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Liv.52 trial in Infective Hepatitis

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INTRODUCTION

Infective hepatitis which occurs in all parts of the World is caused by a virus which was named Virus IH by Neefee. Later an 'Expert Committee on Hepatitis' of the World Health Organisation named it Virus A. There is, yet no specific treatment for infective hepatitis though various drugs have been tried and several authors have claimed their beneficial effects. Liv.52 (The Himalaya Drug Co.) is an indigenous drug used in various hepatic disorders and claimed to have beneficial effects.

COMPOSITION

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.

in each tablet.
(Prepared with the juices and decoctions of many hepatic stimulants).

The present study was undertaken to evaluate its efficacy in acute infective hepatitis and to find out the clinical and biochemical changes in infective hepatitis of varying severity.

MATERIAL AND METHODS

Fifty patients with infective hepatitis (30 males, 20 females) in the age-groups of 15 to 50 years, who were admitted from July to December 1970 in the Medical Wards of S.N. Hospital, Agra, formed the material for this study. Thirty five patients were taken for trial in Group I while 15 acted as control, (Group II). Group I patients were given 2 tablets of Liv.52 t.d.s., along with intravenous glucose, while the control group received 500 mg. Vitamin C b.d. with intravenous glucose and corticosteroids.

Table I: Showing the age incidence in the different groups

Age distribution in years	No. of patients in Group I	No. of patients in Group II
10 – 20	10	5
21 – 30	22	6
31 – 40	2	2
41 – 50	1	2

All the patients were clinically investigated and liver function tests were performed which included serum bilirubin, alkaline phosphatase and zinc sulphate turbidity. These tests were repeated on the 7^{th}, 14^{th} and 21^{st} days. The efficacy of the drug was estimated by the relief of symptoms and restoration of liver function towards normal.

OBSERVATIONS

In both groups the largest number of patients were between 10 and 30 years.

As will be seen from the above tables, yellow coloration of eye (74%), loss of appetite (72%), pain in the abdomen (58%), nausea (48%), fever (34%), and vomiting (14%) were the common presenting symptoms. Eighty eight per cent of the patients had jaundice, at the time of admission, and the rest of the patients developed jaundice later on. Liver tenderness was found in 76% and enlargement was observed in 64% of the patients. One patient each in both the groups had cirrhosis of the liver with infective hepatitis superimposed on it. (see Table II).

Table II: Giving the symptoms and signs in the 2 groups of patients

Symptoms	Group I	Group II	Incidence %
Yellow coloration of the eyes	27	10	74
Loss of appetite	27	9	72
Pain in the abdomen	21	8	58
Nausea	14	10	48
Fever	15	2	34
Lassitude	8	1	18
Weakness and fatiguability	3	1	8
Vomiting	6	1	14
Haematemesis	2	—	4
Constipation	2	1	6
Loose motions	3	—	6
Swelling over feet	2	—	4
Bleeding per rectum	2	1	6
Itching	2	1	6
Burning during micturition	1	—	2
Drowsiness	1	—	2
Signs			
Jaundice	32	12	88
Tenderness of the liver	28	10	76
Enlarged liver	25	7	64
Oedema	2	1	6
Ascites	1	—	2
Spleen enlargement	1	1	4
Lymph nodes	—	1	2

Table III: Showing clinical improvement in symptoms

Symptoms	Group I: 35 cases treated with Liv.52	Group II: 15 cases control group
Anorexia	Within 7 days	More than 9 days
Pain in the abdomen	2 days	4 days
Nausea	3 days	7 days
Fever	2 days	7 days
Vomiting	3 days	More than 7 days
Sense of well-being	Within 3 days	More than a week

Various biochemical values at the time of admission and during the treatment, of the two groups, are given in Tables IV to VI.

Table IV: Showing the comparative evaluation of serum bilirubin improvement (Bilirubin level less than 2. mg.%)		
No. of days	Group I 35 patients No. of %	Group II 15 patients No. of cases
7 days	8 or 229%	2 or 13.3%
14 days	19 or 54.3%	4 or 26.%
21 days	6 or 17.1%	5 or 33.3%
More than 21 days	2 or 5.7%	4 or 26.6%

Table V: Comparative evaluation of serum alkaline phosphatase improvement less than 13 KA units		
No. of days	Group I No. of patients	Group II No. of patients
7 days	8 or 22.8%	2 or 13.3%
14 days	16 or 45.7%	3 or 20.0%
21 days	10 or 28.6%	9 or 60.0%
More than 21 days	1 or 2.9%	1 or 6.7%

EFFICACY OF THE DRUG

1. *Jaundice*: In 65.7% (23 patients of Group I) jaundice disappeared within 14 days as against the control group of 46.6%.

2. *Loss of appetite*: The appetite was improved within 7 days in Group I, while it took 9 days in Group II.

3. *Pain in the abdomen*: In most patients pain in the abdomen was relieved within two days with Liv.52 while in Group II it took four days or more.

4. *Nausea*: Nausea was another major complaint of the patients (48%) and most of them had anorexia and aversion for food. In 88% this symptom disappeared within 3 days in Group I, but in Group II patients nausea continued for more than a week.

5. *Fever*: Fever subsided in 2 days in Group I, but took about a week for Group II patients, to shed the fever.

6. *Lassitude, weakness and fatiguability*: Ten per cent of the patients, had these symptoms during the disease process. Weakness and fatiguability got ameliorated within a week after the start of treatment. All the patients treated with Liv.52 tablets reported a sense of well-being in 3 days' time.

7. *Vomiting*: In Group I patients, vomiting stopped in 3 days but lasted for a week in Group II patients.

8. *Serum bilirubin*: In 27 patients of Group I, the serum bilirubin level was less than 2 mg% as compared to only 6 patients in the control group, within 14 days.

9. *Alkaline phosphatase*: In the group of patients treated with Liv.52, alkaline phosphatase level reverted to normal (less than 13 KA units) in 24 or 68.8% as compared to only 5 or 33.3% in the control group, within 14 days (see Table V, above).

10. *Zinc sulphate turbidity*: In Group I patients zinc sulphate turbidity returned to normal in 21 or 60% within 14 days whereas in the control group only 83.3% showed this change (see Table VI).

DISCUSSION

Liv.52 is an indigenous drug and has been tried in various hepatic disorders. In the present series this drug was used to treat patients with infective hepatitis. The results of the clinical trial showed that Liv.52 is effective in the treatment of patients suffering from infective hepatitis. Clinical evaluation has also shown that there is marked improvement within a week in relieving symptoms like pain in the abdomen, vomiting and anorexia. Improvement in appetite and a sense of well-being were marked features in the patients treated with Liv.52 tablets. Similar observations have been reported also by Athavale (1966) and Sule *et al* (1968). This improvement is probably due to hepatic stimulation which was also claimed by Joglekar and Leevy (1970), Joglekar *et al* (1963), Karandikar *et al* (1963) and Sule *et al* (1968).

It may be noted that in patients with infective hepatitis the serum bilirubin levels remained high for a long time after the jaundice had subsided, which is due to intrahepatic cholestasis (Bockus, 1966) but in the group of patients treated with Liv.52 the serum bilirubin returned to near normal in 76.8% of the patients indicating that cholestasis was greatly relieved by reducing the intrahepatic oedema.

High levels of alkaline phosphatase which were present in 86.4% of the patients returned to normal in 68% within 14 days also indicating the relief of intrahepatic cholestasis.

In the present series, zinc sulphate turbidity which indicates the serum gamma globulin levels and hepatocellular necrosis, also returned to normal in 60% of the patients indicating that the drug helps in the regeneration of the hepatic cells, damaged during the disease process and prevents further necrosis of the cells. No patient in the present series treated with Liv.52 has reported till now with relapse of the jaundice and no side-effect of toxicity was met with during this study.

The mechanism of action of this drug seems to be by improved liver function and all observations, clinical, biochemical and histopathological researches may, with advantage, be directed to it.

SUMMARY: Fifty cases of infective hepatitis were studied in this controlled trial. Marked improvement in the symptoms like nausea, vomiting, anorexia, pain in the abdomen were observed within 3 days. Biochemically two patients showed rapid improvement in this series. Serum bilirubin in 78.8%, alkaline phosphatase in 68.8% and zinc sulphate turbidity in 60% returned to normal within 14 days of treatment.

No side effect, or toxicity was noted during the study and no patient returned to hospital with relapse of the jaundice.

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