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V.V. Petrushenko, D.I. Grebeniuk, K.L. Lonskii, V.Y. Gladkykh, O.O. Kedyk, L.H. Rosha[1]
National Pirogov Memorial Medical University, Vinnytsya, Vinnytsya
[1]Odessa State Agrarian University, Odessa

EFFICACY OF L-ORNITHINE L-ASPARTATE IN PATIENTS WITH ESOPHAGEAL VARICEAL BLEEDING

e-mail: Doctor.Svo@gmail.com

The study analyzed the effectiveness of L-Ornithine L-Aspartate in patients with esophageal variceal bleeding. The study included 67 patients with a confirmed diagnosis of liver cirrhosis complicated by portal bleeding. The experimental group consisted of patients who, in addition to complex treatment in order to maintain liver function, were prescribed intravenous L-Ornithine L-Aspartate with subsequent change to oral administration. The comparison group included patients who did not receive this drug. To assess the effectiveness of treatment, general clinical indices, biochemical indices of the functional state of the liver, indices of quality of life were studied. The use of this drug made it possible to shorten the length of hospital stay and significantly faster improve the main clinical and laboratory indices of the functional state of the liver and the quality of life of patients.

Key words: L-Ornithine L-Aspartate, liver cirrhosis, esophageal variceal bleeding, quality of life.

В.В. Петрушенко, Д.І. Гребенюк, К.Л. Лонський, В.Ю. Гладких, О.О. Кедик, Л.Г. Роша

ЕФЕКТИВНІСТЬ ЗАСТОСУВАННЯ L-ORNITHINE L-ASPARTATE У ПАЦІЄНТІВ ІЗ КРОВОТЕЧОЮ ІЗ ВАРИКОЗНО РОЗШИРЕНИХ ВЕН СТРАВОХОДУ

Дослідження присвячене аналізу ефективності застосування L-Ornithine L-Aspartate у пацієнтів із кровотечою із варикозно розширених вен стравоходу. У дослідження було включено 67 пацієнтів із підтвердженим діагнозом цирозу печінки ускладненого кровотечою портального генезу. Дослідну групу склали пацієнти, яким додатково до комплексного лікування з метою підтримки функції печінки призначали препарат L-Ornithine L-Aspartate внутрішньовенно із наступним переведенням на пероральний прийом. В групу порівняння увійшли хворі, які даний препарат не отримували. Для оцінки ефективності лікування досліджували загально-клінічні показники, біохімічні показники функціонального стану печінки, показники якості життя. Застосування даного препарату дозволило скоротити тривалість перебування у стаціонарі та достовірно швидше покращити основні клініко-лабораторні показники функціонального стану печінки та якості життя пацієнтів.

Ключові слова: L-Ornithine L-Aspartate, цироз печінки, кровотеча із варикозно розширених вен стравоходу, якість життя.

The study is a fragment of research work "Development and implementation of innovative technologies in the treatment and prevention of bleeding from varicose veins of the esophagus", state registration no. 0120U101363.

Liver cirrhosis occupies a significant place in the structure of the digestive system diseases, causing disturbing issues of health care in socio-economical aspect and in clinical epidemiology as well all over the world [13, 14].

Complications of liver cirrhosis are the most common cause of death in patients with gastrointestinal problems, accounting for at least 40 % of the total number of patients. The overall mortality due to liver cirrhosis varies by country. Thus, in Europe it ranges from 4.6 per 100,000 inhabitants in Norway, to 103.8 per 100,000 people in Moldova. According to the WHO, a high mortality rate from liver cirrhosis is considered to exceed 25 deaths per year per 100,000 inhabitants, and low – less than 10 cases [6].

The appearance of portal hypertension is extremely important in the course of the disease. Arising as an adaptive phenomenon at the beginning of the disease, portal hypertension with the progression of the process acquires the role of a leading pathogenetic clinical factor. With a significant increase in portal pressure (25–30 mm Hg) develops intense collateral circulation, which prevents further increase in portal hypertension. Particularly dangerous is the appearance of anastomoses shunting portal blood through the unpaired and left gastric veins (coronary veins) of the stomach into the thin submucosal venous plexuses of its cardiac department and the lower third of the esophagus, which often leads to gastrointestinal bleeding.

Esophageal and gastric variceal bleeding occurs in 50–70 % of cases in patients with cirrhosis. Recurrence of bleeding occurs in 70 % of patients within the first year after the incident. Mortality in each episode is up to 40 %. Extremely high risk of recurrence of bleeding, especially during the first week, reaching up to 50 %. The risk remains high for up to 3 months after primary bleeding, so such patients require dynamic dispensary monitoring and active tactics of the doctor and patient [1, 2, 7, 9, 10, 12].

Given the urgency of this problem, there is no doubt about the search for new and clinical evaluation of the effectiveness of existing hepatotropic drugs, which are assigned to one of the leading roles in the treatment of liver cirrhosis and its complications. One of them is L-Ornithine L-Aspartate [3, 5, 11].

The purpose of the study was to evaluate the effectiveness of L-Ornithine L-Aspartate in the complex treatment of liver cirrhosis complicated by esophageal variceal bleeding.

Materials and methods. Prospective study was performed at the Department of Endoscopic and Cardiovascular Surgery of National Pirogov Memorial Medical University, Vinnytsya on the base of the Clinical Highly Specialized Surgical Center with Minimally Invasive Technologies of Vinnytsya Regional Clinical Hospital named after Pirogov.

According to the purpose and objectives, 67 patients with a confirmed diagnosis of cirrhosis complicated by esophageal variceal bleeding were included in the study.

Criteria for inclusion in the study were:

1. Liver cirrhosis classes A and B according to the Child-Pugh classification.
2. Active bleeding from one or more varices of the esophagus at the time of admission to the hospital.
3. Endoscopic ligation of bleeding varices as the main method of hemostasis.
4. Absence of manifestation of any concomitant pathology at the time of admission to the hospital.

The exclusion criteria were:

1. Manifestations of any concomitant pathology during the patients' hospital stay.
2. Diagnosis of acute pathology not related to the underlying disease during the patients' hospital stay.
3. Refusal of the patients from further treatment.

There were 19 women (28.4 %) and 48 men (71.6 %) in the study. The mean age was 45.1±14.4 years.

All patients from the study contingent underwent a full range of diagnostic measures in accordance with current standards and local clinical protocols.

In order to stop the bleeding, all patients underwent endoscopic band ligation and, if necessary, prophylactic ligation of potentially dangerous varices in terms of the risk of bleeding.

For therapeutic purposes, infusion-transfusion therapy, hemostatic, antisecretory drugs, antibiotic prophylaxis, stimulation of peristalsis, symptomatic therapy were prescribed in accordance with the recommendations of current standards and protocols.

All patients were randomly assigned to two groups. The experimental group consisted of 34 patients who, in order to maintain liver function, were prescribed intravenous infusion of L-Ornithine L-Aspartate (JSC Farmak, Ukraine) at a dose of 10 ml per 500 ml of saline 2 times a day throughout the hospital stay, followed by change to L-Ornithine L-Aspartate granules at a dose of 3 grams 1 time per day for up to 1 month. The comparison group (33 patients) included patients who did not receive this drug.

To assess the dynamics of changes in the functional state of the liver, we analyzed the following indices: total bilirubin, Alanine aminotransferase (ALT), Aspartate aminotransferase (AST), Gamma-glutamyltranspeptidase (γ-GT), alkaline phosphatase, albumin, prothrombin index, blood urea.

The impact of treatment on quality of life was evaluated using the quality of life questionnaire – Gastrointestinal Symptom Rating Scale (GSRS) – on day 1^{st}–2^{nd} (after endoscopic hemostasis and emergency treatment), on days 7^{th} and 30^{th}.

The obtained data were processed using the statistical software SPSS 20.0 for Windows. Student's t-test for parametric quantities and Mann-Whitney test for nonparametric quantities were used to determine the statistical significance of differences between groups. Differences were considered statistically significant at $p<0.05$.

Results of the study and their discussion. In the statistical analysis of the main indices, the studied groups were homogeneous in terms of gender-age and clinical-laboratory indices.

The duration of hospital stay was significantly shorter ($p<0.05$) in the experimental group (7.5±2.7 days) than in the comparison group (8.7±1.2 days).

The dynamics of changes in the main laboratory indices of the functional state of the liver in the studied contingent are shown in table 1.

As can be seen from table 1, all the studied indices at the beginning of the study differed from normal values. These indices did not differ significantly when compared between groups, which can be explained by the homogeneity of the contingent of patients in both study groups.

In the study of the dynamics of changes in the levels of total bilirubin, ALT, AST, γ-GT, alkaline phosphatase on day 7^{th} of the study, their levels in patients of the experimental group were significantly lower than similar indices in the comparison group. A similar pattern was observed on day 30^{th}, when differences between groups were also significant.

In the statistical analysis of the dynamics of changes in these indices within each group, the following data were obtained.

In the experimental group, the indices on day 7th were significantly lower than the similar indices on day 1st–2nd. A further decrease in the numerical values of the studied indices from 7th to 30th days was also significant. In the comparison group, the studied indices on day 7th were also significantly lower than at on day 1st–2nd. In the period from 7th to 30th days, although there was a slight decrease in the numerical values of the studied biochemical parameters, but the statistical significance of the difference was not confirmed.

Table 1

Dynamics of changes in laboratory parameters of the functional state of the liver in the studied contingent

Terms	Group		Statistical significance
	Experimental	Comparison	
Total bilirubin, μMol/L			
1st–2nd day	36.15±3.82	36.28±3.94	p>0.05
7th day	26.67±2.11 $^{\Delta 1-2}$	31.03±4.04 $^{\Delta 1-2}$	p<0.01
30th day	19.39±3.25 $^{\Delta 7}$	30.69±3.62	p<0.01
Alanine aminotransferase (ALT), IU/L			
1st–2nd day	56.62±4.44	56.27±4.58	p>0.05
7th day	50.12±4.76 $^{\Delta 1-2}$	51.27±3.99 $^{\Delta 1-2}$	p<0.01
30th day	43.29±3.27 $^{\Delta 7}$	49.88±4.55	p<0.01
Aspartate aminotransferase (AST), IU/L			
1st–2nd day	68.68±4.12	68.73±4.18	p>0.05
7th day	56.03±3.59 $^{\Delta 1-2}$	61.24±3.17 $^{\Delta 1-2}$	p<0.01
30th day	48.24±5.53 $^{\Delta 7}$	60.97±3.36	p<0.01
Gamma-glutamyltranspeptidase (γ-GT), IU/L			
1st–2nd day	110.82±15.92	111.30±15.55	p>0.05
7th day	96.24±11.31 $^{\Delta 1-2}$	103.82±13.35 $^{\Delta 1-2}$	p<0.01
30th day	84.09±9.18 $^{\Delta 7}$	100.70±10.21	p<0.01
Alkaline phosphatase, IU/L			
1st–2nd day	156.68±10.60	155.91±10.83	p>0.05
7th day	132.53±13.22 $^{\Delta 1-2}$	141.03±19.49 $^{\Delta 1-2}$	p<0.01
30th day	121.82±13.22 $^{\Delta 7}$	139.18±18.32	p<0.01
Albumin, g/L			
1st–2nd day	28.15±8.83	28.82±8.95	p>0.05
7th day	33.32±6.57 $^{\Delta 1-2}$	33.55±6.54 $^{\Delta 1-2}$	p>0.05
30th day	37.12±4.38 $^{\Delta 7}$	34.15±6.61	p<0.01
Prothrombin index, %			
1st–2nd day	68.76±12.46	67.55±15.86	p>0.05
7th day	84.35±9.05 $^{\Delta 1-2}$	77.15±9.15 $^{\Delta 1-2}$	p<0.01
30th day	92.50±8.00 $^{\Delta 7}$	78.06±10.67	p<0.01
Blood urea, mmol/L			
1st–2nd day	3.10±0.43	3.11±0.40	p>0.05
7th day	3.26±0.26 $^{*1-2}$	3.28±0.26 $^{\Delta 1-2}$	p>0.05
30th day	4.01±0.31 $^{\Delta 7}$	3.25±0.26	p<0.01

Note. * – significant differences, p<0.05; $^{\Delta}$ – significant differences, p<0.01; the numbers indicate the study periods for which there is a significant difference in this index.

When studying the dynamics of changes in albumin and urea levels on day 7th of the study, their levels in patients of the experimental group did not differ significantly from similar indices in the comparison group, which can be explained by prescribing albumin infusion to all patients as an element of blood loss correction. When evaluating the values of these indices on day 30th of the study, their levels in patients of the experimental group were significantly higher than similar indices in the comparison group.

In the statistical analysis of the dynamics of changes in albumin within each group, the following data were obtained.

In the experimental group, the values of albumin and urea on day 7th were significantly higher than those on day 1st–2nd. A further increase in the numerical values of these indices from 7th to 30th days was also significant. At the same time, on day 30th of the study, their levels were within normal limits. In the comparison group, albumin and urea values on day 7th were also significantly higher than on day 1st–2nd. In the period from 7th to 30th days, although there was a slight increase in numbers, the statistical significance of the difference was not confirmed.

When evaluating the values of the prothrombin index on the day 7th of the study, its levels in patients of the experimental group were significantly higher than similar indices in the comparison group. A similar pattern was observed on the day 30th, when differences between groups were also significant.

In the statistical analysis of the dynamics of changes in the prothrombin index within each group, the following data were obtained.

In the experimental group, its value on day 7th was significantly higher than the same parameter on day 1st–2nd. A further increase in numerical values from 7th to 30th days was also significant. In the comparison group, the prothrombin index on 7th day was also significantly higher than on the day 1st–2nd. In the period from 7th to 30th days, although there was a slight increase in numbers, the statistical significance of the difference was not confirmed.

It should be noted that on day 30th of the study, the levels of all studied indices reached the upper limit of physiological values or approached it.

When analyzing the quality of life for each syndrome in the studied contingent, we obtained the following data.

Numerical indices of intensity of all syndromes in the studied contingent are given in table 2.

Table 2

Indices of intensity of all syndromes in the studied contingent

Terms	Group		Statistical significance
	Experimental	Comparison	
Indigestion			
1st–2nd day	4.02±0.72	4.02±0.73	p>0.05
7th day	3.34±0.47 $^{\Delta 1-2}$	3.67±0.58 $^{*1-2}$	p<0.01
30th day	2.82±0.64 $^{\Delta 7}$	3.54±0.52	p<0.01
Abdominal pain			
1st–2nd day	3.00±0.69	2.97±0.67	p>0.05
7th day	2.62±0.45 $^{\Delta 1-2}$	2.64±0.42 $^{*1-2}$	p>0.05
30th day	2.13±0.41 $^{\Delta 7}$	2.50±0.35	p<0.01
Diarrhoea			
1st–2nd day	2.57±0.49	2.60±0.42	p>0.05
7th day	2.33±0.45 $^{*1-2}$	2.40±0.36 $^{*1-2}$	p>0.05
30th day	2.12±0.42 ^{*7}	2.35±0.31	p<0.05
Constipation			
1st–2nd day	2.70±0.54	2.74±0.49	p>0.05
7th day	2.43±0.44 $^{*1-2}$	2.45±0.34 $^{*1-2}$	p>0.05
30th day	2.21±0.39 ^{*7}	2.37±0.34	p<0.05
Reflux			
1st–2nd day	2.04±0.64	2.01±0.63	p>0.05
7th day	1.91±0.57	1.84±0.52	p>0.05
30th day	1.57±0.35 ^{*7}	1.76±0.45	p<0.05

Note. * – significant differences, p<0.05; $^{\Delta}$ – significant differences, p<0.01; the numbers indicate the study periods for which there is a significant difference in this index.

As can be seen from table 2, the intensity of all syndromes at the beginning of the study in both groups did not differ significantly (p>0.05), which can be explained by the homogeneity of the contingent of patients in the study groups.

When assessing the quality of life on day 7th of the study, the indigestion intensity in patients of the experimental group was significantly lower than the same index in the comparison group. A similar tendency was observed when analyzing the quality of life of patients on day 30th, when the differences between the groups were also significant.

In the statistical analysis of the dynamics of changes in the indigestion intensity within each group, the following data were obtained.

In the experimental group, the indigestion intensity on day 7th was significantly lower than the same rate on day 1st–2nd. A further decrease in the intensity of this index from 7th to 30th days was also significant. In the comparison group, the indigestion intensity on day 7th was also significantly lower than on day 1st–2nd, but the reliability was lower than in the experimental group at similar terms of the study. In the period from 7th to 30th days, although there was a slight decrease in the numerical indices of the indigestion intensity, but the statistical significance of the difference was not confirmed.

The dynamics of changes in the intensity of abdominal pain, diarrhea and constipation syndromes showed similar trends.

When assessing quality of life on day 7th of the study, no statistical differences were found between the groups. However, when analyzing the quality of life of patients on the 30th day, the differences between the study groups were significant.

In the statistical analysis of the dynamics of changes in each of the studied indices within each group, the following data were obtained.

In the experimental group, the indices on day 7th were significantly lower than the similar indices on day 1st–2nd. A further decrease in the intensity of the studied indices from 7th to 30th days was also significant.

In the comparison group, the studied indices on day 7th were also significantly lower than the indices on day 1st–2nd, but the reliability was lower than in the experimental group on similar terms of the study. In the period from 7th to 30th days, although there was a slight decrease in numerical indices, but the statistical significance of the difference was not confirmed.

Numerical indices of the intensity of reflux at all times of the study were within normal values.

The intensity of reflux at the beginning of the study and on day 7th both groups did not differ significantly. However, when analyzing the quality of life of patients on the 30th day, the differences between the study groups were significant.

Although in both groups during the stay in the hospital (from day 1st–2nd to 7th) there was a decrease in the numerical values of the intensity of the studied index, but the differences were insignificant. Similarly, in the period from 7th to 30th days in the comparison group no statistically significant changes were observed, in contrast to the experimental group, where the decrease in the severity of reflux was significant.

In terms of its importance, drug support of liver function occupies one of the leading places in the treatment of patients with liver cirrhosis. In contrast to endovascular interventions [1, 7], aimed at reducing blood flow to the liver or increasing blood flow from the liver, hepatoprotectors, as pathogenetically determined drugs, allow to maintain liver function without the need to subject the patient to invasive interventions. For a long time, hepatoprotectors, in particular, L-Ornithine L-Aspartate have been used for the prevention and treatment of chronic complications of liver cirrhosis [3, 5, 11]. Our data indicate the effectiveness of supplementing the treatment of liver cirrhosis complicated by esophageal variceal bleeding, by prolonged use of L-Ornithine L-Aspartate. As a result of the administration of infusion of L-Ornithine L-Aspartate during inpatient treatment, there was a tendency to more rapid progressive normalization of the studied indices of liver function and quality of life. A study by Higuera-de-la-Tijera and co-authors with a focus on the prevention of hepatic encephalopathy showed similar trends in the normalization of liver function [8]. Further improvement of the studied indices after discharge of patients of the experimental group from the hospital, in our opinion, is associated with the continuation of the course of L-Ornithine L-Aspartate in granules, which also coincides with the literature data [4]. A slight improvement in laboratory parameters of liver function and a moderate decrease in the intensity of the studied syndromes during hospital stay in patients of the comparison group, in our opinion, can be explained by the prescribing to patient's only standard intensive care. After discharge from the hospital and cessation of intensive care, no changes in laboratory parameters and quality of life were observed, in contrast to patients in the experimental group. In our opinion, this can be explained by the lack of drug support for liver function in the post-hospital period.

Conclusions

1. The use of L-Ornithine L-Aspartate in the complex treatment of patients with liver cirrhosis complicated by esophageal variceal bleeding can significantly improve the basic clinical and laboratory parameters of liver function and reduce the length of hospital stay from 8.7±1.2 to 7.5±2.7 days.
2. Infusion of L-Ornithine L-Aspartate to patients during inpatient treatment for liver cirrhosis complicated by esophageal variceal bleeding can significantly improve the basic clinical and laboratory indices of liver function and quality of life, as well as reduce the intensity of indigestion.
3. Administration of L-Ornithine L-Aspartate granules to patients after inpatient treatment for liver cirrhosis complicated by esophageal variceal bleeding allows to bring closer to normal values the main clinical and laboratory indices of liver function, significantly improve quality of life and intensity of indigestion, abdominal pain, diarrhoea, constipation and reflux.

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N.O. Pylypenko, E.Ya. Nikolenko, K.V. Vovk, O.G. Reznichenko, G.S. Kratenko, S.V. Gridnieva, M.V. Martynenko, V.V. Pilipenko[1]
V.N. Karazin Kharkiv National University, Kharkiv, [1]Poltava Applied Oil and Gas College of National University, [2]"Yuri Kondratyuk Poltava Polytechnic", Poltava

THE STATE OF BLOOD INDICES IN THE FOUNDRY WORKERS

e-mail: npylypenko.kharkiv@gmail.com

The study of hematological parameters of 42 healthy people who have been working for more than ten years under the influence of dust-forming factors of production environment, among which silicon dioxide dominates, revealed: redistribution of white blood cell percentage; changes in erythrocyte membrane permeability; reduced blood clotting time; erythrocyte sedimentation rate; significant differences compared with control values of integral indices. Such changes are likely to have an adaptive focus, however – with continued contact of the subjects with the harmful factor, such changes can become markers of the development of disorders of innate immunity, with a subsequent risk of occupational chronic bronchopulmonary diseases.

Key words: industrial dust, hematological indices, markers of inflammatory processes.

Н.О. Пилипенко, Є.Я. Ніколенко, К.В. Вовк, О.Г. Резніченко, Г.С. Кратенко, С.В. Гріднєва, М.В. Мартиненко, В.В. Пилипенко

СТАН ПОКАЗНИКІВ КРОВІ У ОСІБ, ЯКІ ПРАЦЮЮТЬ В УМОВАХ ПИЛОУТВОРЮЮЧИХ ВИРОБНИЦТВ

За результатами вивчення гематологічних показників 42 практично здорових осіб, які більше десяти років працювали в умовах впливу пилоутворюючих факторів виробничого середовища, серед яких домінував діоксид кремнію, було виявлено перерозподіл відсоткового вмісту клітин білої крові, зміни проникності еритроцитарних мембран, скорочення часу згортання крові, збільшення швидкості осідання еритроцитів та достовірні відмінності в порівнянні з контрольними значеннями показників інтегральних індексів. Такі зміни, вірогідно, мають адаптаційну спрямованість, однак, при продовженні контакту обстежуваних зі шкідливим фактором можуть стати маркерами розладів з боку природженого імунітету, з подальшим ризиком розвитку професійних хронічних бронхолегеневих захворювань.

Ключові слова: виробничий пил, гематологічні індекси, маркери запальних процесів.

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Incidence of occupational etiology, as part of morbidity of the working population, has social significance for a number of countries, regardless of their level of economic development [2]. In Ukraine, occupational morbidity also remains a complex hygienic and socio-economic problem [4], in particular mechanical engineering is ranked second after coal industry in terms of contribution to the pool of occupational morbidity [5].