Clinical Study

Livercare in the Management of Hepatic Disorders - A Placebo Controlled Clinical Study

J.K.L. Das, Pralhad S. Patki, S.K. Mitra

ABSTRACT

Background: The action of hepatoprotective drugs is a subject of great discussion. In the literature are reports on LiverCare 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 LiverCare was investigated in a prospective study in 60 patients with liver disorder as a placebo controlled study. In the majority of patients involved, liver damage was caused by alcohol, steatosis and persistent hepatitis with no evidence of chronic hepatitis B and C. This study investigated effect of drug therapy on biochemical parameters (bilirubin, ALT, AST, ALP, cholesterol). The size of the liver was assessed by ultrasonography and the subjective status of the patients was recorded. Within one month of administration of the preparation, subjective improvement occurred, hepatomegaly diminished and the activity of aminotransferases declined. Patients on placebo therapy however did not show any changes in any of the parameters.

Conclusion: Administration of LiverCare 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 LiverCare, better lifestyle and dietary measures. After six months of treatment, no undesirable side effects were detected.

Key words: Hepatoprotective drugs, LiverCare, steatosis of the liver, ethanol liver damage.

INTRODUCTION

The liver holds a position of singular importance in the human system. It effectively controls the numerous metabolic processes via the "Metabolic Pool" by its secretary and excretory functions, plasma protein synthesis, reticuloendothelial storage and other important functions. Its metabolic functions include detoxification and active participation in the metabolism of proteins, fats, carbohydrates, minerals and water. Diseases of the liver throw the entire system out of gear.1 So also many systemic diseases are responsible for affections of the liver. In spite of the tremendous strides in modern medicine, as yet there is no drug developed in modern medicine that stimulates the functions of the liver, protects it from damage or helps in the regeneration of hepatic cells. Clinical studies including therapeutic functional results or response, and acute and chronic toxicity studies have shown LiverCare to be an effective therapeutic agent as reported in many research studies.

Cirrhosis of the liver, enlarged liver either due to fatty changes or cloudy degeneration due to some toxic causes, chronic active hepatitis and other cases of supposed liver affection or enlargement were studied in this series.2 The therapy of these and other conditions still remains limited in spite of the advances in knowledge of etiological factors, pathogenesis, diagnosis etc.

LiverCare is reported to improve the hepatic cell function, act as a hepatic stimulant, anabolic, choleretic and as a corrective and curative in many hepatic disorders including precirrhotic and early cirrhotic conditions, enlarged or toxic liver, infantile liver disorders, nutritional disorders, hyperlipaemia etc.

LiverCare capsules contains extracts of Capparis spinosa, Cichorium intybus, Solanum nigrum, Terminalia arjuna, Cassia occidentalis, Achillea millefolium and Tamarix gallica.

Present study was carried out to evaluate the efficacy and safety of LiverCare capsules in the management of liver diseases in comparison to placebo.

MATERIAL AND METHODS

Sixty two cases of liver disorders were admitted at the Patna Medical College Hospital and are included in the study. Diagnosed cases of infective hepatitis were not included in the study. Out of 62 cases, 2 cases were excluded as these were of amoebic hepatitis and Wilson’s disease, and diagnosis was confirmed by hepatic biopsy and histological studies. Thus 60 cases were studied in the final phase reported in this clinical trial. Thirty patients received LiverCare capsules where as remaining 30 patients were on conventional therapy and identical. Patients were free to withdraw from...
the study if they so desired. The study protocol was approved by local ethics committee.

On admission history, symptoms, signs and clinical findings were noted. Blood counts, urine examination, liver function tests and other investigations were performed. Liver biopsy with VIM-Silverman needle was performed in all cases at suitable times during their illness to confirm diagnosis. The histopathological studies and reports were carefully studied and analysed.

Signs and symptoms, and biochemical tests were recorded after a few days and the results were tabulated as “Good”, “Fair” and “Poor” on the basis of clinical scores. The side or toxic effects of LiverCare, if any, were carefully looked for and noted.

All the patients were put on conventional line of treatment according to their main affliction. In addition they were given LiverCare capsules or placebo, 1 capsule twice a day, for one month. Later on they were maintained on LiverCare1 capsule once a day or placebo for six months. The response was judged as “Good” when there was total clinical improvement, regression of signs and biochemical findings: “Fair”, when there was partial clinical improvement and regression of signs; and “Poor” when there was no change in the clinical status. 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.

RESULTS

Demographic data of patients included in the study (Table 1) indicates that majority of the patients were men.

Clinical results were favourably influenced by LiverCare in almost all patients. Appetite improved for 21 patients during first month of drug therapy in LiverCare group (Table 2 and Figure 1). Fatigue symptoms were evident for 26 patients before drug therapy and decreased after one month therapy in 21 patients and for 6 patients, in placebo group. The dyspeptic troubles present in 19 patients were favourably influenced by this treatment in 14 cases. The tenderness in the right subcostal region found in 18 patients in LiverCare group, receded in 11. All these findings were statistically significant (Table 3 and Figure 2). ‘Good’ response was evident in 21 out of 30 patients in LiverCare group.

Though the values of bilirubin after treatment declined the results were not statistically significant, however, in all patients on Livercare therapy the bilirubin was normal at six months. The serum levels of liver enzymes showed statistically decreased trend in LiverCare group where as placebo group showed a non significant change (Figures 3-5).

There was no significant change in other parameters like skin and temperature. Nausea and vomiting showed significant improvement in LiverCare group.

The adverse effect profile was studied in these patients. It was seen that the formulation was very well tolerated. (Table 4). Gastric irritation in one patient on LiverCare eventually subsided without any change in medication and the patient continued on LiverCare. Three patients on placebo had gastric irritation.

DISCUSSION

Liver disorders are a common group of diseases in tropical countries due to poor hygiene and dietary habits. In addition, alcohol consumption is also increasing adding
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Figure 1: Effect of LiverCare therapy on Loss of Appetite

![Bar chart showing effect of LiverCare therapy on Loss of Appetite](image1)

Figure 2: Effect of LiverCare therapy on Liver Tenderness

![Bar chart showing effect of LiverCare therapy on Liver Tenderness](image2)

Figure 3: Effect of LiverCare therapy on Serum Bilirubin

![Bar chart showing effect of LiverCare therapy on Serum Bilirubin](image3)

Figure 4: Effect of LiverCare therapy on SGPT

![Graph showing effect of LiverCare therapy on SGPT](image4)

Figure 5: Effect of LiverCare therapy on SGOT

![Graph showing effect of LiverCare therapy on SGOT](image5)

Further problems in liver problems. Cirrhosis is a chronic disease due to liver cell damage and proliferation of fibrous tissue. The damage eventually becomes extensive and normal structure of the liver is distorted and its function becomes impaired. This abnormality affects almost every physiologic process including digestion, endocrine, circulatory and other metabolic functions. These changes themselves slowly aggravate liver damage. The aim of the medication in these patients is to prevent metabolic abnormalities and the progression of the liver cell damage. The traditional healers approach to management of the chronic liver disease is to regulate and strengthen the liver, gastrointestinal and immune system. The regulation of gastrointestinal system may improve the general well being of the patients as well as improvement of the constipation may prevent the absorption of harmful substances and indirectly decrease ascites. The protection of liver cells against toxic materials including drugs, lipid peroxidation and free radical injury may decrease inflammation, improve liver blood flow and ultimately help in reduction of ascites and blood pressure. Immune dysfunction is component of liver disease and thus immunomodulation by herbal therapy prevent oxidative stress, inflammation and strengthens the detoxifying power of liver cell. All these effects strengthen liver and regulate body metabolism and ultimately inhibit further liver cell damage in the favor of their regeneration. In present study, the efficacy of herbal medicine LiverCare medication on liver cirrhosis was investigated. In cirrhotic patients treated with LiverCare for 6 months, the serum ALT and AST levels were significantly decreased. This decrease in serum ALT and AST levels in LiverCare treated patients in part may be due to the protective effect of this drug on liver cells following restoration of liver cell membrane permeability. Long term study may be necessary to know the effect of Livercare on regression of enlarged liver in various liver diseases.

CONCLUSION

Present study indicates good clinical efficacy of LiverCare in management of liver diseases. This novel herbal formulation is well tolerated.

REFERENCES