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EFFICACY OF ALBUMIN IN THE TREATMENT OF ALCOHOLIC CIRRHOSIS OF THE LIVER IN COMBINATION WITH OBESITY

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Annotation. Liver cirrhosis is characterized by an increase in morbidity and prevalence, life-threatening complications, disability and increased mortality of the working population. The aim of the study was to study the effect of albumin on the course of alcoholic liver cirrhosis in combination with obesity at the stage of decompensation. The study included 52 patients with alcoholic liver cirrhosis in combination with obesity (confirmed before the onset of ascites) with the primary uncomplicated ascites of 2-3 degrees, 46 men and 6 women aged 35 to 59 years; 32 patients were diagnosed with class B and 20 - with class C according to the Child-Pugh score. Depending on the treatment, patients were divided into 2 groups: Group I included 26 patients who received in their combination therapy albumin 40.0 g/week for 2 weeks of inpatient treatment and 20.0 g/week for 12 weeks of outpatient treatment, followed by a maintenance dose of 20.0 g/month (10.0 g/2 weeks) for 12 weeks; 24 weeks after the start of treatment, 16 patients gave their consent and continued maintenance therapy for another 24 weeks. Group II included 26 patients who received basic therapy without albumin. Assessment of patients was performed before treatment, 12, 24, 48 weeks after treatment onset; in 96 weeks - according to medical documentation. Statistical processing of the results was performed using software Microsoft Excel spreadsheet and application package Statistica v. 12.0 StatSoft, USA. In patients with alcoholic liver cirrhosis in combination with obesity, the inclusion in the complex therapy of long-term use of albumin improves the course of the disease according to the Child-Pugh score, MELD, DMF and CLIF-SOFA indices. There was a reduce the recurrence of ascites, the number of complications, a re-hospitalization within a year, an increase in the survival of patients within 48 months. No side effects of albumin were noted. Thus, long-term use of albumin in complex treatment of patients with alcoholic liver cirrhosis in combination with obesity contributes to an increase in the effectiveness of treatment.

Key words: liver cirrhosis, alcoholic, obesity, decompensation, albumin.

Introduction

Liver cirrhosis (LC) is characterized by an increase in morbidity and prevalence, life-threatening complications, disability and increased mortality of the working population [1, 13]. About 2 million people die annually as a result of complications of LC - this is 71.0 % of all diseases of the digestive system [1, 10]. Alcohol is the leading cause of death owing to liver disease in Europe. Alcoholic LC (ALC) leads to the loss of 22.2 million years of life, taking into account disability [10, 15].

Treatment of LC, especially at the stage of decompensation, is rather complicated due to the variety of links in the pathogenesis, metabolic disorders of a number of drugs in the affected liver, the need for an individual approach; it is usually expensive, but not effective enough [9, 13].

A new concept and prospects for the treatment of decompensated LC includes long-term use of albumin in combination therapy [6, 7]. Albumin has been shown to have pleiotropic properties and, in addition to oncotic properties, has non-oncotic effects, including antioxidant, detoxifying, immunomodulatory antioxidant, neutralizing, immunomodulatory and protective effect against endothelial function [4, 5, 11, 14].

The aim of the study was to study the effect of albumin on the course of ALC in combination with obesity at the stage of decompensation.

Materials and methods

The work was performed in the framework of research work of Ivano-Frankivsk National Medical University of the Ministry of Health of Ukraine "Non-alcoholic fatty liver disease: impact on cardiovascular disease, treatment optimization" (state registration number 0118U004756), "Diseases of internal organs in modern conditions, combined pathology and lesions of target organs: features of the course, diagnosis and treatment" (state registration number 0115U000995).

The study included 52 patients with ALC in combination with obesity (confirmed before the onset of ascites) with the primary uncomplicated ascites of 2-3 degrees, 46 men and 6 women aged 35 to 59 years; 32 patients were diagnosed with class B and 20 - with class C according to the Child-Pugh score. Depending on the treatment, patients were divided into 2 groups: Group I included 26 patients who received in their combination therapy albumin 40.0 g/week for 2 weeks of inpatient treatment and 20.0 g/week for 12 weeks of outpatient treatment, followed by a maintenance dose of 20.0 g/month (10.0 g/2 weeks) for 12 weeks; 24 weeks after the start of treatment, 16 patients gave their consent and continued maintenance therapy for another 24 weeks. Group II included 26 patients who received basic therapy without albumin.

Diagnosis and treatment of ALC were performed in

accordance with the Adapted Clinical Guidelines "Alcoholic Liver Disease" (State Expert Center of the Ministry of Health of Ukraine, Ukrainian Gastroenterological Association, Kyiv, 2014) [1], the protocol of medical care in "Alcoholic Hepatitis" of Order of the Ministry of Health of Ukraine 06.11.2014 [2], Order of the Ministry of Health of Ukraine № 826 of 06.11.2014 "Unified clinical protocol of primary, secondary (specialized) medical care: non-alcoholic steatohepatitis" [3], Recommendations of the European Association for the Study of the Liver (EASL), the European Association on the study of diabetes (EASD), the European Association for the Study of Obesity (EASO) [8], the protocols of the European Association for the Study of the Liver (EASL) [10], the American College of Gastroenterology for the management of patients with decompensated cirrhosis [9].

Assessment of patients was performed before treatment, 12, 24, 48 weeks after treatment onset; in 96 weeks - according to medical documentation.

The severity of LC was assessed by Child-Pugh score (Child-Pugh, Child-Turcotte, Child-Turcotte-Pugh, sometimes Child-Paquet) [1, 2, 10]. Calculation of the MELD (Mayo Endstage Liver Disease, 2001) was performed; it's a prognostic index for liver disease, which takes into account bilirubin, international normalized ratio (INR) and serum creatinine using an electronic calculator.

MELD index = $3.8 \times \log_e$ serum bilirubin level (mg/dL) + $11.2 \times \log_e$ INR + $9.6 \times \log_e$ serum creatinine level (mg/dL).

The CLIF-SOFA index (assessment of internal organ failure in chronic liver failure) was calculated according to the recommendations of the Consortium's CLIF (European Foundation for the Study of Chronic Liver Failure) [12].

Patients underwent general clinical examination (analysis of complaints, medical history, and confirmation of alcohol etiology of LC on the basis of international questionnaires CAGE, AUDIT and MAST, objective status, general blood and urine tests, biochemical analysis of blood), ultrasound of the abdominal cavity, electro- and echocardiography. The criteria proposed by West-Haven were used to assess encephalopathy. The functional state of the liver was estimated by the content of bilirubin, total protein and albumin, fibrinogen, activation of aspartate aminotransferase (AST), alanine aminotransferase (ALT), gammaglutamyltranspeptidase (GGTP), alkaline phosphatase according to the standard methods.

Statistical processing of the results was performed using software Microsoft Excel spreadsheet and application package Statistica v. 12.0 StatSoft, USA. Estimation of the probability of discrepancies in the values was performed using a paired Student's t-test.

Results. Discussion

Among the examined patients in both groups at baseline there was no significant difference in clinical parameters, except for a slightly higher number of patients with LC of C class according to the Child-Pugh score in Group I with combined pathology compared with Group II (Table 1). In

Table 1. Characteristics of the examined patients with alcoholic liver cirrhosis in combination with obesity.

Parameters	Groups of patients	
	Group I, n=26	Group II, n=26
Age (years) (M±m)	52.2±6.0	49.7±5.8
Duration of LC (years) (M±m)	5.4±2.8	5.5±3.1
Alcohol abuse (n %)	26 (100.0)	26 (100.0)
Smoking (n %)	10 (38.5)	11 (42.3)
Class of LC according to Child-Pugh score (n %)		
B	14 (53.8)	18 (69.2)
C	12 (46.2)	8 (28.9)
MAP (mm Hg Art) (M±m)	88.40 3.91	93.63 4.25
Serum albumin content (g/l) (M±m)	31.8±1.20	33.4±1.36
Serum bilirubin content (μmol/l) (M±m)	70.43±5.91	59.96±5.24
Prothrombin index (%) (M±m)	70.35 2.82	74.63 3.05
INR (M±m)	1.68 0.12	1.52 0.09
Serum creatinine content (μmol/l) (M±m)	90.51±6.07	87.48±5.63
GFR (CKD-EPI) (ml/min/1.73 m ²) (M±m)	65.82 3.37	69.04 3.80

Notes: * - p, the significance of the difference, $p < 0.05$; MAP - mean arterial pressure; INR - international normalized relationship; GFR - glomerular filtration rate.

Table 2. The effect of complex treatment with albumin on the course of alcoholic liver cirrhosis in combination with obesity (M±m).

Parameters	Groups of patients - Group I			
	before treatment, n=26	after 12 weeks, n=26	after 24 weeks, n=26	after 48 weeks, n=16
Child-Pugh (score)	9.85±0.42	6.44±0.25*	6.72±0.31*	7.30±0.43*
MELD index (score)	16.29±0.73	7.50±0.31*	8.14±0.56*	8.98±0.72*
DMF index (score)	22.43±1.30	13.16±1.09*	14.38±1.22*	15.10±1.45*
CLIF-SOFA (score)	6.92±0.24	3.27±0.15*	3.65±0.24*	4.02±0.36*

Notes: * - the significance of the differences in parameters compared to baseline, $p < 0.05$; - the significance of the difference in parameters after the treatment compared with the 12-week period, $p < 0.05$; # - the significance of the difference in parameters after the treatment compared with the 24-week period, $p < 0.05$.

particular, the Child-Pugh score in Group I patients was (9.85±0.42) and exceeded that in Group II patients by 19.10% ($p < 0.05$) before treatment onset.

Within 24 weeks, all patients in both groups remained alive, but higher efficacy of treatment according to the Child-Pugh score, MELD, DMF and CLIF-SOFA was observed in patients of Group I (Table 2, Table 3).

In particular, in patients of Group I after 12 weeks of treatment the Child-Pugh score decreased by 37.53 % ($p < 0.05$), DMF index - by 41.33 % ($p < 0.05$) and then they did not change significantly until 48 weeks on albumin maintenance therapy. After 12 weeks of treatment, the MELD index decreased by 53.50 % ($p < 0.05$), CLIF-SOFA - by

Table 3. The effect of albumin-free treatment on the course of alcoholic liver cirrhosis in combination with obesity (M±m).

Parameters	Groups of patients - Group II			
	before treatment, n=26	after 12 weeks, n=26	after 24 weeks, n=26	after 48 weeks, n=14
Child-Pugh (score)	8.27±0.33	8.84±0.40	10.23±0.65*	12.45±0.78*#
MELD index (score)	14.12±0.59	15.63±0.62*	16.91±0.65*	18.53±0.72*#
DMF index (score)	21.75±1.13	24.37±1.34*	28.02±1.58*	31.76±1.64*#
CLIF-SOFA (score)	6.35±0.22	6.52±0.39	7.54±0.46*	8.69±0.58*#

Notes: * - the significance of the differences in parameters compared to baseline, $p < 0.05$; - the significance of the difference in parameters after the treatment compared with the 12-week period, $p < 0.05$; # - the significance of the difference in parameters after the treatment compared with the 24-week period, $p < 0.05$.

52.74% ($p < 0.05$) and then they did not change significantly until 24 weeks, but up to 48 weeks maintenance therapy increased by 19.73 % and 22.93 %, respectively. There were no side effects of albumin.

In patients of Group II after 12 weeks the Child-Pugh score and CLIF-SOFA index did not change significantly, until 24 weeks they increased by 23.70 % and 18.74 % ($p < 0.05$), until 48 weeks - by 50.54 % and 36.85 % ($p < 0.05$), respectively, compared to baseline. After 12 weeks, MELD and DMF indices increased by 10.69 % and 12.04 % ($p < 0.05$), until 24 weeks - by 19.75 % and 28.83 % ($p < 0.05$), until 48 weeks - by 31.23 % and 46.02 % ($p < 0.05$), respectively, compared to baseline. At all periods of ALC control in combination with obesity, the studied parameters were higher in Group II compared with Group I ($p < 0.05$), which indicates the progression of hepatic and multiorgan

failure.

During 48 weeks, the following was noted among 26 patients of Group II: in 3 (11.53 %) - 3 recurrences of ascites in every person; in 6 (23.07 %) - 2 episodes of ascites in every person; 1 patient (3.84 %) had refractory ascites; in 1 person (3.84 %) - syndrome of excessive bacterial growth; re-hospitalization was in 4 (15.38 %) patients for three times, in 8 (30.76 %) patients - twice, in 10 patients (38.46%) - once. During this period, among 26 patients of Group I the following was noted: in 2 (7.69 %) - 2 episodes of ascites in every patient; in 8 (30.77 %) - 1 episode of ascites; in 1 (3.84 %) patient refractory ascites developed; re-hospitalization was observed in 1 (3.84 %) patient for three times, in 3 (11.53 %) - twice, in 9 (34.61 %) - once.

None of the patients in either group died within 24 weeks; up to 48 weeks among 26 patients of Group I 25 (96.15 %) patients were alive; up to 96 weeks - 23 (88.46%) patients survived; among 26 patients of Group II - 23 (88.46 %) and 18 (69.23 %) patients survived, respectively, which confirms the better survival of patients of Group I, who received long-term albumin therapy in combination therapy.

Conclusions and prospects for further research

1. In patients with ALC in combination with obesity, the inclusion in the complex therapy of long-term use of albumin improves the course of the disease according to the Child-Pugh score, MELD, DMF and CLIF-SOFA indices.

2. Long-term use of albumin in the complex treatment of patients with ALC in combination with obesity helps to reduce the recurrence of ascites, development of complications, re-hospitalization and is accompanied by greater survival of patients.

Studying the effect of albumin on the main pathogenetic components of ALC in combination with obesity.

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ЕФЕКТИВНІСТЬ АЛЬБУМІНУ В ЛІКУВАННІ АЛКОГОЛЬНОГО ЦИРОЗУ ПЕЧІНКИ У ПОЄДНАННІ З ОЖИРІННЯМ

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Анотація. Цироз печінки характеризується зростанням захворюваності і поширеності, загрозливими життю ускладненнями, інвалідизацією і збільшенням смертності працездатного населення. Метою було вивчення впливу альбуміну на перебіг алкогольного цирозу печінки (АЦП) в поєднанні з ожирінням на стадії декомпенсації. Об'єктом дослідження були 52 хворих на АЦП у поєднанні з ожирінням (підтверджено до появи асцитом) з вперше виниклим неускладненим асцитом 2-3 ступеня, 46 чоловіків і 6 жінок, віком від 35 до 59 років; у 32 пацієнтів діагностовано клас В за Чайльд-П'ю, у 20 - клас С за Чайльд-П'ю. Залежно від лікування пацієнти були розділені на 2 групи: I група включала 26 пацієнтів, котрі отримували комплексній терапії альбумін 40,0 г/тиждень впродовж 2 тижнів стаціонарного лікування і 20,0 г/тиждень впродовж 12 тижнів амбулаторного лікування, потім підтримуючу дозу 20,0 г/місяць (по 10,0 г/2 тижні) впродовж 12 тижнів; через 24 тижні від початку лікування 16 пацієнтів надали свою згоду і продовжили підтримуючу терапію ще впродовж 24 тижнів; II група включала 26 пацієнтів, котрі отримували базову терапію без введення альбуміну. Оцінку стану пацієнтів проводили до лікування, через 12, 24, 48 тижнів від початку лікування; через 96 тижнів - за медичною документацією. Статистичну обробку результатів проводили за допомогою електронної таблиці Microsoft Excel та програмного пакету Statistica v. 12.0 StatSoft, США. Комплексна терапія хворих на АЦП в поєднанні з ожирінням з тривалим застосуванням альбуміну сприяла поліпшенню перебігу захворювання за індексами Чайльд-П'ю, MELD, ДМФ і CLIF-SOFA. Відзначалося зниження рецидивів

асцит, кількості ускладнень, зменшення повторних госпіталізацій впродовж року, збільшення виживання хворих впродовж 48 місяців. Побічної дії альбуміну не відзначалося. Таким чином, тривале використання альбуміну в комплексній терапії сприяє підвищенню ефективності лікування хворих на АЦП в поєднанні з ожирінням.

Ключові слова: алкогольний цирроз печінки, ожиріння, декомпенсація, альбумін.

ЭФФЕКТИВНОСТЬ АЛЬБУМИНА В ЛЕЧЕНИИ АЛКОГОЛЬНОГО ЦИРРОЗА ПЕЧЕНИ В СОЧЕТАНИИ С ОЖИРЕНИЕМ

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Аннотация. Цирроз печени характеризуется ростом заболеваемости и распространенности, угрожающими жизни осложнениями, инвалидизацией и увеличением смертности трудоспособного населения. Целью было изучение влияния альбумина на течение алкогольного цирроза печени (АЦП) в сочетании с ожирением в стадии декомпенсации. Объектом исследования были 52 больных АЦП в сочетании с ожирением (подтвержденным к появлению асцита) с впервые возникшим неосложненным асцитом 2-3 степени, 46 мужчин и 6 женщин в возрасте от 35 до 59 лет; у 32 пациентов диагностирован класс В по Чайльд-Пью, у 20 - класс С по Чайльд-Пью. В зависимости от лечения пациенты были разделены на 2 группы: I группа включала 26 пациентов, которые получали в комплексной терапии альбумин 40,0 г/неделю в течение 2 недель стационарного лечения и 20,0 г/неделю в течение 12 недель амбулаторного лечения, затем поддерживающую дозу 20,0 г/месяц (по 10,0 г/2 недели) в течение 12 недель; через 24 недели после начала лечения 16 пациентов дали свое согласие и продолжили поддерживающую терапию еще в течение 24 недель; II группа включала 26 пациентов, которые получали базовую терапию без введения альбумина. Оценку состояния пациентов проводили до лечения, через 12, 24, 48 недель от начала лечения; через 96 недель - по медицинской документации. Статистическую обработку результатов проводили с помощью электронной таблицы Microsoft Excel и программного пакета Statistica v. 12.0 StatSoft, USA. Комплексная терапия больных АЦП в сочетании с ожирением с длительным применением альбумина способствовала улучшению течения заболевания по индексам Чайльд-Пью, MELD, ДМФ и CLIF-SOFA. Отмечалось снижение рецидивов асцита, количества осложнений, уменьшение повторных госпитализаций в течение года, увеличение выживаемости больных в течение 48 месяцев. Побочного действия альбумина не отмечалось. Таким образом, длительное использование альбумина в комплексной терапии способствует повышению эффективности лечения больных АЦП в сочетании с ожирением.

Ключевые слова: алкогольный цирроз печени, ожирение, декомпенсация, альбумин.