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Оцінка якості життя у хворих на хронічний гепатит С, поєднаний з неалкогольною жировою хворобою печінки та ожирінням, після проведеного лікування із застосуванням комплексної терапії

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Assessment of quality of life in patients with chronic hepatitis C combined with non-alcoholic fatty liver disease and obesity after comprehensive therapy

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Introduction

Direct-acting antiviral drugs (DAAs) have revolutionized the treatment of chronic hepatitis C (CHC), achieving a sustained virological response (SVR) of over 95% in most patients [1]. In many of those who achieve SVR, there is a reduction in liver fibrosis and a lower risk of hepatocellular carcinoma (HCC) [2]. However, in some patients, despite the successful eradication of the hepatitis C virus with DAAs, progression of liver fibrosis and/or development of HCC may still occur [3]. This is particularly true for patients with advanced stages of liver fibrosis prior to treatment. The rate of fibrosis progression is linked to various factors, including other liver diseases, such as alcoholic and non-alcoholic fatty liver disease (NAFLD), co-infection with hepatitis B, and HIV [4]. Therefore, studying the clinical efficacy of comprehensive treatment in patients with CHC combined with NAFLD and obesity represent a promising area of research [5]. In global medical practice, key criteria for evaluating treatment effectiveness include patient longevity and quality of life (QoL) [6]. The primary tool for assessing QoL in modern clinical studies is questionnaires. The most widely used questionnaires in scientific studies are the Medical Outcomes Study 36-Item Short-Form Health Status (SF-36) and EuroQoL-5D (EQ-5D) [7]. The limitation of general questionnaires is the inability to account for specific symptoms and QoL changes characteristic of certain diseases [8]. Thus, factors unrelated to the disease under study may influence the results [9; 10]. To more accurately assess QoL changes in specific diseases, relevant questionnaires are used [11]. These can include questions about the characteristics of a particular disease or evaluate certain categories of QoL. To increase the significance of QoL assessment, it is appropriate to combine both general and specific questionnaires [12].

Study objective: to assess quality of life indicators in patients with chronic hepatitis C combined with non-alcoholic fatty liver disease and obesity after comprehensive therapy including ademetionine and ursodeoxycholic acid.

Object, materials and research methods

A prospective study involved 70 patients with a verified CHC diagnosis, of whom 58.6% (41) were male and 41.4% (29) were female. The average age of the patients was 58.5 ± 1.5 years. A control group (n = 25, average age 33.2 ± 1.5 years) consisted of healthy individuals. All patients provided written informed consent to participate in the study in accordance with the Declaration of Helsinki, the European Council Convention on Human Rights and Biomedicine, relevant Ukrainian laws, and international regulations. The study was approved by the Bioethics Commission of Uzhhorod National University (Protocol No. 5/2, May 30, 2024). The study was conducted between 2021 and 2025 at the Clinical Base of the Department of Faculty Therapy, Medical Faculty of Uzhhorod National University; at outpatient clinics of the Regional Clinical Infectious Disease Hospital of the Transcarpathian Regional Council in Uzhhorod; and at the "UzhMED" medical center. Inclusion Criteria: patients with confirmed CHC diagnosis with or without NAFLD. Exclusion Criteria: presence of markers for infection with other hepatitis viruses (A, B, D), autoimmune hepatitis markers, liver damage due to toxins, cirrhosis, acute coronary syndrome within the first 6 months, diabetes mellitus, presence of decompensated internal organ diseases, and a patient's decision to withdraw from the study. The CHC diagnosis was established according to ICD-10 (International Classification of Diseases, 10th revision) and confirmed by the detection of HCV RNA in the patients' blood using real-time polymerase chain reaction (RT-PCR), including viral load determination and genotyping. The NAFLD diagnosis was confirmed in accordance with the Unified Clinical Protocol "Non-Alcoholic

Steatohepatitis" (2014), the adapted evidence-based clinical guidelines "Non-Alcoholic Fatty Liver Disease" (2012), and the recommendations of the European Association for the Study of the Liver (EASL).

Patients underwent anthropometric measurements and body mass index (BMI) calculation. All patients successfully completed treatment with direct-acting antiviral drugs (DAAs), specifically, sofosbuvir 400 mg + daclatasvir 60 mg, 1 tablet daily for 12 weeks. However, patients with concomitant NAFLD and dyslipidemia required further treatment after complete eradication of the hepatitis C virus. Depending on the prescribed treatment, patients were divided into 3 groups: Group A (n = 20, CHC with NAFLD + dyslipidemia) received rosuvastatin 10 mg daily + UDCA at 15 mg/kg, Group B (n = 24, CHC with NAFLD) received ademetionine 1000 mg IV once daily for 10 days followed by oral administration of 500 mg twice daily for 20 days, along with UDCA at 15 mg/kg at night for 6 months, and Group C (n = 26, CHC) received no additional treatment and formed the control group. All patients underwent psychological examination, which included individual interviews and psychodiagnostic testing using questionnaires that allowed for quantitative assessment of the studied characteristics. Patients completed the questionnaires independently according to standard requirements.

The following questionnaires were used: the Self-Rating Anxiety Scale (Spielberger-Hanin Scale), the Hospital Anxiety and Depression Scale (developed by Zigmond A.S. and Snaith R.P. in 1983), and a general quality of life assessment related to health using the SF-36 questionnaire. QoL was assessed using both SF-36 and EQ-5D questionnaires.

For all patients with CHC and those from the control group, a general QoL assessment was performed using the SF12 – a shortened and more accessible version of the widely known SF36 questionnaire. This questionnaire provides information on physical and mental health status and includes the following parameters: physical functioning (PF), role physical functioning (RP), pain intensity scale (BP), general health (GH), vitality (VT), social functioning (SF), role emotional functioning (RE), and mental health (MH) [13]. The scores on each scale range from 0 to 100, where a higher score indicates better QoL. Physical and mental health component scores from 0 to 20 points correspond to poor QoL; 21-40 – fair; 41-60 – good; 61-80 – very good; 81-100 – excellent [14]. The overall QoL score is calculated as the arithmetic mean of the individual scale scores. The test scales evaluate two main parameters related to QoL: the "physical component of health" (PCH) and the "mental component of health" (MCH).

The EQ-5D questionnaire helps describe issues related to household activities, family affairs, leisure participation, pain, discomfort, and social aspects affecting the patient [15]. Assessment is done using a 0–2 scale, where 0 denotes no problems, 1 denotes mild problems, and 2 denotes severe problems. The general health status is measured using the visual analog scale (VAS), where 0 represents the worst state and 100 represents the best state [16].

Data analysis and processing were performed using the Jamovi software with both parametric and non-parametric methods to evaluate the results. A p-value of <0.05 was considered statistically significant.

Results

Analyzing the age categories of the examined patients, it was found that the most frequent increase in BMI was observed in the age group of 45–59 years, accounting for 68.3%. Abdominal obesity was diagnosed in the patients according to generally accepted criteria for central obesity. Female patients had significantly higher BMI and waist-to-hip ratio (WHR) compared to male patients ($p<0.05$).

Evaluation of the quality of life (QoL) after the course of treatment in patients with CHC combined with NAFLD showed a trend toward improvement in all parameters. Analyzing the integrated scores for physical and mental health components across the entire SF-36 scale in patients with CHC combined with NAFLD, the following dynamics were observed: the average score for the physical health component (PH) in Group B patients showed the greatest improvement–by 8±1.7 points, compared to pre-treatment values, while the scores in Groups A and C increased by 5±1.5 and 6±0.2 points, respectively ($p<0.05$).

When evaluating the integrated mental health component (MH1), it was found that in Group B, the score increased by 11±0.5 points, while in Groups A and C, the increases were 7±1.8 points and 7±4.1 points, respectively.

The reduction in pain intensity, improvement in general health, vitality, and social functioning in Group B increased by 1.8 times ($p<0.01$), while in Group A, these indicators increased by 1.3 times ($p<0.05$), and pain intensity and social functioning increased by 1.2 times. A significant increase of 1.5 times ($p<0.01$) was also observed in the scores for role functioning and physical functioning in Group B, while in Group A, these scores increased by 1.3 times ($p<0.05$). Role functioning and mental health indicators also significantly improved more frequently in Group B, which received the proposed treatment. The number of patients who showed no signs of anxiety and depression according to the Spielberger-Hanin self-assessment scale in Group B increased by 9.3 times ($p<0.01$), while in Group A, it only increased by 3.2 times ($p<0.05$). Consequently, this was accompanied by a reduction in the number of individuals with situational anxiety by 8.3 times ($p<0.01$) in Group B, compared to 1.5 times in Group A patients (Table 1).

Assessment of quality of life indicators after treatment using the EQ-5D questionnaire demonstrated a significant positive dynamic in quality of life across all indicators. Specifically, in terms of the Visual Analog Scale (VAS), the average score reflecting health status in patients of group B-a gradually increased to 70.2 points, while in patients of group B-b, the average score increased to 60.4 points with $p<0.05$ (Table 2).

A reduction in disease symptoms (pain in the right hypochondrium, feelings of heaviness, bloating, weakness,

Table 1

Dynamics of quality of life indicators after comprehensive treatment

Indicator	Group					
	A		B		C	
	а	б	а	б	а	б
PF	77±2,5	86±1,4	72±1,2	79±1,8	77±2,1	77±2,1
RP	39±2,2	45±1,5	41±3,6	49±2,5	51±3,3	51±3,3
BP	35±41	42±1,7*	42±4,2	45±3,1	53±1,1	53±1,1
GH	36±3,5	45±4,4*	43±3,1	49±2,1	52±2,0	52±2,0
VT	37±4,2	46±5,4*	46±2,0	51±2,5	54±2,3	54±2,3
SF	45±1,2	50±2,5	52±2,5	58±2,7	59±2,0	59±2,0
RE	27±1,7	33±2,1*	33±2,5	39±2,1	41±2,1	41±2,1
MH	41±3,5	48±1,1*	44±3,3	48±2,0	51±1,9	51±1,9
PH	44±1,8	52±3,5	50±1,2	56±1,4	55±2,2	55±2,2
MH1	40±1,7	51±1,2	44±1,1	51±5,2	48±3,3	48±3,3

Note: * - the difference is significant ($p<0.05$); a – before treatment; b – after treatment.

Table 2

Quality of life indicators before and after treatment according to the EQ-5D questionnaire

Indicators of Quality of Life (QoL)	Groups			
		A	B	C
General Test Indicator	a	2,4±0,2	2,0 ±0,5	1,7±0,5
	b	1,6 ± 0,2	1,8±0,6* **	1,6 ±0,6
VAS	a	50,1±2,3	60,4 ±3,0	66,1 ±2,3
	b	60,2± 2,1	70,2 ±1,7* **	64,1 ±2,7

Note: a – before treatment, b – after treatment; statistical significance of differences: * – compared with Group 2, ** – statistical significance of differences between post-treatment indicators, VAS – Visual Analog Scale.

and fatigue) was directly associated with an improvement in the patients' quality of life (QoL) indicators. During the study, a significant correlation was found between the reduction of these symptoms and the improvement of aspects of QoL such as physical health, emotional state, and social integration.

It was found that the reduction in pain (a decrease in pain intensity by 3 or more points on a 10-point scale) correlates with a 20-30% improvement in physical functionality. This confirms that significant symptom reduction can lead to improvements in physical condition and the ability to perform daily tasks.

A positive correlation between the reduction of symptoms (right hypochondrial pain, heaviness, bloating, weakness, and fatigue) and overall health improvement was observed. Patients who reported significant relief from these symptoms also noted a general improvement in their quality of life. Increased self-care ability, reduced physical limitations, and improved overall work capacity were closely linked to improved EQ-5D scores.

The results of the study suggest a strong correlation between improvements in the physical, mental, and social states of patients and the reduction of disease symptoms, allowing the conclusion that a comprehensive approach to treatment is essential for achieving the maximum improvement in the quality of life in patients with HCV combined with NAFLD and obesity.

Discussion

Assessing the QoL indicators in patients after treatment, a positive trend was observed across all patient groups. However, the most pronounced improvements were found in Group B, which received ademetionine and UDCA. The study by Hadefi et al. (2023) investigated the use of ademetionine in patients with chronic hepatitis C and hepatic steatosis. The results demonstrated that ademetionine significantly improves both physical functioning and emotional well-being, thereby supporting the efficacy of this therapy in managing such conditions [17].

Combined therapy with ademetionine and UDCA led to significantly greater improvements in physical and mental health indicators compared to standard treatment. Patients in Group B experienced a more substantial reduction in pain, improved vitality, enhanced social and role functioning, and better overall mental well-being. The therapy also resulted in a marked decrease in anxiety and depression levels, highlighting its effectiveness in enhancing both the physical and emotional quality of life in patients with CHC and NAFLD. Similar results were reported in the study by Sanyal et al. (2010), which assessed the use of ademetionine in patients with NAFLD and chronic hepatitis C. They observed a significant improvement in quality of life and physical functioning, as well as a reduction in depression and anxiety. The most pronounced effects of ademetionine were noted in patients with NAFLD [18].

Accordingly, a significantly greater increase in quality of life was observed in patients in Group B-a, confirming the effectiveness of the combined therapy with the addition of ademetionine and UDCA compared to standard baseline therapy. Our findings are consistent with data obtained in 2020 by Gordon McGregor and colleagues, who conducted a study using the EQ-5D questionnaire to assess patients' health status. This research not only evaluated physical and mental health but also provided insights into

patients' perception of their illness. The EQ-5D questionnaire is a valuable tool for assessing quality of life and helps to understand how the disease affects daily living, particularly in the context of chronic or severe illness [19].

The data obtained indicate an improvement in patients' quality of life following treatment, especially in the group receiving combined therapy with ademetionine and UDCA. According to the study, the reduction of pain and fatigue was directly correlated with enhancements in physical functioning, including the ability to perform daily activities, improved physical endurance, and the restoration of overall physical condition. Patients experiencing less pain and fatigue showed significantly better results on the physical health component (PH) of the QoL scale compared to those who continued to experience these symptoms.

Reductions in depression and anxiety symptoms, improvements in mood, and decreased emotional stress contributed significantly to improvements in the mental health component (MH) of the QoL scale. These changes also included greater emotional stability, increased social interaction, and improved ability to cope with stressful situations. Patients with significant improvements in mental state, as measured by depression and anxiety scales, demonstrated higher scores on the emotional health component, indicating a clear link between reduced mental symptoms and improved QoL. It was found that the less pronounced the psycho-emotional symptoms, the higher the patients' scores on the mental health component (MH).

A similar trend in the improvement of both physical and emotional aspects of quality of life in NAFLD patients treated with obeticholic acid was reported in a study by Neuschwander-Tetri, B. A., Loomba, R., Sanyal, A. J., et al. (2015) [20].

Prospects for future research

Prospects for future research are focused on evaluating the long-term effects of combined therapy on the quality of life in patients with HCV combined with NAFLD and obesity. Studying changes in the physical and psychoemotional states of patients after treatment, as well as analyzing the impact of therapy on reducing the risk of disease progression and improving overall health, are critical areas for future investigation.

Conclusions

1. In patients with HCV combined with NAFLD and obesity, combination therapy with ademetionine and UDCA is effective as it reduces disease symptoms and improves quality of life, as evidenced by the high correlation between symptoms and overall health indicators.

2. The inclusion of ademetionine in the combined treatment reduces the manifestations of anxiety and depression in patients with HCV combined with NAFLD and concomitant obesity. Improvement in physical and mental components of quality of life was confirmed by a direct correlation between the reduction of clinical manifestations of the disease and an increase in scores on the SF-36 and EQ-5D scales.

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The aim of this study was to assess the effectiveness of combined therapy using ademetionine and ursodeoxycholic acid (UDCA) in patients with chronic hepatitis C (CHC), non-alcoholic fatty liver disease (NAFLD), and obesity. The main objective was to evaluate how this treatment regimen affects clinical indicators, liver function, and overall quality of life, particularly physical and psychological well-being.

Materials and methods. A prospective study involved 70 patients with verified CHC diagnosis, NAFLD and obesity. The average age of patients was 58.5 ± 1.5 years. A control group (n = 25, average age 33.2 ± 1.5 years) consisted of healthy individuals. The participants were divided into three groups. The first group received standard antiviral therapy. The second group received antiviral therapy plus ademetionine, and the third group received a combination of ademetionine and UDCA along with antiviral therapy. Quality of life was assessed using SF-36 and EQ-5D questionnaires at the beginning of treatment, and after three and six months of therapy.

Results. Patients receiving the combined treatment with ademetionine and UDCA showed the most significant improvements in quality of life, particularly in physical function, pain reduction, and mental health. They reported decreased anxiety and depression and improved social activity. Those receiving antiviral therapy with ademetionine also showed improvement, but to a lesser degree. No significant changes were observed in the control group.

Conclusion. Combined therapy with ademetionine and UDCA alongside antiviral treatment is an effective approach for patients with CHC, NAFLD, and obesity, improving both clinical outcomes and quality of life, particularly in physical and psychological domains.

Key words: HCV, NAFLD, combined therapy, quality of life, questionnaire.

Мета наукового дослідження полягала в оцінці ефективності комплексної терапії, що включала адеметіонін та урсодезоксихолеву кислоту (УДХК), для поліпшення якості життя у пацієнтів з хронічним гепатитом С (ХГС), поєднаним із неалкогольною жировою хворобою печінки (НАЖХП) та ожирінням. Основним завданням було оцінити, як таке лікування впливає на клінічні показники здоров'я, а також на загальну якість життя пацієнтів, зокрема фізичну та психічну активність.

Матеріали та методи. У дослідженні взяли участь 70 пацієнтів, які хворіли на ХГС з супутньою НАЖХП та ожирінням. Всі пацієнти мали підтверджений діагноз ХГС, який був верифікований на основі серологічних та молекулярно-генетичних методів, а також результатів ультразвукових досліджень печінки, що свідчили про наявність НАЖХП. Середній вік пацієнтів становив 58,5±1,5 років. Для порівняння, контрольну групу склали 25 здорових осіб, які не мали хронічні захворювання печінки та метаболічні розлади.

Пацієнти були розподілені на три групи. Перша група отримувала стандартну терапію прямими противірусними препаратами (ППРД). Друга група крім ППРД отримувала адеметіонін, а третя – комплексну терапію з додаванням як адеметіоніну, так і УДХК. Для оцінки якості життя пацієнтів використовували два стандартизовані опитувальники: SF-36 (для оцінки фізичного та психічного компонентів здоров'я) і EQ-5D (для загальної оцінки функціонального стану та життєвої активності). Обстеження проводилось на початку лікування, через три місяці та через шість місяців після початку терапії.

Результати. Усі групи продемонстрували певне покращення показників якості життя, однак найбільш виражене покращення спостерігалося в групі, що отримувала комплексну терапію з адеметіоніном та УДХК. У порівнянні з початковими даними, пацієнти цієї групи продемонстрували статистично значуще зменшення інтенсивності болю, поліпшення фізичної функціональності, зниження рівня тривожності та депресії. Також у них спостерігалося значне поліпшення показників соціального функціонування та здатності до виконання щоденних справ.

Пацієнти, які отримували тільки ППРД та адеметіонін, також продемонстрували покращення якості життя, але результати були менш вираженими порівняно з тими, хто проходив комплексну терапію. Пацієнти контрольної групи не мали значущих змін у стані здоров'я, що підтвердило ефективність застосовуваних лікувальних методів в основних групах.

Висновки. Комплексна терапія з використанням адеметіоніну та урсодезоксихолевої кислоти в поєднанні з прямими противірусними препаратами є високоефективним підходом до лікування хворих на хронічний гепатит С з супутньою НАЖХП

та ожирінням. Така терапія не лише сприяє покращенню клінічних показників та лабораторних результатів, але й значно покращує якість життя пацієнтів, зокрема, їх фізичне, психологічне та соціальне функціонування. Виявлено, що додавання урсодезоксихолевої кислоти разом з адеметіоніном виявляється більш ефективною, порівняно з іншими схемами лікування, і дозволяє досягти більш тривалого та стійкого результату у покращенні стану пацієнтів.

Ключові слова: ХГС, НАЖХП, комплексна терапія, якість життя, опитувальник.

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