UDC 616.35:36-004-085.272:615.275/.276:615.375-036.8 DOI http://doi.org/10.30978/GS-2022-1-54

Effectiveness of the Erbisol[®] class in complex treatment of patients with liver cirrhosis

Y. Susak¹, I. Slychko², O. Nikolayenko³, O. Dyrda⁴, V. Korobko⁴, M. Maksymenko¹

¹ Bogomolets National Medical University, Kyiv

² Shupyk National Healthcare University of Ukraine, Kyiv

³ Erbis Ltd, Kyiv

⁴ Emergency Hospital of Kyiv

⁵ Institute of Nuclear Medicine and Radiation Diagnostics of the National Academy of Medical Sciences of Ukraine, Kyiv

🖂 Ivan Slychko: slich46@gmail.com

Y. Susak, https://orcid.org/0000-0002-5102-485X I. Slychko, https://orcid.org/0000-0001-5964-3287 O. Nikolayenko, https://orcid.org/0000-0002-5371-7983 O. Dyrda, https://orcid.org/0000-0002-0736-5905

V.Korobko, https://orcid.org/0000-0002-8948-5459

M. Maksymenko, https://orcid.org/0000-0003-2507-1238

Liver cirrhosis (LC) frequently results in severe complications, high mortality rate and disability in patients suffering from this disease, thus necessitating the study of its course, diagnosis and management. The principle of gradual elimination of pathological syndromes is fundamental in the treatment of LC. Complex therapy requires the use of medicines that act on the general links of pathogenesis. As LC causes damage to the cellular structure of the liver as well as interferes with the normal functioning of other organs and systems, it requires the prescription of medicines with metabolic and immunomodulatory properties. Experimental and clinical results of trials of *Erbisol* injections necessitated the study of their therapeutic properties in patients with LC. Immunomodulation, hepatoprotection and hepatoreparation play a crucial role in the management of LC.

OBJECTIVE — to investigate the effectiveness of the *Erbisol*[®] class medications in complex treatment of patients with liver cirrhosis.

MATERIALS AND METHODS. The analysis of treatment outcomes in 57 patients with LC was carried out and is presented in this study. Patients were divided into two groups with 28 patients (15 males and 13 females) in the main group and 29 patients (18 males and 11 females) in the control group. All patients received a comprehensive basic therapy for the management of LC. The main group was also prescribed intramuscular injections of the *Erbisol®* class medicines (*Erbisol® Extra, Erbisol® Ultrapharm*) that were administered according to the manufacturer's instructions (Erbis Ukraine, https//erbisol.com.ua). Specific guidelines were followed during the examination of the patients. In both groups, patients with compensated LC had their liver function assessed according to the Child-Pugh scoring system. Their point scores were added and classified as class B: 8—9 points. All patients were distributed according to gender, age, duration of the disease and severity of the main syndromes. The effectiveness of treatment was evaluated based on clinical symptoms, severity, blood tests, elastography ultrasound and Doppler ultrasonography.

RESULTS. The use of *Erbisol*[®] medicines significantly improved the dynamics of the clinical course of cirrhosis, relieved astheno-vegetative disorders, had a pronounced immunocorrective effect that was evidenced by changes in the ratio of serum protein fractions. In the main group, treatment outcomes were characterized by moderate regeneration of the liver parenchyma. It was confirmed by hemodynamic parameters and elastography data. The complex use of *Erbisol*[®] drugs helps to slow down and regress fibrosis, contributing to the favorable course of the disease.

CONCLUSIONS. Complex treatment with the *Erbisol*[®] class medications had a positive action on clinical and blood biochemical parameters and ensured a membrane-protective effect, regression of fibrosis, and improved hepatic blood flow.

KEYWORDS

liver cirrhosis, management, hepatocytes, Erbisol® class medication, elastography.

ARTICLE • Received 2021-12-21 • Received in revised form 2022-02-16 © General Surgery, 2022 Liver cirrhosis (LC) is a life-threatening global health problem that is characterized by the formation of regenerative nodules due to different liver diseases [4, 7]. Many patients can progress to upper gastrointestinal bleeding (UGIB), hepatic encephalopathy (HE), hepato-renal syndrome and hepatocellular carcinoma (HCC) in the decompensated stage. Hepatitis B virus (HBV) infection, hepatitis C virus (HCV) infection, and alcohol consumption are considered to be the major etiological factors of LC [1, 11, 14].

Liver cirrhosis (LC) frequently results in severe complications, high mortality rate and disability in patients suffering from this disease, thus necessitating the study of its course, diagnosis and management [2, 3, 10]. Liver cirrhosis is a serious, relatively prevalent, cause of global morbidity and mortality; recent estimates demonstrated that liver cirrhosis accounted for nearly 2.5% of the total global deaths in 2017 — around 1.3 million deaths, ranking it as the 11th leading contributor to global mortality [6, 9, 12]. The distribution of liver cirrhosis shows notable ethnic and socioeconomic variations.

LC should be considered as a severe, progressive disease with systemic manifestations [7].

Until recently, liver cirrhosis was considered an irreversible process, which is manifested by «degradation» of the liver parenchyma and its replacement by collagen-rich tissues. Nowadays, most scientists consider fibrosis as a result of repeated damage and restoration of hepatocytes, and replacement by connective tissue — as a reparative process in response to chronic inflammation [4, 8, 17].

About 80.0 % of all diagnosed LC cases had an active course, and more than half of them were complicated with ascites. From 23.0 % to 43.0 % of patients passed away about one year after the onset of ascites. Early recognition and monitoring of liver cirrhosis are the cornerstones of optimal treatment outcomes and risk reduction in terms of complications observed in cirrhotic patients [6, 10]. The problem of surgical treatment and conservative therapy for LC has been comprehensively covered in the studies of many authors, however, surgical interventions are not effective enough, often entailing severe consequences [16]. Liver transplantation in LC effectively prevents the development of complications and, since 1980, has been excluded from the category of experimental operations. Nevertheless, Ukraine is experiencing certain difficulties in making this operation common in the treatment of patients with LC due to its high cost and the problems connected with organ donation [12, 15]. Implementation of the efferent methods allows producing syndromic effects on various pathogenetic factors that determine the activity of the pathological process [6, 13, 14].

Thereby, many issues, regarding the treatment tactics of LC, remain unresolved. The principle of gradual elimination of pathological syndromes becomes the main vector in the treatment of LC. Complex therapy in management of patients with LC requires drugs that act on the general links of pathogenesis. As LC causes damage to the cellular structure of the liver as well as interferes with the normal functioning of other organs and systems, it requires the prescription of medicines with metabolic and immunomodulatory properties [3, 8].

Experimental and clinical results of trials of *Erbisol* injections necessitated the study of their therapeutic properties in patients with LC. Immunomodulation, hepatoprotection and hepatoreparation play a crucial role in the management of LC.

In the pharmacological market of Ukraine there are original drugs of the *Erbisol*[®] class (*Erbisol*[®] *Extra*, *Erbisol*[®] *Ultrapharm*, *Erbisol*[®]) manufactured by Erbis Ukraine LLC (erbisol.com.ua). The drugs are composed of a complex of natural non-hormonal organic compounds, isolated from animal embryonic tissue, which contains glycopeptides, peptides, nucleotides, and amino acids. The immunomodulatory effect of these drugs is characterized by activation of macrophages of NK cells (CD3-/CD16/CD56⁺) and T-killers (CD3⁺/CD16⁺/CD56⁺), which have a high potential and destroy abnormal cells, thereby providing antifibrotic protection of the body [5].

Additionally, in patients with immunosuppression of T-cell immunity, the *Erbisol*[®] class normalizes the number of T-lymphocytes (CD3⁺), T-helpers (CD4⁺), cytotoxic T-lymphocytes (CD8⁺), reducing the number and activation of B-lymphocytes. These drugs restore the balance of Th1 and Th2 cytokines by enhancing the production of interleukins (IL)-1, IL-2, IL-12, tumor necrosis factor α (TNF- α), and interferons (α , γ , β), which generally activate cellular immunity and suppress the production of IL-4 and IL-10. *Erbisol*[®] drugs activate hepatocyte repair processes, thus promoting liver regeneration, which is important in improving the course of the disease [5].

OBJECTIVE — to investigate the effectiveness of the *Erbisol*[®] class medications in complex treatment of patients with liver cirrhosis.

Materials and methods

The investigation is based on the analysis of treatment outcomes in 57 patients with liver cirrhosis, who were treated at the Kyiv Emergency Hospital from 2019 to 2021. Patients were randomly divided into two groups (the main group and the control group). The main group included 28 patients (15 males and 13 females). The control group consisted of 29 patients (18 males and 11 females). The age of patients ranged from 38 to 65 years (mean age 53.2 ± 1.2 years), mean disease duration -5.6 ± 0.6 years.

The degree of liver failure was determined according to the scoring system suggested by C. Child, J. Turcotte (1964) and modified by R. Pugh et al. (1973). In the main and control groups, patients with compensated LC had their liver function assessed according to the Child-Pugh scoring system. Their point scores were added and classified as class B: 8–9 points respectively. Patients were distributed according to gender, age, duration of the disease, and severity of the main syndromes.

Chronic alcoholism accounts for 65 % of LC cases, being the most common cause of LC, viral hepatitis -13 %, contact with pesticides -14 %, cryptogenic cirrhosis -8 %.

All patients (main and control groups) received a comprehensive basic therapy for the treatment of LC, which included infusions, aminoacids, saluretics, hepatoprotectors, glucose, vitamins, antioxidants, etc. For the treatment of ascites syndrome, the efferent methods were used and included staged treatment: laparocentesis, ascitoexfusion, ascitosorption-filtration, reascitoinfusion [2, 4]. The efferent treatments are performed at the department of extracorporeal detoxification.

During laparocentesis, withdrawal of ascitic fluid was performed into sterile containers. In order to achieve a higher concentration of ascitic fluid, it was necessary to remove residual water, electrolytes and low molecular weight compounds by using ultrafiltration with a multiFiltrate system. Immediately after ultrafiltration, the concentrate was sorbed on a hemosorbent for detoxification. *Extra*corporeally concentrated ascitic fluid was reinfused intravenously over one to three sessions. 1.0-1.5 L of concentrated ascitic fluid was injected in one session. The rate of reinfusion was 3-5 ml/min.

Plasmophoresis was performed on domestic blood fractions. Plasma exfusion was up to 1.0 to 1.4 L (average 1.2 ± 0.1 L) per operation. Replacement of plasma of concentrated ascitic fluid was performed at a rate of 1:1 or 1.0:1.5 in relation to the volume of exfused plasma, depending on the protein content in ascitic fluid concentrate [16].

The main group was also prescribed intramuscular injections of the *Erbisol*[®] class medicines (*Erbisol*[®] *Extra*, *Erbisol*[®] *Ultrapharm*) that were administered according to the manufacturer's instructions (*Erbis Ukraine*, https://erbisol.com.ua) (Table 1).

One treatment course lasts 22 days: 20 ampoules of *Erbisol*[®] *Ultrapharm* (U) + 40 ampoules of *Erbisol*[®] *Extra* (+).

All patients, who were admitted to the clinic, were examined according to a special algorithm, which included the study of complaints, medical history, objective examination data, and the results of laboratory, instrumental, radiological and ultrasonographic examination.

Elastography was performed on a Radmir Ultima scanner in the area of the right intercostal spaces using transabdominal convex (5 mHz) and linear (10 MHz) sensors for surface structures (3.5 MHz) sensor. The median value of these measurements characterized the liver parenchyma stiffness, and the result was expressed in kilopascals (kPa).

For interpretation of the results and staging of fibrosis, we referred to the study by L. Castera et al., according to which the level of fibrosis F0 corresponded to the value of elastography $5.8 \text{ kPa} \le \text{F1} \le 7.2 \text{ kPa}$ (minimal changes), $7.2 \le F2 \le 9.5$ kPa (moderate), $9.5 \le F3 \le 12.5$ kPa (significant), $F4 \ge 12.5$ kPa (liver cirrhosis) [9]. In addition to general clinical blood tests and coagulogram, laboratory parameters of the functional state of the liver were studied. The immune status was also assessed at various stages of treatment, which included determination of plasma protein composition and immunoglobulins. Ultrasound Doppler flowmetry was used. The following parameters of hepatic blood flow were determined: artery diameter, blood flow velocity, portal vein was visualized so that the angle between the vessels and the sensor was less than 60°. The velocity of blood circulation in the portal vein and its diameter were measured during exhalation for 2-3 s [4].

This study evaluated the effectiveness of the $Erbisol^{\mathbb{B}}$ class medicines in the treatment of patients with LC based on clinical symptoms, biochemical

Table 1. Recommended regimen of drugs administration of Erbisol® Extra and Erbisol® Ultrapharm

Hours -	Day																					
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22
6:00-9:00				2E																		
21:00-24:00	U	U	U	U	U	U	U	U	U	U	U	U	U	U	U	U	U	U	U	U	Е	Е

Note. $E - Erbisol^{\circ} Extra (1 ampoule = 2 ml), 2E - 2 ampoules of Erbisol^{\circ} Extra (4 ml); U - Erbisol^{\circ} Ultrapharm (1 ampoule = 2 ml).$

parameters, and the findings of shear wave elastometry and doppler flowmetry.

Informed consent was given by patients and the study was conducted in compliance with the Helsinki Declaration of 1975 and its revision in 1983.

Statistical processing was performed by using a licensed computer application program *Statistica (Stat-graf* and *StatSoft)*. The data was entered and verified using *Microsoft Excel*. The quantitative data were expressed as mean and standard error of the mean. Student's t-test and Mann–Whitney U-test were used to analyze quantitative data. Normality of the data was assessed using Shapiro–Wilk test. A two-tailed $p \leq 0.05$ was considered statistically significant.

Results

The findings of the study demonstrated that, in the main group, the *Erbisol*[®] class medicines significantly improved the dynamics of the clinical course of LC (Table 2), which was evidenced by reduced symptoms of astheno-vegetative disorders (weakness, fatigue and inhibition) and dyspepsia (flatulence, heaviness and pain in the right hypochondrium). In almost all patients, icteric skin and sclera were successfully treated. In contrast to the main group, after treatment, patients in the control group were still complaining of nausea, pain in the epigastric region and in the right hypochondrium (p < 0.05). In the control group, patients had yellowing of the skin and sclera (p < 0.05). Both subjective and objective signs of the disease after treatment indicate poorer treatment outcomes in the control group.

In patients, who received complex treatment with the *Erbisol*[®] class medication, the duration of dyspeptic and astheno-neurotic syndromes was significantly reduced. The duration of hyperenzymemia was decreased by 4 days and hyperbilirubinemia — by 3 days. Complex therapy helped reduce the average number of hospital bed days by 6.5 days.

These data demonstrate a positive effect of the *Erbisol*[®] class medications on the duration of clinical symptoms. The dynamics of the laboratory data shows that, in the main group, the liver synthesis and detoxification function started improving within the 1st week of treatment, while, in the control group, in most cases, these indicators did not improve by the end of treatment (Table 3).

Table 2. Clinical and laboratory characteristics
of the effectiveness of comprehensive treatment
of patients with LC

Syndromo	Duration, days					
Syndrome	Main group	Control group				
Dyspeptic syndrome	8.6 ± 0.6	$10.8\pm0.8^{*}$				
Astheno-vegetative syndrome	13.8 ± 1.2	$17.6\pm1.2^{*}$				
Jaundice syndrome	16.2 ± 1.8	19.2 ± 1.0				
Hyperenzymemia — ALT	10.1 ± 1.3	$13.5\pm1.2^{*}$				
Ascitic syndrome	10.9 ± 1.1	19.2 ± 2.1 **				
Average bedday	11.3 ± 1.6	$17.8\pm0.9^{*}$				

Note. Statistically significant difference: * p < 0.05; ** p < 0.01.

Table 3. The main biochemical indicators of the functional state of the liver before and after treatment

Indicator	Norm	Main	group	Control group			
Indicator	Norm	Before	After	Before	After		
Total protein, g/L	65 - 85	56.20 ± 0.85	63.40 ± 0.81	56.10 ± 0.72	$57.6\pm0.6^*$		
Albumins, g/L	35 - 50	22.50 ± 0.15	28.6 ± 0.2	22.6 ± 0.2	23.6 ± 0.2		
Total bilirubin, µmol/L	8.5 - 20.5	57.22 ± 0.24	34.22 ± 0.24	57.12 ± 0.24	52.22 ± 0.24		
ALT, U/L	4-40	89.2 ± 2.2	51.4 ± 2.4	90.4 ± 2.8	$76.3\pm2.6^*$		
AST, U/L	5 - 34	76.4 ± 1.8	41.2 ± 1.6	75.5 ± 1.6	48.3 ± 1.3		
GGTP, U/L	8-54	83.4 ± 2.2	56.3 ± 2.1	82.4 ± 2.2	60.2 ± 2.1		
Thymol test, units	0-4	4.9 ± 0.2	3.2 ± 0.3	4.9 ± 0.3	3.8 ± 0.2		
Alkaline phosphatase, U/L	35-123	150.2 ± 4.6	128.6 ± 3.8	149.8 ± 4.4	130.6 ± 3.6		
Urea, mmol/L	2.5 - 8.2	9.8 ± 0.2	7.8 ± 0.5	9.9 ± 0.4	8.4 ± 0.6		
PTI, %	90-100	68.8 ± 1.2	88.7 ± 0.14	68.4 ± 1.3	69.1 ± 0.2		

Note. * Statistically significant difference (p < 0.05) comparing with the main group after medical treatment.

Term	Main group	Control group			
1st day	21.5 ± 1.6	23.4 ± 1.3			
30th day	20.7 ± 1.5	23.1 ± 1.2			
3 month	19.3 ± 1.3	22.9 ± 1.2			
6 month	16.6 ± 1.7	22.6 ± 1.2			
12 month	14.2 ± 1.1	21.2 ± 1.2			

Table 4. Dynamics of elasticity index in patientswith LC, kPa

It should be noted that, in the main group, complex use of medications of the *Erbisol*[®] class allowed to achieve a pronounced immunocorrective effect, which was manifested by significant changes in the percentage of serum protein fractions. The percentage of albumin increased from $37.3\% \pm 5.1\%$ to $51.3 \pm 6.3\%$ (p<0.01). The level of γ -globulins decreased from $37.5\% \pm 8.3$ to $22.6 \pm 5.3\%$ (p < 0.01), and the albumin-globulin ratio (A/G) decreased accordingly, exceeding one. As shown by our study, in the main group, after treatment, patients with LC had a moderate regeneration of the liver parenchyma, which was confirmed by hemodynamic parameters and elastography. Immediate and longterm treatment outcomes were analyzed using the average elasticity index (Young's index) according to shear wave elastography (Table 4). The elasticity index (Young's index) was 21.5 ± 1.6 kPa in the main group, 23.2 ± 1.3 kPa in the control group, which corresponds to the fibrosis index (F4).

Analysis of fibrosis (Young's index) stiffness showed that patients, who received the *Erbisol®* class medicines, had moderate reduction in fibrosis for 12 months, and the study reached the F4-F3 limit.

Analysis of hemodynamic parameters of hepatic blood flow showed a relative improvement in the main group (Table 5).

There was a moderate decrease in the diameter of the portal vein by 2.0 ± 0.6 mm in 11 patients of the main group and by 1.1 ± 0.1 mm in 9 patients of

the control group; improvement of the portal blood flow was observed in the main group. During the period of conservative treatment, a decrease in the amount of ascitic fluid was observed in 7 patients of the main group (in two patients, decompensated ascites became compensated) and in 2 patients of the control group. Surgical and efferent staged methods (laparocentesis, ascitoexfusion, ascitofiltrationsorption, reascitoinfusion) were used in 15 patients with refractory ascites (7 — in the main group and 8 — in the control group). In the main group, recurrence of refractory ascites occurred in 1 patient and in the control group — in 4 patients.

In the main group, 3 patients died: 2 patients had bleeding from varicose veins of the esophagus and 1 patient had progressive hepatic decompensation. In the control group, 4 patients died: 2 patients had bleeding from varicose veins of the esophagus, 1 - hepato-renal decompensation, and 2 - infectious complications.

It should be noted that, in the main group, the patients, who underwent several courses of *Erbisol*[®] drugs, had reduced symptoms of edema-ascitical and dyspeptic syndromes, which resulted in improving the quality of life of patients with LC. It indicates a pronounced membrane-protective effect of the complex use of drugs of the *Erbisol*[®] class, which helps to slow down and regress fibrosis, reduce the production of collagen in the liver, thus contributing to a favorable course of the disease.

Discussion

Over the past 10 years, the prevalence of chronic hepatitis and LC has increased by 2.5 times in Ukraine. It should be noted that the main cause of death in patients with LC is liver failure and coma. That is why in decompensated patients with cerebral palsy (Child-Pugh class B, C), surgical treatment is risky. A comprehensive treatment aimed at improving liver function and reducing fibrotization by various methods can be the only effective option. Patients with LC need medications that have an

Table 5. Parameters of hepatic blood flow before and after treatment

I. Product	Main	group	Control group			
Indicator -	Before	After	Before	After		
Blood flow velocity in the portal vein, cm/s	21.3 ± 1.6	26.6 ± 1.2	22.3 ± 1.1	$23.2\pm1.5^*$		
The diameter of the portal vein, sm	1.44 ± 0.09	1.26 ± 0.07	1.43 ± 0.05	$1.42 \pm 0.07*$		
Volumetric blood flow velocity in the hepatic artery, mL/min	135.3±14.1	148.5 ± 13.9	135.7 ± 1.6	137.1±11.2*		

Note. * Statistically significant difference (p < 0.05) comparing with the main group after medical treatment.

effect on the general links of pathogenesis. Various disorders causing damage to the liver cells as well as affecting other organs and systems in LC prompted the authors to use drugs with metabolic and immunomodulatory effects. Many approaches to treating LC have been proposed over the last decade, but none have shown a clear positive effect [2, 4, 16].

The results of this study indicate that drugs, domestically manufactured and known as the *Erbisol*® class, are promising for the treatment of LC, especially in patients with LC class A, B by Child-Pugh. However, these findings should be confirmed by larger clinical trials with a more homogeneous sample of patients. More studies on the effectiveness of the Erbisol class medications in the treatment of patients with cyrotic liver damage are required to determine its role in the management of various degrees of liver cirrhosis. Apparently, insufficient information on the effectiveness of the Erbisol class medications is largely due to the significant heterogeneity of the clinical variants of LC as well as lack of generally accepted recommendations on the dosage of the drug and the duration of the therapeutic course for this pathology. Nevertheless, the variety of biochemical and immunological effects determines the possibility of its prescription for almost any clinical form of liver cirrhosis. However, the effect on the histological characteristics of LC requires further study. Thus, by reducing liver damage, medications of the *Erbisol* class can prevent the development of liver failure. This explains their greater efficiency in compensated and subcompensated stages of LC, in which liver function is relatively preserved. The obtained results indicate that prolonged use (for 2 years) of the Erbisol class medications does not trigger any serious adverse reactions as they are well tolerated and safe.

Conclusions

Complex treatment with the *Erbisol*[®] class medications has a positive effect on clinical and biochemical parameters, induces a membrane-protective effect, and improves hepatic blood flow, which results in a favorable course of the disease.

The study found that, within 6 and 12 months, the *Erbisol*[®] class medications used in the treatment of patients with LC significantly reduced (p < 0.05) the density of the liver parenchyma according to shear wave elastography, indicating a slowdown and regression of fibrosis.

No side effects were observed during the treatment with the $Erbisol^{\mathbb{B}}$ class medications. The results of our research allow us to recommend the $Erbisol^{\mathbb{B}}$ class medications for the treatment of patients with LC.

DECLARATION OF INTERESTS

The authors, who participated in this study, stated that they had no conflicts of interest regarding this manuscript.

AUTHOR CONTRIBUTIONS

The contribution of all authors to this work is the same.

REFERENCES

- Cantero I, Elorz M, Abete I, Marin BA, Herrero JI et al. Ultrasound/ Elastography techniques, lipidomic and blood markers compared to Magnetic Resonance Imaging in non-alcoholic fatty liver disease adults. International Journal of Medical Sciences. 2019; 16(1), 75-83. https://doi.org/10.7150/ijms.28044.
- Dzygal OF, Deykalo IM, Gertsev VM. Zastosuvannia reinfuzii astsytychnoi ridyny dlia likuvannia khvorykh iz tsyrozom pechinky. Klinicheskaia Khirurgiia. 2018; 85(8):18-20. DOI: 10.26779/2522-1396.2018.08.18 (Ukrainian).
- Garcia-Tsao G, Bosch J, Kayali Z, Harrison SA, Abdelmalek MF, Lawitz E, et al. Randomized placebo-controlled trial of emricasan for non-alcoholic steatohepatitis-related cirrhosis with severe portal hypertension. J Hepatol. 2020; 72:885-95. doi: 10.1016/j. jhep.2019.12.010.
- Ge PS, Runyon BA Treatment of Patients with Cirrhosis. N Engl J Med. 2016;375(8):767-777.
- Inamova TT, Mirzakarimova DB. Novyi preparat u likuvanni khronichnoho hepatytu erbisol ultrafarm. Novyi den v medytsyni. 2018; 2(22):104-106 (Uzbekistanian).
- Kabbany MN, Conjeevaram Selvakumar PK, Watt K, et al. Prevalence of nonalcoholic steatohepatitis-associated cirrhosis in the United States: an analysis of national health and nutrition examination survey data. Am J Gastroenterol. 2017; 112:581-587.
- Mansour D, McPherson S. Management of decompensated cirrhosis. Clinical Medicine. Journal of the Royal College of Physicians of London. 2018; 18: s60-s65. DOI:10.7861/ clinmedicine.18-2-s60.
- Matkovska NR, Virstiuk NH, Herych PR, Balan UV, Pertsovych YV. Changes in indicators of fibrosis in patients with alcoholic liver cirrhosis associated with non-alcoholic fatty liver disease depending on the stage of cirrhosis Patolohiia. Tom 17, № 1(48), sichen – kviten 2020 r. DOI: 10.14739/2310-1237.2020.1.203626 (Ukrainian).
- Papadopoulos N, Vasileiadi S, Michalea S, et al. The use of APRI and FIB-4 scores versus transient elastography for the assessment of liver fibrosis stage in patients with chronic hepatitis C: Is it possible to reduce the need for elastography? Journal of Hepatology. 2019; 70(1): E191-E191. https://doi.org/10.1016/s0618-8278(19)30354-8.
- Patel K, Sebastiani G. Limitations of non-invasive tests for assessment of liver fibrosis. JHEP Reports. 2020; 2(2):100067.
- Quaranta MG, Ferrigno L, Tata X, D'Angelo F, et al Liver function following hepatitis C virus eradication by direct acting antivirals in patients with liver cirrhosis: data from the PITER cohort..BMC Infect Dis. 2021; May 4;21(1):413. doi: 10.1186/s12879-021-06053-3.
- Reddy S, Civan J. From Child-Pugh to model for end-stage liver disease: Deciding who needs a liver transplant. Med. Clin. North. Am. 2016;100(3):449-64. DOI: 10.1016/j.mcna.2015.12.002.
- Rusyn AV, Balazh OP. Setsialni metody diahnostyky funktsionalnoho stanu pechinky u khvorykh na tsyroz pechinky. Pytannia khirurhii pankreatobiliarnoi systemyiu DOI: https://doi. org/10.37699/2308-7005.5-6.2020.02 (Ukrainian).
- Rueschenbaum S, Ciesek S, Queck A, Widera M, et al. Dysregulated Adaptive Immunity Is an Early Event in Liver Cirrhosis Preceding Acute-on-Chronic Liver Failure. Front Immunol. 2021 Jan 26;11:534731. doi: 10.3389/fimmu.2020.534731.
- Wang K, Lu X, Zhou H, et al. Deep learning radiomics of shear wave elastography significantly improved diagnostic performance for assessing liver fibrosis in chronic hepatitis B: a prospective multicentre study. Gut. 2019;68:729-41. DOI: 10.1136 / gutjnl-2018-316204.
- Yoshiji H, Nagoshi S, Akahane T, et al. Evidence-based clinical practice guidelines for Liver Cirrhosis. 2020. Gastroenterol. 2021 Jul;56(7):593-619. doi: 10.1007/s00535-021-01788-x. Epub 2021 Jul 7.PMID: 34231046.
- 17. Zemlianitsyna OV, Sinaiko VM, Savenkov VI, Kravchun PP, Kravchun NO, Goncharova OA. Non-invasive fibrosis markers and elastography in diagnosis of fibrosis severity in patients with type 2 diabetes mellitus and non-alcoholic fatty liver disease. Zaporozhskyi medytsynskyi zhurnal. 2020;22(1):48. (Ukrainian).

Ефективність застосування препаратів класу «Ербісол[®]» у комплексному лікуванні хворих на цироз печінки

Я. Сусак¹, І. Сличко², О. Ніколаєнко³, О. Дирда⁴, В. Коробко⁵, М. Максименко¹

¹ Національний медичний університет імені О. О. Богомольця, Київ

² Національний університет охорони здоров'я України імені П.Л. Шупика, Київ

³ ТОВ «Ербіс», Київ

⁴ Київська міська клінічна лікарня швидкої медичної допомоги, Київ

⁵ДУ «Інститут ядерної медицини та променевої діагностики НАМН України», Київ

Необхідність вивчення особливостей перебігу, діагностики та лікування хворих на цироз печінки (ЦП) зумовлена розвитком тяжких ускладнень, високою летальністю і частою інвалідизацією хворих. Принцип поетапного усунення патологічних синдромів є основним у лікуванні ЦП. Комплексна терапія хворих на ЦП потребує застосування лікарських препаратів, які діють на загальні ланки патогенезу. Порушення клітинної структури печінки та інших органів і систем при ЦП є підставою для використання препаратів метаболічної та імуномодулювальної дії. Експерементальні та клінічні результати випробовувань препаратів класу «Ербісол[®]» зумовили необхідність вивчення їх лікувальних властивостей у хворих на ЦП, в яких імуномодуляція, гепатопротекція і гепаторепарація відіграють важливу роль.

Мета — дослідити ефективність використання препаратів класу «Ербісол[®]» у комплексному лікуванні хворих на ЦП.

Матеріали та методи. Проаналізовано результати лікування 57 хворих на ЦП. Пацієнтів розподілили на дві групи: основну — 28 пацієнтів (15 чоловіків та 13 жінок) і контрольну — 29 пацієнтів (18 чоловіків та 11 жінок). Усі пацієнти отримували комплексну базисну терапію ЦП. Основна група додатково отримувала внутрішньом'язові ін'єкції препаратів класу «Ербісол®» («Ербісол® Екстра», «Ербісол® Ультрафарм») за схемою, рекомендованою виробником («Ербіс Україна», erbisol.com.ua). Стадія компенсації хворих на ЦП за системою Чайлда-Пью становила 9—11 балів (клас В), відповідно у хворих основної та контрольної груп. Пацієнти в групах були співставними за розподілом статей, віком, тривалістю захворювання, ступенем вираженості основних синдромів.

Оцінювали ефективність лікування хворих на ЦП за клінічною симптоматикою, біохімічними показниками, результатами зсувнохвильової еластометрії та допплерофлуометрії.

Результати. Використання препаратів класу «Ербісол[®]» сприяло значному поліпшенню динаміки клінічного перебігу захворювання та зменшенню астено-вегетативних порушень, дало змогу досягти виразного імунокоригувального ефекту, про що свідчила зміна свіввідношення білкових фракцій сироватки крові. В динаміці лікування хворих основної групи спостерігали помірну регенерацію паренхіми печінки, що підтверджено гемодинамічними показниками та даними еластографії. Комплексне застосування препаратів класу «Ербісол[®]» сприяє уповільненню та регресу фіброзу, що зумовлює сприятливий перебіг захворювання.

Висновки. Комплексне лікування хворих на цироз печінки, з використанням препаратів класу «Ербісол[®]», має позитивний ефект на клінічні та біохімічні показники, мембранопротекторну дію, сприяє регресу фіброзу, поліпшує печінковий кровоплин.

Ключові слова: цироз печінки, гепатоцити, «Ербісол®», еластографія.

FOR CITATION

Susak Y, Slychko I, Nikolayenko O, Dyrda O, Korobko V, Maksymenko M. Effectiveness of the Erbisol® class in complex treatment of patients with liver cirrhosis. General Surgery (Ukraine). 2022:1;54-60. http://doi.org/10.30978/GS-2022-1-54.