THERAPEUTIC AND PROPHYLACTIC EFFECT OF LIPAMIDE ON THE FUNCTIONAL STATE OF THE LIVER AND THE CLINICAL COURSE OF CIRRHOSIS AND CHRONIC HEPATITIS

Bekmuradova Makhsuda Salkhidinovna, PhD, Assistant
Department of Propaedeutics of Internal Diseases
Samarkand State Medical University
Samarkand, Uzbekistan

Abstract: The present study investigates the therapeutic and prophylactic effect of lipamide on the functional state of the liver and the clinical course of cirrhosis and chronic hepatitis. An analysis of clinical and biochemical parameters demonstrated that the use of lipamide contributes to the improvement of liver function, normalization of key biochemical indicators, and reduction in the severity of clinical manifestations of the disease. The obtained results indicate the potential of lipamide as a component of комплексной терапии chronic liver diseases and substantiate its clinical efficacy.

Keywords: lipamide, liver, liver function, liver cirrhosis, chronic hepatitis, hepatoprotectors, clinical course, biochemical parameters, treatment, prevention, combination therapy.

ЛЕЧЕБНО-ПРОФИЛАКТИЧЕСКОЕ ВЛИЯНИЕ ЛИПАМИДА НА ФУНКЦИОНАЛЬНОЕ СОСТОЯНИЕ ПЕЧЕНИ И КЛИНИЧЕСКОЕ ТЕЧЕНИЕ ЦИРРОЗОВ И ХРОНИЧЕСКИХ ГЕПАТИТОВ.

Бекмурадова Махсуда Салхидиновна PhD, ассистент
кафедры пропедевтики внутренних болезней
Самаркандский государственный медицинский университет
Самарканд, Узбекистан

Аннотация: В настоящем исследовании изучено лечебно-профилактическое влияние липамида на функциональное состояние печени и особенности клинического течения циррозов и хронических гепатитов. Проведён анализ

клинико-биохимических показателей позволил установить, что применение липамида способствует улучшению функции печени, нормализации основных биохимических параметров и снижению выраженности клинических проявлений заболевания. Полученные результаты свидетельствуют о перспективности использования липамида в составе комплексной терапии хронических заболеваний печени и обосновывают его клиническую эффективность.

Ключевые слова: липамид, печень, функция печени, цирроз печени, хронический гепатит, гепатопротекторы, клиническое течение, биохимические показатели, лечение, профилактика, комплексная терапия.

Introduction. Liver cirrhosis (LC) and its treatment remain among the most challenging problems of modern hepatology. The severe course of the disease, the frequent ineffectiveness of therapy, and the unfavorable prognosis place this condition among the most pressing issues in contemporary medicine [1,2]. Chronic diffuse liver diseases occupy a leading position in the structure of digestive system disorders and represent an important epidemiological, social, and clinical problem in modern healthcare [5,6]. In the human body, lipoic acid amide is formed from lipoic acid under the influence of enzymes. Lipamide acts as a coenzyme actively involved in the oxidative decarboxylation of pyruvic acid, α-ketoglutaric acid, and other α-keto acids. In patients with chronic liver diseases, the levels of lipoic acid and its amide in the blood are reduced. Several authors [3,4] have reported a beneficial effect of lipamide on liver function and the clinical course of chronic hepatitis and cirrhosis. However, existing studies have been conducted on small and clinically heterogeneous samples [7]. Moreover, lipoic acid amide has often been used in combination with other medications.

Objective of the study. To evaluate the immediate and long-term effects of lipamide on the functional state of the liver and the clinical course of cirrhosis and chronic hepatitis.

Materials and Methods. Lipamide was administered to 95 patients with liver cirrhosis (75 with portal cirrhosis, 12 with biliary cirrhosis, and 8 with post-

necrotic cirrhosis) and 42 patients with chronic hepatitis. Mild hepatocellular insufficiency was observed in 15 patients, moderate in 118, and severe in 4. Marked ascites was present in 2 patients, moderate ascites in 2, and mild ascites in 10 patients. All patients had a history of Botkin's disease (hepatitis A). Among patients with chronic hepatitis, mild hepatocellular insufficiency was observed in 30 cases and moderate in 12. Clinical complaints and objective findings corresponded to the severity of hepatocellular insufficiency and portal hypertension. All patients received only the study drug (lipamide) in tablets at a dose of 25 mg twice daily for 20 days, along with diet No. 5 as recommended in clinical nutrition.

Results. Clinical parameters were monitored daily, and liver function tests were performed on days 10 and 20. At the end of the treatment course, patients showed significant improvement in general well-being, reduction in pruritus, and decreased jaundice severity. There was also a reduction in the size and intensity of telangiectasias. Headaches became less frequent or disappeared. Enlarged liver and spleen sizes decreased, particularly in patients with chronic hepatitis. Hemorrhagic manifestations resolved, tongue coating diminished, and hepatic fetor disappeared. Liver functional status improved significantly, as evidenced by statistically significant reductions in serum bilirubin, γ-globulins, and α2-globulins (in chronic hepatitis), as well as shortening of heparin time. At the same time, levels of albumin, prothrombin, total choline, serum cholinesterase, and total protein (in cirrhosis) increased. The detoxification function of the liver also improved. Normalization of total cholesterol levels was observed. Additionally, favorable changes were noted in urinary urobilin, urobilinogen, and bilirubin levels, along with increased daily diuresis. These positive changes in clinical and functional parameters were already evident by day 10 of treatment. However, in two patients with advanced portal cirrhosis (one in terminal dystrophic stage and another with severe hepatocellular insufficiency and pronounced ascites), lipamide showed no beneficial effect. Twenty days after discontinuation of lipamide, 42 patients were re-examined, and a partial reduction in therapeutic effects was observed, likely due to persistent or reactivated pathological processes. To further confirm the

beneficial effect of lipamide and exclude confounding factors such as diet, hospitalization, and psychotherapeutic influence, an acute study was conducted to assess its effect on serum total choline and cholinesterase levels. In 21 patients with cirrhosis and chronic hepatitis, these parameters, along with lipamide levels, were measured before administration and 2 and 24 hours after a single oral dose of 50 mg. Lipamide levels were determined using thin-layer chromatography. The results showed that after 2 hours, total choline increased from 0.22 to 0.25 mg% (±0.0014; $p<0.001$), and cholinesterase from 11.04 to 12.1 mg/mL/hour (±0.15; $p<0.001$). After 24 hours, levels decreased toward baseline (choline to 0.23 mg%, cholinesterase to 11.6 mg/mL/hour; $p<0.001$). Thus, the acute study confirmed the positive effect of lipamide on liver function tests. Serum lipamide levels increased from 7.2 μg/mL to 10.6 (±0.28; $p<0.001$) after 2 hours and returned to baseline after 24 hours (7.9 ±0.22; $p<0.001$). Control data from 42 patients receiving only Lushkevich's mixture alongside diet No. 5 for 20 days showed no improvement, thereby confirming the beneficial effect of lipamide on clinical manifestations and liver function.

Conclusion. In patients with chronic hepatitis and liver cirrhosis with mild to moderate hepatocellular insufficiency, lipamide administered at a dose of 50 mg per day (25 mg twice daily) for 20 days has a beneficial effect on the clinical course and functional state of the liver. The absence of side effects and its positive impact on clinical and biochemical parameters support the recommendation of lipamide for the treatment of chronic hepatitis and liver cirrhosis. However, the treatment course should last at least 20 days.

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