EVALUATION REPORT OF DRUG KAMALAHAR

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KAMALAHAR DRUG TRIAL

Final Consolidated report of observation

INTRODUCTION

Viral hepatitis, drugs and alcohol induced jaundice still finds no effective remedy in modern system of medicine, But our indigenous system of medicine ''Ayurveda'' may offer some hope. Many herbal medicines have been advocated, to be effective in curing jaundice, in our old text book of Ayurveda, but none of them have found any acceptance in the present times. For the same reason we conducted a therapeutic trial of drug KAMALAHAR (Sponsored by Khatore Pharmaceutical Pvt. Ltd) Which has been claimed to offer miraculous cure for jaundice.

Kamalahar is a mixture of many herbal medicine and exact composition and formulation can be obtained from the manufacturer Khatore Pharmaceutical Pvt. Ltd., and Dravyagun- Vinana Vol. II by Prof. P.V. Sharma.

MATERIAL AND METHODS

The study was carried out on a total of 50 patients of jaundice both male and females, attending O.P.D. and wards of M.L.B. Medical College, Jhansi during the period from 15th June, 1987 to 15th Nov, 1987. Informed consent was taken from patients and/or their attendant. Facts as told by manufacturer were explained in detail. Only patients who volunteered were included in the study. Patients were randomly assigned to two groups, each group having 25 patients. In group I patients were given drug Kamalahar two capsules thrice daily for 12 days. In group II or control group similar coloured and sized placebo capsule were given for the same duration.

(Drug Kamalahar and placebo capsules were supplied by Khatore Pharmaceutical Pvt. Ltd.)

No other drugs that could affect the outcome of trial were given in any group. Both groups were advised bed rest with limited mobility. Similar dietary restrictions were imposed on both groups.

Criteria adopted for diagnosing infective Hepatitis and other Liver disorders

Infective Hepatitis

Patients presenting with jaundice, tender hepatomegaly, malaise, mild fever, anorexia, nausea, passage of yellow coloured urine and on biochemical examination showed raised serum bilirubin levels to 72 mg/100ml, without use of any drug or alcohol, were labelled as cases of infective hepatitis. In patients with above findings plus loss or impairment of consciousness were labelled as cases of hepatic coma.

Anti-tubercular drug induced Jaundice

Patients developing jaundice while on anti-tubercular drug (Rifampicin, Isonex, Pyzinamide) with rise of serum bilirubin and SGPT were labelled as cases of drug induced Jaundice.

Alcoholic Hepatitis

Patients developing jaundice while consuming two pegs or more of alcohol for a prolonged period with slight increase in serum bilirubin and enzyme SGPT levels were labelled as cases of alcoholic hepatitis. No liver biopsy was done in any case and diagnosis was solely based on clinical and biochemical findings.

A detailed history and thorough clinical examination was carried out, duration of jaundice, loss of appetite, nausea/vomiting, history of itching and haematemesis, malena with duration was recorded. Degree of hepatomegaly with or without tenderness was also noted. Any regression or progression of symptoms was periodically entered. On first day of patient attendance, TLC, DLC, HB, ESR, urine routine and microscopic examination, blood sugar, serum bilirubin and enzyme SGPT levels estimation were carried out.

Serum bilirubin levels were repeated on fourth, eighth, twelfth day respectively. Offending drug and alcohol was withdrawn in both groups before starting the treatment. Student's t-test was applied for knowing statistical significance of changes in parameters.

RESULTS

In each group there were 17 patients of infective hepatitis, two each of drug induced hepatitis and alcoholic hepatitis and four patients of hepatic coma in each group.
In group I, in which drug ''Kamalahar'' was used. There were 20 males and five females with an age of 13-55 years. In group II, (Placebo or control group) there were 18 males and 7 females with an age range of 14 to 65 years.

Table A and B shows the serum bilirubin levels of patients of infective hepatitis on 1^{st} , 4^{th} and 8^{th} and 12^{th} day respectively along with blood SGPT levels on first day of both groups. Serum bilirubin levels on first day in group I mean was 8.61±2.49 mg/100 ml with a range of 4.2 to 12 mg/100 ml. This compared well with the first day serum bilirubin levels of group II mean 8.73±2.71 mg/100 ml with a range of 4.2 to 13.2 mg/ 100ml. Enzyme levels of SGPT were considerably raised in both the groups.

After four days of treatment with Kamalahar serum bilirubin levels have fallen to mean 6.61±.31 mg/100 ml (P < 0.05 in group I) while it was 8.17±2.21 mg/100 ml in control group II (P < 0.05). Thus there was statistically significant fall in serum in bilirubin level in group I while in group II it was insignificant.

Similarly after eight days of treatment the levels in group I further fell to mean 4.7±1.9 mg/100 ml (P < 0.05), while in control group the levels of serum bilirubin was 7.33±2.49 mg/100 ml (P < 0.05) indicating a very marginal fall. Again the fall in group I was statistically significant as compared to 4^{th} day levels. **Finally in the 12^{th} day the levels in group I were mean 2.10±1.34 mg/100 ml (P < 0.001) while in group II the levels of serum bilirubin was 6.16±3.25 mg/100 ml (P < 0.05)**.

Thus there was a statistically highly significant fall in serum bilirubin level between 8-12th day in group I while in group II the fall was insignificant. Out of 17 patients of infective hepatitis in group I, 14 showed regression of serum bilirubin levels to less than 3 mg/100 ml (82.35%) after 12 days of treatment and in only 3 patients (17.65%) levels persisted to more than 3 mg/100ml while in group II in only four patients (23.52%) the levels of serum bilirubin fell to 3 or less than 3 mg/100 ml, and in the remaining 13 cases (76.47%) the levels were considerably more than 3 mg/100ml after 12 days of treatment.

In group I only 2 patients (11.76%) showed rise of serum bilirubin after start of treatment while in group II or control group 7 patients (41.17%) showed rise of serum bilirubin after start of drug (Placebo) therapy. **In group I, in 5 patients (29.4%) the serum bilirubin level after 12th days of treatment dropped to 0.8 mg/100 ml or less, while in control group II in none of the subjects (0%) the level dropped to such all time low.** There was no mortality in group I, but in group II one patient died (5.88%) due to progressive increase in serum bilirubin and patient passing into hepatica coma.

Tables C and D show the comparative levels of serum bilirubin in patients of drug induced jaundice and alcoholic hepatitis. In cases of drug induced jaundice the first day serum bilirubin levels were 6.0$\pm$1.41 mg/100ml and 5.2$\pm$0.56 mg/100ml in group I and II respectively. **After treatment with drug Kamalahar there was significant fall of serum bilirubin level in group I and it fell to less than 1 mg/100ml after 12 days of treatment (100%),** while in group II levels of serum bilirubin persisted around 3.6$\pm$1.9 mg/100ml after 12 days of treatment. **Similarly in cases of alcoholic hepatitis in group I the levels of serum bilirubin fell from 4.1+0.42 mg/100ml to less than 1 mg/100ml after 12 days of treatment with Kamalahar,** but in placebo group II, there was an insignificant change of serum bilirubin levels form 3.9$\pm$0.14 mg/100ml to 3.25$\pm$0.35 mg/100ml after same duration of treatment.

In cases of hepatic coma one patient survived in group I, rest all were dead within four days of admission to hospital in both groups. There was also a general symptomatic improvement in patients of group I. **In 13 out of 17 patients of infective hepatitis in group I (76.47%) there was definite improvement of appetite after 4 days of treatment**, while in group II only 5 patients (29.41%) reported improvement in their appetite.

Hepatomegaly and liver tenderness disappeared in 12 out of 17 patients of infective hepatitis (70.58%) in group I while in group II only in 6 cases (35.52%) hepatomegaly and liver tenderness regressed after eight days of treatment.

Side Effect Observed

Except for loose motion in two patients no significant side effects were observed. Loose motion disappeared on withdrawal of the drug.

Comparative Result in Group I and II

		Group I (%)	Group II (%)
1.	Percentage of patients in which Serum bilirubin fell to < 3 mg/100ml (After 12 days in infective hepatitis patients).	82.35	23.52
2.	Percentage of patients in which there was rise of serum bilirubin level after 4 days of treatment	11.66	41.17
3.	Improvement in appetite in cases of Infective Hepatitis after 4 days of treatment.	76.47	29.4
4.	Clinical improvement in form of regression of tender hepatomegaly after 8 days of treatment in cases of Infective Hepatitis.	70.58	35.52

Table 'A' : Serum bilirubin levels in patients of infective hepatitis of Group I

Sl No.	Name	Age/ Sex	Serum Bilirubin Mg / 100 ml				SGPT (I.U./L)
			1st I	4th II	8th III	12th IV	
01	Bhima	40/M	12.0	10.0	8.0	4.2	350
02	Guniya	35/F	7.0	4.0	2.5	0.6	240
03	Rakesh	18/M	9.0	7.0	5.0	2.8	300
04	Ram Batele	22/M	10.0	8.0	5.2	2.3	240
05	Jiddi	30/M	7.0	9.0	7.0	2.2	210
06	Sohan	20/M	14.0	9.07	6.0	5.0	350
07	Durga Pd.	40/M	7.7	4.0	3.0	0.6	150
08	Shanti	28/F	4.8	3.0	2.2	3.0	160
09	Babu lal	40/M	12.0	10.0	7.2	0.8	130
10	Ram Bharose	28/M	7.0	4.0	2.5	1.8	240
11	Vijay Rani	25/M	9.0	7.0	4.0	1.2	140
12	Lakhan	48/M	6.0	4.0	3.0	4.0	110
13	Dr.Mahore	29/M	11.0	9.0	7.7	2.2	300
14	Bilati	27/M	7.7	5.2	4.0	2.1	191
15	SS Sexena	45/M	6.0	7.2	5.0	1.6	220
16	Batasi Lal	39/M	9.0	6.0	4.0	0.8	180
17	Vivek	13/M	7.2	6.0	3.6	0.6	240
		Mean	8.61	6.61	4.70	2.10	
		S.D	±2.49	±2.31	±1.90	±1.34	
		T	1:2=2.4	2:3=2.63	3:4=4.61		
		P	<0.05	<0.05	< 0.001		

TABLE B : Serum bilirubin levels in cases of infective hepatitis of group II (Control group).

Sl.No:	Name	Age (Yers.) Sex	Serum BIlirubin mg/100 ml Day 1st (I) Mg	4th (II) mg	8th (III) mg	12th (IV) mg	SGPT IU/Lit
1.	Mata Pd	35/M	7.2	9.0	7.0	5.2	300
2.	Saligram	60/M	12.0	10.0	8.8	7.0	220
3.	Narmada Pd.	29/M	6.0	5.2	4.0	2.8	140
4.	Ram Narain	24/M	8.8	9.0	7.6	6.0	190
5.	Murari Lal	26/M	11.0	9.0	8.0	7.0	200
6.	Purushottam	19/M	4.8	6.2	7.6	7.0	120
7.	Deen Dayal	40/M	9.0	9.2	7.0	6.2	70
8.	Girdhari Lal	46/M	11.8	7.2	5.4	3.0	87
9.	Shiv Narain	45/M	8.0	9.6	9.0	8.0	180
10.	Santosh	47/M	6.4	7.8	8.0	6.0	220
11.	Gullab	21/M	13.2	10.0	7.0	6.2	190
12.	Prem Wati	19/F	7.8	6.0	5.0	5.0	120
13.	Ram Rani	38/F	9.0	8.0	7.0	3.0	160
14.	Rakhee	14/F	5.6	4.0	3.8	2.2	100
15.	Yogesh	18/M	12.0	9.8	7.7	7.2	160
16.	Kamal	22/M	4.9	6.0	6.2	6.0	130
17.	Naina Devi	28/F	11.0	13.0	15.0	17.0	400
		Mean	8.73	8.17	7.33	6.16	
		S.D.	±2.71	±2.214	±2.49	±3.25	
		T	1:2=0.659		2:3=1.039		3:4=1.178
		P	<0.01		<0.05		<0.05

TABLE C : Serum bilirubin levels in patients of drug induced hepatitis and alcoholic jaundice of group I.

Sl.No.	Name	Age (Yrs.)/ Sex	Serum bilirubin mg/100 ml day 1st (I) Mg	4th (II) Mg	8th (III) Mg	12th (IV) Mg	SGPT IU/Lit	Diagnosis
1.	Vishwanath	28/M	5.0	3.3	1.2	/1.0	300	Antitubercular durg induced
2.	Har Prasad	55/M	7.0	3.0	/ 2	/1	210	-do-
		Mean	6.0					
		S.D.	±1.41					
3.	Deen Dayal	48/M	4.4	3.0	2.8	/ 1	50	Alcoholic hepatitis
4.	HD Sharma	45/M	3.8	1.8	1.2	/1	74	-do-
		Mean	4.1					
		S.D.	±0.42					

TABLE D : Serum bilirubin levels in patients of drug induced hepatitis and alcoholic jaundice of group II

Sl. No.	Name	Age (Yrs.)/ Sex	Serum bilirubin mg/100 ml Day 1st (I)	4th (II)	8th (III)	12th (IV)	SGPT IU/Lit		Diagnosis
1.	Shanta Pu.	32/M	4.8	4.0	3.0	2.8	90	Anti tubercular drug induced hepatitis	
2.	Lalita	20/F	5.6	5.0	5.2	5.0	88	-do-	
		Mean	5.2						
		S.D.	±0.56						
3.	Devi Das	38/M	4.0	4.2	3.8	3.0	70	Alcoholic hepatitis	
4.	Laxmi Narain	69/M	3.8	3.8	3.5	3.5	96	-do-	
		Mean	3.9						
		S.D.	±0.14						

TABLE E : Serum bilirubin levels of cases of hepatic coma of group I and group II.

Sl.No.	Name	Age (Yrs.)/ Sex	Serum bilirubin mg/100 ml Day 1st	4th	8th	12th	SGPT IU/Lit.
			(I)	(II)	(III)	(IV)	
Group I							
1.	Devi Deep	50/M	16.0	18.0	-Died-	-----	300
2.	Binno	20/F	7.7	6.0	5.0	4.8	320 Survived
3.	Bhoori	24/F	15.5	17.0	-Died-	-----	380
4.	Baiju 30/F	22.0	-Died-	-----	----		400
Group II							
1.	Kalika Pd	65/M	16.0	17.0	-Died-	----	450
2.	Sagun Bai	24/F	17.0	---Died	---	---	400
3.	Sharda	18/F	10.0	12.5	-Died-	-----	350
4.	Bhagirath	28/M	19.0	---Died--		----	300