUI	FUII	AT	BT-AT	't' value	'p' value	't' value	'p' value
	Mean±SD	Mean±SD	Mean±SD	Mean±SD	Mean±SD				
A	1.6 ±0.8	1.3 ±0.6	0.9 ±0.83	0.6 ±0.66	1.0 ±0.45	7.04	<0.001	0.6	A vs C >0.05 NS
B	1.1 ±0.7	1.1 ±0.7	0.7 ±0.45	0.7 ±0.45	0.4 ±0.48	2.66	<0.05	2.85	B vs C >0.02 S
C	1.4 ±0.49	1.4 ±0.49	0.8 ±0.6	0.5 ±0.5	0.9 ±0.3	3.33	<0.01	--	--
D	1.3 ±0.45	1.0 ±0.00	0.7 ±0.46	0.5 ±0.5	0.8 ±0.6	4.2	<0.02	-0.47	D vs C >0.05 NS

Table 18: Improvement in Fever (Daha).

Gr. (n=10)	Improvement in Fever (Daha)					Intra group comparison		Inter group comparison	
	BT	FUI	FUII	AT	BT-AT	't' value	'p' value	't' value	'p' value
	Mean±SD	Mean±SD	Mean±SD	Mean±SD	Mean±SD				
A	1.2 ±0.98	0.9 ±0.83	0.3 ±0.46	0.1 ±0.3	1.1 ±0.9	3.67	<0.01	1.37	A vs C >0.05 NS
B	0.7 ±0.64	0.8 ±0.74	0.5 ±0.67	0.2 ±0.4	0.5 ±0.5	3.16	<0.02	-0.20	B vs C >0.05 NS
C	0.6 ±0.66	0.4 ±0.49	0.1 ±0.3	0±0	0.6 ±0.66	2.88	<0.02	--	--
D	0.5 ±0.5	0.5 ±0.5	0.1 ±0.3	0.1 ±0.3	0.4 ±0.48	2.60	<0.02	-1.94	D vs C >0.05 NS

Result of all the 4 groups were good & inspiring on all the parameters.

However in Group comparision Group A
(Phaltrikadi Kwatha + Amrita Swaras) showed better results as compared to the other groups.

SUMMARY AND CONCLUSION

Due to excessive propagation of the media about hepatitis there is a havoc in the patient as well as society. But actual picture is different nothing to worry about that. Among the all infected persons only 01% convert into fetal condition i.e. fulminant hepatitis. In the remaining 99% cases recovered from disease. But its clear that the risk of Cirrhosis, Hepato cellular carcinoma increases in the HBV (Hepatitis B virus) infected person compared to normal population. This condition may be more grave when co infection of HDV (Hepatitis D virus) with the HBV. In this research work 12 patients were Hepatitis B (Australian antigen surface +ve). I would like to convey personal experiences that treatment period of a Kamala patient should not be less than three months, in this period patient must be in continuous and close supervision to avoid the post hepatic residual symptoms i.e. cirrhosis and malignancy of liver. I hope that this little effort will stimulate & pave the path for the research workers in the various institute in the same area & field.

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