[*The Antiseptic* (1978): 75, 491]

Liv.52 in acute viral Hepatitis — Results of a double blind study

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INTRODUCTION

A double blind trial with Liv.52 in acute viral hepatitis was carried out in the Department of Gastroenterology, Osmania General Hospital, Hyderabad. Liv.52 is an indigenous compound (The Himalaya Drug Co.) useful in the management of viral hepatitis.

At present there is no specific drug available for the management of viral hepatitis which can ameliorate the symptoms and enhance recovery. Steroids, which enjoyed a prime position as the mainstay in the management of this condition in the past, have been shown to have no material effect on the recovery time, even though there was an initial rapid fall in the bilirubin levels. On the other hand, a high incidence of relapse and chronicity has been observed (Blum *et al* 1969).

Liv.52, whose composition is shown in Table I, has been claimed to be very effective protecting the liver, during experiments with animals on exposure to various hepatotoxic agents (Joglekar *et al* 1963), (Joglekar and Leevy 1970). A number of clinical trials have been conducted with this preparation in acute viral hepatitis and many of them have observed that this product has brought about rapid amelioration of symptoms (Ramalingam *et al* 1971-Gupta *et al* 1972).

Table I: Composition of Liv.52 tablets	
Capparis spinosa	65 mg
Cichorium intybus	65 mg
Solanum nigrum	32 mg
Cassia occidentalis	16 mg
Terminalia arjuna	32 mg
Achillea millefolium	16 mg
Tamarix gallica	16 mg
Mandur bhasma	33 mg
(Prepared in the juices and decoctions of various hepatic stimulants)	

MATERIAL AND METHODS

Fifty consecutive patients admitted to our Department, suffering from viral hepatitis were included in this trial. They were alternately allotted to one of the two groups, Group 'A' and Group 'B'. The diagnosis of viral hepatitis was based on clinical and biochemical features. Patients in whom there was a rapid deterioration and who lapsed into coma were excluded from this study. The response to treatment was recorded carefully at weekly intervals and liver function tests were also carried out at weekly intervals till the patients showed total biochemical recovery. No histological criteria were used. Patients in Groups 'A' were given Tab. 'A' and patients in Group 'B' received Tab. 'B' both in a dosage of 2 tabs/three times daily. Any side effects to the drug therapy were noted. In addition, all the patients were given complete bed rest. Supportive therapy with Glucose and B-Complex were given when necessary.

RESULTS AND DISCUSSION

The age and sex distribution in the two groups 'A' and 'B' are shown in Table II below:

Table II: Showing the age distribution in group 'A' and 'B'		
Age in years	Group–A	Group–B
11-20	4	9
21-30	9	4
31-40	4	7
41-50	6	2
51-60	2	3

Most of the cases were seen in the second to fourth decade of life; there was a male predominance in both groups.

On admission, the presenting symptoms were similar in both groups-namely, loss of appetite, high-coloured urine, jaundice, vomiting, fever and itching in a few cases. The period of symptomatology prior to admission varied from 4-10 days and averaged about 6 days in both groups. Physical signs on admission were one of the icterus with mild to moderate Hepatomegaly in both groups. There were no signs of hepatocellular failure.

In this trial, there were no drop-outs due to cases lapsing into hepatic coma. Liver Function Tests on admission are given in Table-III below for Group A and B.

Table III: Showing the liver function test on admission in Group A and B				
	Group-A		Group-B	
	Mean	Range	Mean	Range
Serum bilirubin in mg%	7.5	4 - 15	6.5	3.5-18
S.G.P.T. in units/ml	344	150-500	300	160 - 400
Serum alkaline phosphatase (in K.A. units)	14.5	8 - 27	14	8-16
Serum albumin in gm%	3.2	1.5-4.2	3.1	2.1-4
Serum globulin in gm%	3.6	2-4.8	3.4	2.2-4.4
Serum cholesterol in mg%	200	180-250	210	180-250
Prothrombin time in secs	17	15-25	17.5	15-28

It will be seen from the Table III, that the derangement of liver function in both groups were similar on admission and there was no appreciable dissimilarity.

It will be seen from Table IV, that at the time of discharge there was complete biochemical recovery in both groups. Clinical recovery as judged by return of appetite, sense of well-being, reduction in the degree of icterus, occurred faster than biochemical recovery.

Table IV: Showing liver function tests in both groups A and B at time of discharge				
	Group-A		Group-B	
	Mean	Range	Mean	Range
Serum bilirubin in mg%	1	0.5 to 1	1	0.5-1
S.G.P.T. in units/ml	50	40 to 90	65	50-100
Serum alkaline phosphatase in K.A. units%	10	6 to 11	10.5	5-14
Serum albumin in gm%	3.2	2.5-3.8	3.2	2.4-3.6
Serum globulin gm%	2.4	2.8-4.2	3.3	2.6-4.1
Serum cholesterol in mg%	190	180-220	180	160-230
Prothrombin time in secs	15	15-17	15	15-17

Total biochemical recovery took an average of 2.4 weeks (17 days) in Group-A (Range 2-4 weeks) and an average of 3.8 weeks (26.6 days) in Group-B (Range 2-6 weeks).

In Group-A complete clinical recovery took place by the end of first week, whereas in Group-B, clinical symptoms took much longer to clear. Specially marked was the rapid return of appetite in Group-A. There were no side effects like drug-rash, pruritis, etc., observed in both groups during treatment.

It will be seen that there was a faster total biochemical recovery in Group 'A' (2.4 weeks) compared to Group 'B' (3.8 weeks). Decoding of tablets were done at the end of the trial.

Tablets A contained Liv.52 and Tablets B contained placebo. Thus, it will be seen that in the patients receiving Liv.52 there was a faster biochemical and clinical recovery, compared to placebo group and at the same time there were no side effects in either groups. Thus Liv.52 appears to be an useful preparation in the management of viral hepatitis.

SUMMARY

A doubleblind trial with Liv.52 was undertaken in the Department of Gastroenterology, Osmania General Hospital on fifty cases of acute viral hepatitis; twenty five in each Group A and B and they were put on Tab. A and Tab. B respectively. The dosage schedule was 2 tabs./thrice a day, till they showed a total biochemical recovery. The complete biochemical recovery took an average of 2.4 weeks in Group 'A' (Liv.52 group) and an average of 3.8 weeks in Group 'B' (Placebo group). No side-effects were observed in both the groups. Liv.52 appears to enhance both the biochemical and clinical recovery faster than the placebo group. Total period of both clinical and biochemical recovery is significantly shorter in the patients receiving Liv.52.

ACKNOWLEDGEMENT

We thank Dr. M. Venkata Rao, Superintendent, Osmania General Hospital for allowing us to conduct this study and to publish this report.