ABSTRACT

Background: The action of hepatoprotective drugs is a subject of discussion. Despite the equivocal character of hepatoprotective drugs used, the effect is partly due to the placebo effect. In the literature are reports on Liv.52, a mixture of substances of plant origin that improves the subjective complaints as well as the objective condition of patients with liver disease.

Methods and Results: The effect of Liv.52 was investigated in a retrospective study for 19 patients with liver damage. In the majority of patients involved, liver damage caused by alcohol, steatosis and persistent hepatitis with no evidence of chronic hepatitis B and C. The authors investigated biochemical parameters (bilirubin, ALT, AST, ALP, TZR, cholesterol). The size of the liver was assessed by ultrasonography and the subjective status of the patients was recorded. Within one year of administration of the preparation, subjective improvement occurred, hepatomegaly diminished and the activity of aminotransferases declined.

Conclusions: Administration of Liv.52 can improve the subjective condition and clinical parameters in patients with liver damage, in particular in alcoholic liver damage and in steatosis. The effect is certainly due to better motivation on the patients’ part, better lifestyle and dietary measures. After one year of treatment, no undesirable side effects were detected.

Key words: hepatoprotective drugs, Liv.52, steatosis of the liver, ethanol liver damage.

Liv.52 is non-toxic hepatoprotective substance from THE HIMALAYA DRUG Co., Makali, Bangalore, INDIA.

Each tablet of Liv.52 contains:

Extract of herbs:
- Capparis spinosa: 65 mg
- Cichorium intybus: 65 mg
- Solanum nigrum: 32 mg
- Cassia occidentalis: 16 mg
- Terminalia arjuna: 32 mg
- Achilea milefolium: 16 mg
- Tamarix gallica: 16 mg
- Mandur bhasma: 33 mg

Auxilliary compound:
- Carboxymethylcelulose
- Boricin
- Mag. AL silicate
According to the company, Liv.52 is a mixture of herbal substances, which should improve metabolism of liver and improves secretion of gall bladder.

**GROUPS OF TESTED PATIENTS AND APPLIED METHODS:**
Effect of the hepato-protective, Liv.52 was followed up in a group of 19 patients with liver damage. The group was not homogenous, as it was not a directed study, but a retrospective description of the effect of substances. In a group of 19 sick persons, 13 were men, average age 36.7 (in the age span of 26 to 74 years), the rest were women, average age 37.3 (in the age span of 26 to 74 years). 12 patients had alcoholic damage of liver with proved steatosis, out of which 6 patients were diagnosed with fibrosis. For 4 patients, the diagnosis was chronic persistent hepatitis. Markers for infective hepatitis B and C type were negative in these patients. One of the patients with the addition of the PCR method proved positive for the presence of antibodies of hepatitis C. 12 patients, both alcoholics, there was detected a sporadic form of prophyria cutanea tarda with a certain extent of liver steatosis and secondary hemosiderosis.

Liv.52 was administered in a dosage of 2 x 2 tablets (b.i.d.) for a period of one year. As it was not a directed study, clinical and biochemical findings, which dated one year before initiation of the treatment and one year after the treatment, were used with these patients. The clinical parameters such as appetite, fatigue symptoms, dyspeptic troubles and tenderness pains in the right subcostal region were followed up.

The biochemical parameters were regularly followed up using routine methods, such as the serum bilirubin, activities of ALT and AST aminotransferases, ALP activity in serum, thymol opacity reaction (TZR), serum GMT and cholesterol. Ten patients during the two years of follow-up were simultaneously administered vitamin preparations.

A descriptive study was carried out, which determined averages and standard deviations of individual groups. Evaluation of significant statistical differences was carried out by a test of analysis of variation. The reason for using this test was that the composition of individual groups, was not normal. This was caused by a relatively small count of observations in individual groups and checked with FIT test. Analysis of variation is not so demanding on normal composition as the Student’s ‘T’ test.

**RESULTS**
Clinical studies were favorably influenced by Liv.52 in almost all patients. Appetite was decreased for 11 patients during one year before initiation of treatment, and only the appetite improved after one year of administration of LIV.52 for 8 patients. Fatigue symptoms were evident for 12 patients during one year before cure and decreased after one year therapy in 4 patients and for 6 patients, it disappeared. The dyspeptic troubles present in 10 patients were favorably influenced by this treatment in 9 cases. The tenderness in the right subcostal region found in 13 patients, receded in 8 and was relieved in 4.

From the following biochemical parameters, the results could be due to reduction of activities of ALT and AST aminotransferases. The results are stated in Graphs Nos.1 and 2, where differences of a significant level in conditions before and after treatment with LIV.52, better by 95% is marked with one asterisk and results better than 99% is marked with two asterisks.
Between the control and the group before treatment with LIV.52 there were no statistical differences.

Successful results on follow-up of serum GMT is shown in Graph No. 3.

Statistically significant reduction of cholesterol levels after this treatment is depicted in Graph No. 4.

Though the values of bilirubin after treatment declined the results were not statistically significant, as shown in Graph No. 5. However, in all patients the bilirubin was normal in all groups, which were followed up. There was no influenced on the value of TZR (Graph No. 6), which was normal in all groups. Normal values of ALP were also not influenced.
In the ultrasonic measurement of anteroposterior (AP) size of the right lobe of liver, was done after treatment, where there was significant diminishing (Graph No. 7).

Liv.52 has thus contributed to improvement in some important clinical symptoms and biochemical parameters, especially those that were not physiologically normal during the year of medication.

**DISCUSSION**

The spectrum of current medicinally utilized hepatoprotectives is small. It concerns routinely used preparations similar to Silimar: Flavobion, Legalon and Hepabene. The effectiveness of hepatoprotectives is a matter for continuous discussion, which concerns substances that effect metabolism or reinforce membranes of hepatocytes. The subjective state of patients is often improved by this treatment, even if it is partly a placebo effect. At any rate, these medications improve the patients holistically and also build up confidence of the patients towards their physician.

Clinical studies were carried out with Liv.52 for patients effected with liver damage (1), and cirrhosis of liver (1,2). Accordingly, tests on animals proved the effect of toxic damage of tetrachloride on liver (3) and the protective effect of Liv.52 against beryllium toxicity(4). The mechanism of effect is unclear. In human medicine, Liv.52’s effects on infectious hepatitis (5), chronic damage of liver with alcohol (1,6), steatosis of liver (7), initial state of liver cirrhosis (2), chronic active hepatitis (8), cases of anorexia and non specific cases of dyspepsia have been cited. Physicians in India published most of these clinical studies. In Czech Republic, Liv.52 was first observed in 1980s when patients brought it from Switzerland, USA, India, Australia. At the beginning of the 1990s, this preparation appeared in the market in some pharmacies and was distributed through other means.
The problem of following up the effect of Liv.52 with a homogenous group of patients in Czech Republic was that the preparation was not in current distribution, as it was not registered as a medicine, but only as a supplement. Patients who were followed up bought these medicines on their own and not through the prescription of a physician. The results in the improvement of the subjective state and in many laboratory parameters are promising, and as a consequence there is a demand for this medicine. Liv.52 is well tolerated, non-toxic and there are no side effects.

LITERATURE


