

Liv.52 Studies in Acute Hepatitis

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ABSTRACT

Of 250 cases of acute hepatitis studied and followed for 1 year, half were given Liv.52 and the other half either steroid therapy or placebo. The efficacy of the drug with regard to clinical, biochemical and pathological improvement is discussed. Liv.52 restored the liver functions earlier without any side effects.

INTRODUCTION

The incidence of acute hepatitis in the Institute of Child Health and Hospital for Children, Egmore, Madras-8 is nearly 250 cases per year. Some of them go into complications like acute liver cell failure and a few advance to cirrhosis liver. Drug trial with *Liv.52 was undertaken with a view to study the efficacy of the drug in acute hepatitis in comparison to steroid therapy and placebo.

* Liv.52 is a combination of indigenous drugs said to be widely used in cases of liver diseases. It contains:

<i>Capparis spinosa</i>	65 mg
<i>Cichorium intybus</i>	65 mg
<i>Solanum nigrum</i>	32 mg
<i>Cassia occidentalis</i>	16 mg
<i>Terminalia arjuna</i>	32 mg
<i>Achillea millefolium</i>	16 mg
<i>Tamarix gannlliea</i>	16 mg
<i>Mandur bhasma</i>	33 mg

per tablet.

It is available in the form of drops where 8 drops = 1 tablet.

MATERIAL AND METHODS

Two hundred and fifty cases of acute hepatitis between 1-12 years of age were studied between September 1969 and end of November 1970. Detailed history and physical examination was done in all and only those which satisfied all criteria of acute hepatitis were taken for study. About 125 cases were given Liv.52 (Group I) while another 125 cases served as control. Of the control group, 35 were treated with Prednisone and antibiotics (Group II), the other 90 were treated with vitamin C and B complex tablets (Group III).

All were followed every week for the first 3 months and then monthly for next 6 months and finally once in 3 months, those which could not be followed regularly were excluded. Liv.52 was given as drops or tablet depending upon the age; above 5 years - 2 tablets thrice daily for 3 months, 2 to 5 years - 1 tablet thrice daily for 3 months, below 2 years 15-20 drops thrice daily for 3 months. Vitamin C and B complex were given as 1 tablet thrice daily for 3 months, Prednisone as 1 mg/kg/day for 2 weeks and ½ mg/kg/day for next 2½ months.

Liver function tests were done at the first visit and then every week till they became normal.

Liver biopsies were also done at the time of acute hepatitis in 112. Repeat biopsies were done (once in 3 months) in 52.

Table I						
No.	<1 year 10		1-3 year 176		3-12 year 64	
	M	F	M	F	M	F
250	6	4	102	74	40	24

Table II			
Income in Rs.			
No.	<100	100-200	>300
250	206 82%	39 16%	5 2%

Table III: Symptoms on Admission				
	Absent	+	++	+++
Anorexia	42	66	83	59
Fever	67	105	49	20
Vomiting	72	134	34	10
High coloured yellow urine	—	44	120	86
Pain Abdomen	75	125	50	—
Jaundice	33	75	102	40
Liver	—	50	148	52
Spleen	235	15	—	—
Oedema	208	21	11	10

Table IV		
No. of Days of Jaundice on Admission		
0-5 d	162	(65%)
5-10 d	74	(30%)
10-15 d	11	(4%)
>15 d	3	(1%)

Table V			
No.	Mild	Moderate	Severe
250	122	105	23
on Liv.52 (125)	56	56	13
Control (Vit. C & B-complex, prednisone-125)	66	49	10

Table VI									
Days taken for improvement	Liv.52			B.Complex			Prednisone		
	+	++	+++	+	++	+++	+	++	+++
Vomiting	1	2	3	2	4	6	1	3	5
Anorexia	1	4	6	5	13	24	4	8	9
Fever	1	2	3	3	6	7	1	2	3
Pain abdomen	2	5	5	4	7	10	2	4	6
High coloured yellow urine	5	7	8	8	10	16	6	8	9
Pale stools	2	4	4	3	5	6	4	6	6
Jaundice	5	6	8	7	9	16	6	8	8

The symptomatology like vomiting, anorexia, fever, etc., have improved earlier in the Liv.52 group compared to the placebo group. However there is no significant difference between Liv.52 and Prednisone group.

Table VII: Biochemical Results (in percentages)												
Weeks	Liv.52				B-Complex				Prednisone			
	1	2	4	8	1	2	4	8	1	2	4	8
Bilirubin-fall to 2.5 mgm and less.	30	50	15	5	15	45	20	20	20	50	20	10
Plasma Protein Status Quo			10				20				30	
Raise by 0-5 gm%			30				40				50	
0.5-1.0 gm		20	40			15	25				20	
Fall of SGOT to 40	20	56	20	4	10	50	30	10	15	50	33	2
Fall of SGPT to 40	25	58	10	7	8	57	20	15	16	45	24	15

1. Serum Bilirubin level at the 8th week falls to 2.5 mg and less in 80% in Liv.52 group, 60% in placebo, and 70% in Prednisone groups.
2. Rise of Plasma protein to 1 gm is seen in 60% of cases in Liv.52 group, 40% in placebo group and 20% in the Prednisone group (within 4 weeks).
3. Fall of SGOT to 40 units and below is seen in 76% in Liv.52, 60% in placebo and 65% in Prednisone group within 2 weeks.
4. Fall of SGPT to 40 units and below in 83% in Liv.52 group, 65% in placebo, 60% in Prednisone groups within 2 weeks.

Table VIII: Improvement After Treatment (in percentage)			
	Mild	Moderate	Severe
Liv.52	90	86	86
Controls	75	60	30
Vitamins Prednisone	85	79	80

As in many of disease conditions in children, males are more often affected than females, we do not consider any genetic predisposition for infective hepatitis.

Like any hospital group, majority are from lower economic strata.

Table III presents the symptom complex of infective hepatitis. We have graded the severity as +, ++ and +++. As expected, most of them had fever, vomiting anorexia and high coloured yellow urine; pain abdomen was not a prominent feature. 65% are brought within 5 days of appearance of symptoms of jaundice, and 30% within 10 days.

The distribution according to severity also happens to be more or less the same, even though the selection of cases on Liv.52 and placebo was strictly alternate.

In mild cases improvement with Liv.52 is 90%, improvement with Vitamins 75%, improvement with Prednisone 85%. In moderate, improvement with Liv.52 is 86%, with Vitamins 60% and with Prednisone 79%. In severe, improvement with Liv.52 is 86% with Vitamins 30% and with Prednisone 80% (assessment after 3 months).

PATHOLOGICAL RESULTS

1. Liver biopsy was done in 112 during the acute stage. Repeat biopsy was done in 52 after 3 months, of which 26 belonged to the Liv.52 group and 26 to the steroid and placebo group.
2. Twenty-one cases belonging to the Liv.52 and 21 in control group, Liver biopsy changes were minimal. In 8 (4 of each group) they were in the subsiding phase, 2 cases (one of each group) showed progressive phase.

CONCLUSIONS

1. Definite improvement in symptomatology in Liv.52 group and Prednisone group.
2. Better improvement in weight in Liv.52 group compared to the placebo and prednisone.
3. Restoration of Liver Function tests to normal earlier in Liv.52 group than in the Prednisone group and Vitamin Group.
4. Liv.52 has not produced any side-effects while Prednisone has produced moon face in a few cases.
5. Comparatively Liv.52 is more economical than Prednisone (Cost is about one third).

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