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Features of functional recovery in obese patients with acute myocardial infarction

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Abstract. The increasing prevalence of obesity within the general population necessitates the development of effective rehabilitation strategies for post-myocardial infarction patients with excess body weight. The aim of this study was to determine the impact of obesity on the functional recovery of patients undergoing rehabilitation following acute myocardial infarction. The rehabilitation outcomes of patients experiencing their first-ever acute myocardial infarction were analysed. These individuals had been admitted to a specialised cardiac intensive care and resuscitation unit, receiving treatment in accordance with established clinical protocols. The cohort included patients with class I obesity as well as those with a normal body weight. The rehabilitation programme lasted for three months and comprised physical activity, dietary habit modification, psychological support, and educational interventions aimed at preventing cardiovascular diseases. Recovery efficacy was assessed using body mass index, myocardial functional status, physical endurance level (six-minute walk test), and quality of life (SF-36). The findings demonstrated a positive effect of the rehabilitation measures on patients' functional recovery. However, it was confirmed that individuals with obesity exhibited less pronounced improvements in quality of life ($r = 0.77$; $p < 0.05$), poorer adaptation to physical exertion, and slower recovery of haemodynamic parameters compared with patients of normal weight. Excess body weight was found to complicate the rehabilitation process, reduce its effectiveness, and prolong the recovery period. This underscores the rationale for a personalised rehabilitation approach that takes into account the degree of heart failure, pre-morbid physical fitness, and comorbidities. The results obtained may be applied to the development of individualised rehabilitation programmes aimed at improving treatment efficacy, reducing complication risks, and enhancing quality of life in post-myocardial infarction patients

Keywords: acute coronary syndrome; heart failure; body mass index; rehabilitation; quality of life; exercise tolerance

Introduction

Obesity is one of the key risk factors for developing cardiovascular diseases, in particular acute myocardial infarction (MI). The growing prevalence of obesity in the world,

especially among the young and working-age population, significantly complicates the course of cardiovascular pathologies and affects the effectiveness of treatment and

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rehabilitation. Functional recovery of patients after MI is a critical aspect that determines the quality of their future life, the level of working capacity, and social adaptation. In the presence of concomitant obesity, the rehabilitation process becomes more complicated, since this pathology is associated with an increased risk of recurrent cardiovascular events. In Ukraine, cardiovascular diseases are the leading cause of death, and as a result of a full-scale invasion, the number of cases of such diseases has increased significantly, which is associated with both psychological stress and limited access to timely medical care and preventive measures [1-3]. This reinforces the need to develop effective rehabilitation strategies, including those adapted to obese patients who have suffered MI. Investigation of the features of rehabilitation of such a contingent of patients after MI will improve existing cardiorehabilitation programmes, increase their effectiveness, and reduce the risk of complications.

The scientific medical literature, in the context of the treatment of heart diseases, mainly considers aspects of the correction of motor activity and nutrition in overweight patients. The study by P.A. Ades & P.D. Savage [4] analysed the evolution of cardiorehabilitation from exercise programmes designed to improve physical fitness after prolonged hospitalisation for a cardiac event, to individual interventions with different risks to alter coronary risk factors (and fitness) and the atherosclerotic process. Approaches to weight loss in cardiac patients with a wide range of diseases were considered, but insufficient attention was paid to rehabilitation issues after MI.

A randomised controlled trial of OPTICARE XL described by I. den Uijl *et al.* [5] showed the advantages of an integrated approach to the rehabilitation of obese cardiac patients compared to conventional rehabilitation programmes. But in this study, patients with heart failure were excluded, so the application of the authors' recommendations for the contingent of post-infarction patients looks unfounded. Y. Wang *et al.* [6] emphasised the importance of physical rehabilitation of patients with stable condition after emergency surgical treatment for acute myocardial infarction, which contributes to the rapid improvement of physical functions and can help patients to improve their quality of life.

In a systematic review by S. Barnason *et al.* [7], behavioural change strategies were considered as key influences in the cardiac rehabilitation programme. However, among the analysed sources, in most cases of research, patients who did not tolerate acute cardiac events were involved. C. Schon *et al.* [8] attempted to contextualise early cardiorehabilitation based on physical activity in patients with acute coronary syndrome. The researchers described the dosed exercise programme performed during hospitalisation and its effect on myocardial morphology and heart rate, and functional abilities in the long-term period after discharge. Monitoring the dose of physical activity during cardiorehabilitation was considered as a key to the effectiveness of the rehabilitation process, but only a small proportion of patients in this study showed signs of obesity.

In 2024, the American Heart Association, together with the association for cardiovascular and pulmonary rehabilitation, issued updated recommendations for rehabilitation measures in cardiac patients [9]. The developers have actually updated the scientific basis of the main components of patient assessment, nutrition counselling, weight and body composition control, cardiovascular diseases and risk factors, psychosocial management, aerobic training, strength training, and physical activity counselling. In addition, high-quality cardiac rehabilitation programmes should include a system of self-monitoring and patient feedback. High-quality programme execution is essential to improve widely documented low coverage and adherence rates, and to reduce differences in access to cardiac rehabilitation. This paper focused on weight loss strategies in cardiac patients with concomitant obesity, but does not provide clear recommendations specifically for obese patients who have recently suffered MI.

Thus, there is a lack of information on the course of recovery of functional and haemodynamic parameters in obese patients who have suffered myocardial infarction, primarily in patients after interventional revascularising interventions. The purpose of the current study was to determine the features of functional recovery in obese patients who had suffered acute myocardial infarction.

Materials and Methods

The study was conducted in 2020-2024 at the municipal non-profit enterprise of the Mykolaiv City Council "City Hospital No. 1". During this period, the effectiveness of rehabilitation of patients with grade 1 obesity, whose body mass index (BMI) was 30.0-34.9 kg/m² and who had suffered an acute myocardial infarction for the first time and were undergoing inpatient treatment in the intensive care unit and intensive care unit of a cardiological profile was monitored and analysed.

The study involved 150 people: 100 obese patients, who made up the main group, and 50 patients with normotrophic alimentary status (BMI = 18 - 24.9 kg/m²) [10] – as a control group. The control group was selected according to clinical and anamnestic characteristics that were as similar as possible to the main group. Among the examined patients, men prevailed (57.0% in the main group, 60.0% in the control group). The average age of patients was 62.3 ± 1.1 years in the main group, 61.5 ± 1.8 years in the control group (p > 0.05).

To assess the condition of patients, the visceral obesity index (VOI) was used, which was determined according to the equations by M.C. Amato & C. Giordano [11] for men:

$$VOI = (WC/39.68 + (1.88 + BMI)) \times (TG/1.03) \times (1.31/HDL), \quad (1)$$

for women:

$$VOI = (WC/36.58 + (1.88 + BMI)) \times (TG/0.81) \times (1.52/HDL), \quad (2)$$

where *TG* – triglycerides (mmol/l); *HDL* – high-density lipoproteins (mmol/l); *WC* – waist circumference; *BMI* – body mass index. Normal *VOI* indicator should not exceed 1.1.

In this case, the class of acute heart failure (HF) was determined on the Killip scale [12]. The stage and type of chronic heart failure (CHF) were determined according to the classification of the European Association of Cardiology [13].

The diagnostic, treatment, and clinical management programme in both groups was identical and consistent with current clinical protocols. All patients underwent percutaneous interventions (stenting, balloon angioplasty) and underwent medical treatment in accordance with the current unified clinical protocols, considering concomitant pathology. The complex of rehabilitation measures lasted three months and included physical exercise, dietary modification, psychological support and education on the prevention of cardiovascular diseases. The rehabilitation programme in both groups was identical. The following indicators were used to assess functional recovery: body mass index, myocardial systolic function, exercise tolerance (according to the 6-minute walking test) [14], quality of life (QOL) according to SF-36 [15].

The study was carried out in compliance with modern bioethical requirements [16], including the requirements of Article 8 of the Law of Ukraine No. 123/96-BP “On Medical Products” [17], Directive of the European Parliament and of the Council 2001/20/EC [18]; Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine [19], WMA Declaration of Helsinki – Ethical

Principles for Medical Research Involving Human Participants [20]; recommendations of the World Health Organisation Global Health Ethics [21], provisions of Good Clinical Practice (GCP) [22], and the Order of the Ministry of Health of Ukraine No. 690 [23]. All patients were informed about the risks of conducting the study and publishing materials and signed an informed consent to participate in the study. The authors claim to respect the confidentiality of data and prevent any pressure.

Statistical data processing was performed by the method of variance and correlation analysis using MS Excel software (MicroSoft Inc., USA) [24]. After checking the data array for homoscedasticity depending on the type of distribution and data format, the two-way Student t-test was used for parametric data with a normal distribution, and the Mann-Whitney criterion was used for nonparametric data. When comparing the frequency of registration of various clinical phenomena, the χ^2 criterion was used. Relationship scale data was compared according to Pearson, rank data was compared according to Spearman, and binary data was compared with other data formats using a beaded correlation coefficient.

Results

Examination of patients in both groups showed that most cases of MI met the criteria for STEMI (acute ST – segment elevation myocardial infarction) – 64.0% in the main group and 66.0% in the control group. Accordingly, NSTEMI (Non-ST-elevation Myocardial Infarction) was reported in 36.0% and 34.0% of cases. In terms of the structure of complications of the acute period, the MI groups were also comparable (Table 1).

Table 1. Structure of complications of the acute period of MI

Complications	Main group				Control group			
	STEMI (n = 64)		NSTEMI (n = 36)		STEMI (n = 32)		NSTEMI (n = 17)	
	Abs.	%	Abs.	%	Abs.	%	Abs.	%
Acute left ventricular aneurysm	4	6.3	-	-	1	3.1	-	-
Killip III/IV	9	14.1	3	8.3	2	6.3	1	5.9
Rhythm disorders	3	4.7	1	2.8	1	3.1	1	5.9

Notes: STEMI – ST-Elevation Myocardial Infarction, NSTEMI – Non-ST-Elevation Myocardial Infarction

Source: compiled by the authors

The table below shows that acute left ventricular aneurysm occurred in 4 cases with STEMI in patients of the main group and in 1 case with STEMI in patients of the control group, that is, the clinical groups did not differ in this parameter ($\chi^2 = 0.42$, $p = 0.52$). Severe acute heart failure (stages Killip III/IV) was recorded in 9 cases with STEMI in patients of the main group and in 2 cases with STEMI in patients of the control group, which indicates the comparability of the formed groups ($\chi^2 = 1.28$, $p = 0.26$). In NSTEMI, the incidence of this complication was slightly lower, with 3 cases in the main group and 1 case in the control group, respectively, i.e., no statistically significant differences between the groups ($\chi^2 = 0.13$, $p = 0.72$). Rhythm

disturbances occurred de novo in 3 patients with STEMI in the main group and in 1 – in the control group ($\chi^2 = 0.10$, $p = 0.75$), and one case in each of the clinical groups in NSTEMI ($\chi^2 = 0.31$, $p = 0.58$). Thus, the presence of obesity in MI did not significantly affect the risk of complications.

The clinical manifestations of MI in both groups were the same and included pain (72% in the main group and 76% in the control group), general weakness (64% and 66%), palpitations (22% and 20%, respectively). However, a noticeable difference between the obese group and the control group was observed with minimal physical activity – shortness of breath was recorded in 62% of patients in the main group and 42% in the control group ($p < 0.05$). Patients in the main

and control groups practically did not differ in MI localisation (Fig. 1). This, on the one hand, indicates the similarity of both groups in clinical characteristics, and on the other – the presence of subcompensation phenomena of the cardiorespiratory system in obese patients already at the time of applying to a specialised cardiology hospital.

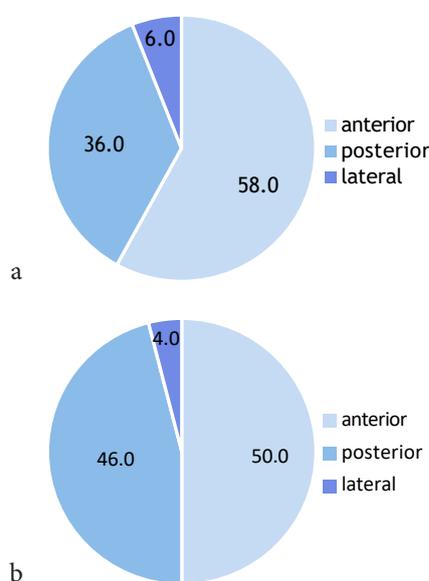


Figure 1. MI localisation

in comparison groups in this study

Notes: a – main group, b – control group

Source: compiled by the authors

When assessing the comorbid background and lifestyle in patients with MI in both clinical groups, the following data were obtained. The risk factors for MI were arterial hypertension (in the main group – 82.0%, in the control group – 88%), CHD (78.0% and 74.0%), type 2 diabetes mellitus (46.0% and 28.0%), dyslipidemia (78.0% and 62.0%), smoking (46.0% and 24.0%), alcohol abuse (32.0% and 28.0%), previous coronavirus infection (10.0% and 14.0%), occupational hazards (8.0% and 12.0%, respectively). Thus, the frequency of detection of risk factors, including those that can be modified, groups practically did not differ ($p > 0.05$). All patients underwent revascularising interventions without complications, as a result of which haemodynamic parameters were improved. At the time of discharge, Simpson's left ventricular ejection fraction (LV EF) averaged $51.1 \pm 0.3\%$ in the main group and $52.6 \pm 0.7\%$ in the control group. BMI was $32.7 \pm 0.3 \text{ kg/m}^2$ in the main group, and in the control – $23.5 \pm 0.4 \text{ kg/m}^2$, VOI – 1.5 ± 0.1 and 1.0 ± 0.1 , respectively ($p < 0.05$).

Each rehabilitation session consisted of warm-ups, up to 20 minutes of circular exercises (10 sets of 2 minutes each), and restorative exercises. All elements of the exercise were aerobic exercise, with a mix of “cardiovascular” exercises such as walking, exercise bike classes, step exercises, and “active recovery” exercises such as light dumbbell exercises or weight support exercises. All physical exercises

were accompanied by respiratory gymnastics with an emphasis on diaphragmatic breathing. All patients showed clinical improvement after treatment, but at the time of discharge they had signs of chronic HF, including NYHA functional class 2 (58.0% in the main group, 66.0% in the control group) and NYHA functional class 3 (42.0% in the main group, 34.0% in the control group). Heart failure with a moderately reduced left ventricular ejection fraction (HFmrEF according to ESC) occurred in 79 (79.0%) patients in the main group and 39 (78.0%) in the control group, with a reduced ejection fraction (HFrEF phenotype according to ESC) – in 21.0% and 22.0%, respectively. These values corresponded to the following test results with a 6-minute walk: in the main group, an average of $266 \pm 9 \text{ m}$, in the control group – $289 \pm 11 \text{ m}$.

All patients after MI experienced a decrease in quality of life indicators, most pronounced in the subscales of physical functioning PF (physical functioning), GH (general health), and VT (vitality). Thus, in the main group, the average values on the PF scale were 59 ± 4 points, on the GH scale – 63 ± 5 points, and VT – 66 ± 3 points. In the control group, the values on the corresponding scales were quite close – 68 ± 7 points, 67 ± 5 points, and 74 ± 6 points, respectively ($p > 0.05$). After the rehabilitation, there was an improvement in systolic function, physical endurance and quality of life. Thus, LV increased in the main group to $53.7 \pm 0.4\%$ ($\Delta = +5.1\%$), and in the control group – to $56.8 \pm 0.6\%$ ($\Delta = +8.0\%$). Relative to the results of the test with 6-minute walking, the increase was on average $43 \pm 3 \text{ m}$ in the main group, and $52 \pm 5 \text{ m}$ in the control group ($p < 0.05$). But according to QOL indicators, positive dynamics were determined in the subscales of physical and role emotional functioning, general health and vitality, which were more pronounced in the control group (Fig. 2).

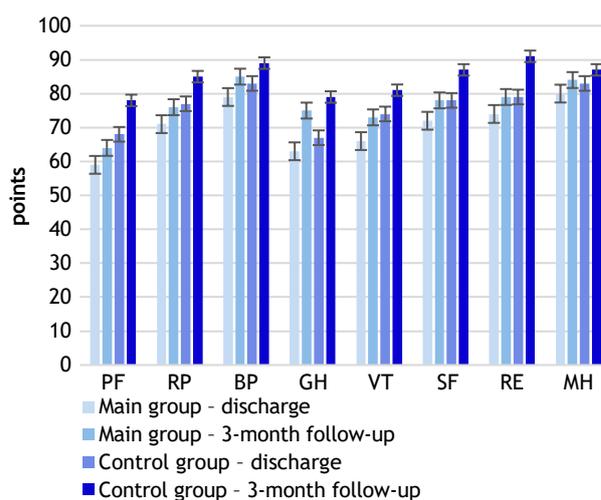


Figure 2. Changes in quality of life indicators in the examined patients

Notes: PF – physical functioning, RP – role physical functioning, BP – body pain, GH – general health, VT – vitality, SF – social functioning, RE – role emotional functioning, MN – health

Source: compiled by the authors

The above figure shows that three months after discharge, the PF subscale indicators showed a greater increase in the main group – up to 64 ± 4 points, while in the control group – up to 78 ± 6 points ($p < 0.05$). For the GH subscale, the indicators were 75 ± 5 points and 79 ± 7 points, respectively ($p > 0.05$), and for the VT subscale – 73 ± 4 points and 81 ± 5 points ($p > 0.05$). On the scale of body pain (BP), indicators in the main group increased from 78 ± 5 points to 85 ± 5 points, and in the control group – from 83 ± 7 to 89 ± 6 points ($p > 0.05$). The absence of significant differences in these subscales may be due to the low incidence of MI complications in the follow-up groups. On the social functioning scale (SF), indicators in the main group increased from 72 ± 4 points to 78 ± 5 points, and in the control group – from 78 ± 6 to 87 ± 5 points ($p < 0.05$). Thus, the QoL of patients in the recovery period after MI significantly depended on the metabolic profile of patients.

The results obtained indicate that a positive rehabilitation result was achieved in both clinical groups, but in the main group the gradients of changes were slightly lower than in the control group. Thus, the increase in the ejection fraction in the main group after 3 months averaged 5.1%, and in the control group – 8.0% ($p > 0.05$). A clinically significant increase in the results of the exercise tolerance test in the main group was recorded in 88% of patients with an increase in the distance travelled to 309 ± 8 m, and in the control group – in all patients with an increase in the distance travelled to 341 ± 11 m ($p < 0.05$).

Thus, as a result of rehabilitation, the best QoL indicators were achieved in patients with normotrophic alimentary status. A marked improvement in QoL was observed as early as 3 months after rehabilitation in all patients, but in patients of the main group, the increment of changes was less than in patients with normal body weight. The correlation between BMI and QoL increment was $r = 0.77$ ($p < 0.05$). The data obtained indicate that obese patients recover worse in terms of exercise tolerance compared to normosthenics. Thus, rehabilitation of post-infarction cardiological patients requires a comprehensive approach aimed at restoring the functional abilities of the cardiovascular system, and lifestyle modification, in particular, eating behaviour and motor activity.

Discussion

The widespread implementation of the revascularisation strategy in the treatment of MI has reduced mortality from this disease, but not all patients who have suffered a myocardial infarction return to normal life [1]. In contemporary cardiorehabilitation practice, there is a growing focus on the impact of obesity on the prognosis, effectiveness of interventions, and individualisation of recovery programmes. Excess body weight significantly modifies the results of cardiac interventions, affects the tolerance of physical exertion, and requires adaptation of the volume and intensity of rehabilitation measures. Thus, research by D. Jones *et al.* [25] showed that obesity is associated with worse outcomes in restenosis after percutaneous coronary interventions: overweight

patients had an increased frequency of repeated interventions and complications, which directly affects the cardio-rehabilitation strategy. The study by M. Husaini *et al.* [26], which was based on a large cohort of Medicare patients, demonstrated the benefits of an intensive rehabilitation programme over a conventional one, especially in subgroups with metabolic disorders, including obesity: a reduction in mortality and cardiovascular complications was noted with a more aggressive approach to lifestyle modification. The study by G. Chaves *et al.* [27] focused on global differences in the “dose” of cardiorehabilitation: overweight patients often do not reach the recommended duration and intensity of physical exercise, which correlates with a decrease in the effectiveness of the programme. In several review publications, in particular, G. Savarese *et al.* [28] and B. Shahim *et al.* [29], obesity was indicated as a key risk factor for heart failure, but the context of rehabilitation is not disclosed in detail. Other sources [30-32] focused on the technical aspects of interventional cardiology or drug therapy, with no emphasis on obesity or rehabilitation. Thus, current data confirm that obesity affects both the clinical effectiveness of cardiorehabilitation and the long-term prognosis, which determines the need for individualised approaches to this category of patients, considering their functional state, load tolerance, and metabolic profile.

Long-term disability, reduced quality of life, loss of self-care ability, and psychological disorders are typical consequences for a significant proportion of patients after MI. J.F. Rodriguez-Palomares *et al.* [33] and H. Yokoyama *et al.* [34] noted that these problems are aggravated in patients who have MI on the background of obesity, which significantly complicates the process of functional recovery. The combination of overweight with a sedentary lifestyle, characteristic of people after MI, forms a negative cycle, which leads to a further decrease in physical activity, the progression of comorbid pathology and a decrease in the effectiveness of cardiorehabilitation programmes.

Obesity has a systemic negative impact on the cardiovascular system not only due to mechanical stress, but also due to a number of metabolic and inflammatory mechanisms. As noted by M.P. Manoharan *et al.* [35], among the key independent risk factors in these patients are atherogenic dyslipidemia (increased triglyceride levels, decreased HDL cholesterol), signs of a chronic systemic inflammatory response (increased levels of C-reactive protein, interleukin-6), and insulin resistance. Taken together, these pathophysiological processes lead to a more severe course of MI, a less favourable response to standard therapy, and a decrease in the effectiveness of rehabilitation treatment.

Obese patients are more likely to develop complications, including acute and chronic heart failure, recurrent ischaemia, and repeated hospitalisations, which increases the overall risk of death after MI. P. Calabrò *et al.* [36] proved that the presence of obesity complicates the use of physical components of cardiorehabilitation, since it is often accompanied by orthopaedic problems, shortness of breath, and impaired load tolerance, which requires

significant adjustment of standard programmes. In addition, such patients have a higher risk of depression, anxiety disorders, and reduced motivation to participate in rehabilitation activities, which further complicates functional recovery and return to an active lifestyle. All of these factors require a multidisciplinary approach to the management of obese patients after MI, including individualisation of cardiorehabilitation programmes, psychoemotional support, and correction of metabolic status.

Features of the course of CHD in obese patients are a fairly rapid development of decompensation changes. Obese patients experience myocardial ischaemia even in the absence of occlusion of large coronary arteries [37]. Regarding the effect of obesity on myocardial perfusion, the literature data are contradictory, but most researchers agree with the presence of numerous negative metabolic changes in the myocardium that contribute to the development of heart failure in obese patients and CHD [35]. The size of myocardial necrosis is a powerful predictor of prognosis after acute myocardial infarction, as noted by I. den Uijl *et al.* [5], M. Sun *et al.* [30] and S.J. Backhaus *et al.* [38]. According to D. Jones *et al.* [25], in obese patients, the relative size of the infarction focus is larger, and reperfusion therapy is less effective due to microvascular obstruction. On the other hand, a well-known paradox is that obese and overweight patients have a lower risk of short-term mortality after MI than normal-weight patients [39, 40]. However, the association of obesity with mortality after MI and the degree of its impact on rehabilitation outcomes remained unknown until recently.

The presented study proves the importance of the comorbid background, and, above all, the features of metabolism and functional reserves in obesity for predicting the results of the rehabilitation process. Even with the first degree of obesity, both the return to a normal lifestyle and the acquisition of tolerance to moderate physical activity slows down. Current literature and large-scale reviews and analyses of registries provide conflicting data on the benefits of rehabilitation after MI, including its impact on mortality, re-hospitalisation, and quality of life [2, 4, 5]. The contradiction lies primarily in the gap between theoretical efficacy (RCT, protocol rehabilitation) and actual efficacy in population cohort data, which often show more modest results. For example, the results of the study by T.M. Brown *et al.* [9] showed that an intensive programme can reduce mortality by 20-30% in a controlled setting, whereas in Medicare or national registries, this impact often does not exceed 10% or is statistically insignificant [26].

The data obtained in the current study show that early comprehensive rehabilitation is an important tool in the treatment of patients with MI. It covers not only a set of physical exercises, but also other influences. This refers to a

comprehensive cardiac rehabilitation strategy that includes, in addition, to the exercise regimen, psychosocial counselling, informing and motivational influences on smoking cessation, compliance with the medication regimen, dietary recommendations, and the use of other tools to reduce the risk of CKD progression, and recurrent acute cardiac events.

Conclusions

The study was devoted to the effect of obesity on functional recovery in patients who have suffered acute myocardial infarction. In the course of the study, the working hypothesis about the presence of a link between the metabolic status and adaptive abilities of the body was confirmed. In both clinical groups, a positive rehabilitation result was achieved, but in the presence of obesity, the positive changes were less pronounced. In particular, the increase in the ejection fraction in the main group after 3 months averaged 5.1%, and in the control group – 8.0% ($p > 0.05$). Despite the fact that these differences are statistically insignificant and were observed at the trend level, further observation revealed that a clinically significant increase in the results of the exercise tolerance test in the main group was recorded in 88% of patients with an increase in the distance travelled to 309 ± 8 m, and in the control group – in all patients with an increase in the distance travelled to 341 ± 11 m ($p < 0.05$). QoL improvement was observed as early as three months after rehabilitation. The most pronounced changes were observed in the subscales of physical and role emotional functioning. The correlation between BMI and QOL increment was $r = 0.77$ ($p < 0.05$), which indicates the importance of body weight control in post-infarction patients when implementing a rehabilitation programme.

The results of this study show that immediately after an acute heart attack, obese patients are more likely to change their lifestyle, which allowed levelling the difference in the subscales of overall health, vitality, and body pain. In addition, these lifestyle changes have been found to persist over time. It remains an open question how exactly the rehabilitation process takes place after MI, depending on the hormonal profile and the severity of oxidative stress. Prospects for further research are related to the study of gender features of functional recovery in obese patients who have suffered a myocardial infarction.

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Conflict of Interest

None.

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Особливості функціонального відновлення у пацієнтів з ожирінням, що перенесли гострий інфаркт міокарда

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Анотація. Зростання частоти ожиріння у популяції зумовлює потребу у створенні ефективних методів реабілітації постінфарктних хворих з надмірною вагою тіла. Метою дослідження було визначити, як ожиріння впливає на функціональне відновлення пацієнтів, що проходять реабілітацію після перенесеного гострого інфаркту міокарда. Були проаналізовані результати реабілітації хворих, що вперше у житті перенесли гострий інфаркт міокарда та перебували у стаціонарному відділенні інтенсивної терапії та реанімації кардіологічного профілю, отримуючи лікування відповідно до клінічних протоколів. Серед хворих були пацієнти з ожирінням I ступеня та з нормальною вагою тіла. Програма реабілітації тривала три місяці й включала фізичну активність, корекцію харчових звичок, психологічну підтримку та освітні заходи з профілактики серцево-судинних захворювань. Ефективність відновлення оцінювали за індексом маси тіла, функціональним станом міокарда, рівнем фізичної витривалості (тест 6-хвилинної ходьби) та якістю життя (SF-36). Результати дослідження засвідчили позитивний вплив реабілітаційних заходів на функціональне відновлення хворих. Водночас було підтверджено, що пацієнти з ожирінням мали менш виражене покращення якості життя ($r = 0,77$; $p < 0,05$), гіршу адаптацію до фізичних навантажень та повільніше відновлення гемодинамічних параметрів порівняно з хворими, які мали нормальну вагу. Виявлено, що надмірна маса тіла ускладнює процес реабілітації, знижує її ефективність та подовжує період відновлення. Це підтверджує доцільність персоналізованого підходу до реабілітації, що враховує ступінь серцевої недостатності, фізичну підготовку до захворювання та супутні патології. Отримані результати можуть бути використані для розробки індивідуальних реабілітаційних програм, спрямованих на підвищення ефективності лікування, зниження ризику ускладнень та покращення якості життя пацієнтів після інфаркту міокарда

Ключові слова: гострий коронарний синдром; серцева недостатність; індекс маси тіла; реабілітація; якість життя; толерантність до фізичного навантаження



Features of clinical course and diagnosis in pediatric otitis media with ARVI

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Abstract. Acute otitis media remains one of the most frequent infectious diseases in paediatric practice, with growing concerns about antibiotic resistance necessitating precise diagnostic and therapeutic approaches. The aim of this study was to establish age-specific aetiological patterns and develop evidence-based criteria for the differential diagnosis of otitis media in children with acute upper respiratory infections. A prospective observational study included 68 patients aged 1 to 13 years. The study demonstrated a clear age-dependent aetiological pattern: viral causes predominated in younger children (67.9% among infants, 63.2% in early childhood, 53.8% in middle childhood), whereas bacterial infections were more prevalent in older children (57.1% in late childhood and 100% in adolescence). Temperature patterns showed a strong correlation with aetiology: subfebrile temperatures (37.1-38.0 °C) were typically associated with viral infections (64.7% of cases), whereas febrile (38.1-39.0 °C) and high febrile temperatures (> 39.0 °C) were characteristic of bacterial infections (54.2% and 20.8%, respectively). Video endoscopy successfully differentiated three main clinical-morphological forms: secretory otitis (38.2%, predominantly viral), acute purulent otitis (35.3%, bacterial), and bullous otitis (26.4%, predominantly viral). Key clinical predictors of a complicated disease course included age under three years, recurrent otitis history, high fever, otorrhoea, hearing loss, and systemic signs of intoxication. Treatment strategies emphasised rational antibiotic use, with amoxicillin as first-line therapy for bacterial cases and symptomatic management for viral aetiology. This study establishes an individualised diagnostic algorithm based on age, temperature patterns, and endoscopic findings, enabling clinicians to optimise treatment decisions and reduce inappropriate antibiotic prescribing. The practical value of this research lies in providing evidence-based tools for paediatricians and otolaryngologists to improve diagnostic accuracy, enhance treatment outcomes, and contribute to antimicrobial stewardship in the management of paediatric otitis media

Keywords: differential diagnosis; viral aetiology; bacterial infection; video endoscopy; age-dependent patterns; temperature patterns; antimicrobial resistance

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Introduction

The issue of acute otitis media (AOM) remains a pertinent topic of research in contemporary paediatric practice, as evidenced by a significant number of recent scientific publications by both domestic and international authors. C. Gavrilovici *et al.* [1], in their study, conducted a comprehensive analysis of the bacterial spectrum associated with AOM in children and antimicrobial resistance profiles. The authors examined 147 samples, of which 97 (65.98%) had positive cultures, with *Streptococcus pneumoniae* and *Haemophilus influenzae* being the most prevalent microorganisms. A concerning proportion – 82.85% (58/70) of *Streptococcus pneumoniae* strains – were found to be multidrug-resistant, highlighting the seriousness of antibiotic resistance even in the era of pneumococcal conjugate vaccines. A. Danishyar & J.V. Ashurst [2] presented a thorough analysis of current approaches to the diagnosis and treatment of AOM. They highlighted that acute otitis media is the second most common paediatric diagnosis in emergency departments, surpassed only by upper respiratory tract infections. The researchers noted that although AOM can occur at any age, it is most frequently observed between 6 and 24 months of ages.

B. Zielnik-Jurkiewicz & A. Bielicka [3] identified *S. pneumoniae* as the most frequently isolated pathogen from the middle ear in children with treatment failure of AOM. The authors found that most strains were antibiotic-resistant and proposed microbiological identification of bacterial strains and determination of their resistance levels as a necessary component of effective treatment. In large-scale epidemiological study, G.J. Huang *et al.* [4] systematically analysed the global burden of otitis media across 204 countries and territories over nearly 30 years. This investigation was part of the Global Burden of Disease study 2021 and provided unique data on the temporal trends in the prevalence of otitis media on a global scale. This investigation, conducted as part of the Global Burden of Disease Study 2021, provided unique insights into temporal trends in the prevalence of otitis media worldwide. V. Frey Esgård *et al.* [5] analysed diagnostic methods and written recommendations for AOM in primary care. The authors underscored the importance of accurate diagnosis at the primary healthcare level and the need to standardise diagnostic approaches.

The study by P. Bajorski *et al.* [6] demonstrated that 80% of recurrent acute otitis media episodes in children occurred between 6 and 21 months of ages, with the majority intervals between episodes being less than 5 months. The researchers identified predictors facilitating the forecasting of further episodes and the assessment of the appropriateness of tympanostomy tube insertion. G. Castelli Gattinara *et al.* [7] presented evidence-based recommendations for antibiotic therapy in acute and recurrent otitis media in children. The authors focused on the rational use of antibiotics for mild, severe, and recurrent forms of otitis in previously healthy children, emphasising the need for an individualised approach. In the systematic review by

H.L. Gaddey *et al.* [8] analysed current approaches to the diagnosis and treatment of AOM. The authors noted that by the age of three, 50% to 85% of children will have experienced at least one episode of AOM, making it a virtually universal childhood experience.

The study emphasised the importance of symptomatic diagnosis and rational antibiotic prescription. Thus, the analysis of contemporary literature demonstrated that the issue of acute otitis media is at the forefront of international medical attention. The main research direction focused on combating antibiotic resistance, developing new diagnostic approaches, implementing rational antibiotic therapy, and creating effective preventive strategies. The paucity of Ukrainian studies in international databases indicated the necessity to intensify scientific efforts in this crucial paediatric field. Therefore, the aim of the study was to comprehensively assess the clinical course of otitis media in children with acute upper respiratory tract infections, contingent upon the aetiology of the disease, to identify key pathogenetic and prognostic factors, and to develop a comprehensive, evidence-based management strategy. This includes the implementation of feasible outpatient diagnostic methods and tailored treatment approaches.

Materials and Methods

The study included 68 patients aged from 1 to 13 years who met the inclusion criteria and did not have any of the exclusion criteria. Inclusion criteria were: presence of symptoms of acute upper respiratory tract infection and clinical signs indicating otitis media. Exclusion criteria included: established immunodeficiency states, chronic otitis media, anatomical malformations of the ear or nasopharynx, oncological diseases, recent (within the last 2 weeks) use of systemic antibiotics, as well as lack of informed consent from parents or legal representatives. According to the features of postembryonic development, the patients were divided into the following age groups: infancy (up to 12 months) – 28 children (41.2% of the total), including 12 boys (42.9%) and 16 girls (57.1%); early childhood (1-3 years) – 19 children (27.9%), including 8 boys (42.1%) and 11 girls (57.9%); first childhood (4-7 years) – 13 children (19.1%), including 6 boys (46.2%) and 7 girls (53.8%); second childhood (8-12 years for boys, 8-11 years for girls) – 7 children (10.3%), including 3 boys (42.9%) and 4 girls (57.1%); adolescence (13-16 years for boys, 12-15 years for girls) – 1 girl (1.5%) aged 13 years.

Patients were consecutively recruited between January and April 2025, allowing coverage of the seasonal increase in viral and bacterial infections. During history taking, special attention was paid to the presence of concomitant diseases, frequent viral upper respiratory infections, allergic conditions, and potential risk factors for complications such as premature birth, gastroesophageal reflux, immunodeficiency states, and anatomical abnormalities of the nasopharynx. Diagnosis of otitis media included video endoscopy of the upper respiratory tract and ear with assessment of tympanic

membrane mobility and condition, the condition of the auditory canal, as well as laboratory methods, including complete blood count and C-reactive protein (CRP) level when necessary to differentiate viral and bacterial aetiology. Since the study was conducted in an outpatient setting with limited diagnostic resources, this approach was the only feasible method for differential diagnosis. The treatment of patients was conducted in accordance with the Unified Clinical Protocol of Primary, Secondary (Specialised), and Tertiary (Highly Specialised) Medical Care: Acute Otitis Media [9], developed by the State Expert Centre of the Ministry of Health of Ukraine. In cases of confirmed bacterial infection, antibacterial therapy was prescribed (amoxicillin as the first-line drug, or amoxicillin/clavulanate in cases of increased resistance risk). In cases of viral infection, symptomatic treatment was provided, which included antipyretics or analgesics, necessarily combined with irrigation therapy of the upper respiratory tract. The study was conducted in accordance with the ethical principles of the Helsinki Declaration [10]. The parents and legal guardians of all participants in the experiment were informed about the risks associated with participation in the study and the publication of data, as well as the conditions for maintaining confidentiality. Written informed consent was obtained prior to inclusion in the study groups. No biological material in the form of tissues or cells was used. Clinical observations complied with modern standards of assessment in paediatric practice.

Parallel to the clinical study, a systematic analysis of contemporary scientific literature was conducted using electronic databases such as PubMed, Google Scholar, and Web of Science. The search was performed using keywords and their combinations: “otitis media”, “acute otitis media”, “middle ear infection”, “upper respiratory tract infection”, “Eustachian tube dysfunction”, “paediatric otitis”, “complications of otitis media”, “antibiotic resistance in otitis media”, and “treatment protocols for otitis media”. Particular attention was paid to articles published during the period from 2020 to 2025, which contained detailed descriptions of clinical manifestations, modern approaches to diagnosis, treatment, and prevention of complications of otitis in the context of upper respiratory tract infections.

Results

Etiological factors in the development of otitis media

Etiologically, middle ear infections may be caused by viral, bacterial, or mixed agents. The most common pathogens of otitis media are *Streptococcus pneumoniae* [11, 12], *Haemophilus influenzae* [13], as well as *Streptococcus pyogenes*, *Moraxella catarrhalis*, *Staphylococcus aureus*, *Viridans streptococci*, and *Pseudomonas aeruginosa* [14]. These microorganisms are characterised by high virulence and the ability to adhere to the mucous membrane of the respiratory tract, facilitating their further penetration into the middle ear. Viral pathogens include rhinoviruses, adenoviruses, influenza and parainfluenza viruses, which commonly trigger upper respiratory tract infections, thereby creating favourable conditions for secondary bacterial infection.

Viral infections of the upper respiratory tract, particularly those caused by respiratory syncytial virus (RSV), influenza virus, and adenovirus, play a leading epidemiological and pathogenetic role, as they are significantly more often associated with the development of otitis media.

Anatomical features of childhood. The middle ear, which is an air-filled cavity lined with respiratory epithelium, is anatomically connected to the nasopharynx via the Eustachian tube, which provides secretion drainage and maintains normal pressure in the middle ear cavity [14]. This anatomical structure ensures ventilation of the tympanic cavity and mucus drainage, so any dysfunction contributes to fluid accumulation and inflammation development. In infants and children, the structure of the Eustachian tube differs from that in adults: it is shorter, positioned more horizontally, and only reaches adult form by approximately seven years of age. At rest, the tube is usually closed. It opens during yawning and swallowing. Any anatomical or physiological dysfunction of the tube can lead to AOM. In children, the Eustachian tube is relatively shorter, wider, and more horizontal than in adults, which creates favourable conditions for unhindered entry of pathogenic microorganisms from the nasopharynx directly into the middle ear [14]. Moreover, insufficient pneumatisation of the mastoid process in children significantly increases the risk of mastoiditis [15] – a potentially dangerous complication of otitis.

Another important factor is the anatomical peculiarity of the aditus ad antrum opening, which connects the tympanic cavity with the antrum and mastoid cells – in children, this canal is wider, facilitating faster spread of the infectious process to adjacent structures. When infectious agents penetrate the mucosa of the Eustachian tube, swelling occurs, leading to its obstruction. Obstruction disrupts normal secretion drainage and tympanic cavity ventilation, resulting in negative pressure formation. Under its influence, the mucosa of the tympanic cavity begins to secrete exudate – fluid that may be serous or purulent depending on the nature of the pathogen. In viral infections, the exudate is usually clear and contains no significant leukocytes, whereas in bacterial infections it becomes thicker and purulent due to active migration of neutrophils and other immune cells to the site of inflammation. This pathological process causes characteristic clinical manifestations, including ear pain, hearing loss, and fever. From a pathogenetic point of view, otitis development is closely related to Eustachian tube dysfunction, which often occurs against the background of infection. As a result, negative pressure forms in the tympanic cavity, exudate accumulates, and favourable conditions arise for colonisation and multiplication of bacterial pathogens.

Routes of infection spread. Infection can enter the middle ear through various pathways, the most common of which is the retranasal route – the penetration of infection from the nasopharynx through the Eustachian tube into the middle ear [14]. Under normal conditions, the Eustachian tube plays an important role in ventilating the middle ear and maintaining pressure equilibrium between

the tympanic cavity and the external environment. However, during inflammatory processes in the nasopharynx, especially in acute respiratory viral infections, the mucosa of the tube swells, which reduces its patency. This creates favourable conditions for the retrograde spread of pathogenic microorganisms into the middle ear. Children, especially those under three years of age, have an increased risk of this infection mechanism due to the anatomical characteristics of the Eustachian tube – its short, wide, and horizontal structure.

Another mechanism is the haematogenous route, where pathogens reach the middle ear through the bloodstream. This route of spread occurs less frequently than the retranasal pathway but becomes important in systemic infectious diseases. For example, measles, scarlet fever, or influenza may be accompanied by generalised bacteraemia or viraemia, resulting in pathogens reaching various organs and tissues, including the middle ear.

The third infection route is the so-called traumatic pathway, which occurs when the tympanic membrane is damaged. Normally, this structure is a reliable barrier protecting the middle ear from the external environment. However, as a result of trauma, tympanic membrane perforation, or complicated acute purulent otitis, a hole may form through which pathogenic microorganisms directly enter the middle ear. Without appropriate treatment, purulent fluid from the middle ear can spread to adjacent

anatomical areas and lead to complications such as tympanic membrane perforation, mastoiditis, labyrinthitis, petrositis, meningitis, brain abscess, hearing loss, lateral or cavernous sinus thrombosis, and other complications [15].

In this context, early diagnosis and timely treatment of otitis are particularly important for preventing such complications. Although acute otitis media is a very common disease among children [9], the precise benefit of antibiotic therapy in paediatric AOM remains a subject of debate. The global problem of increasing antibiotic resistance among the main bacterial pathogens of otitis significantly complicates the choice of effective antibacterial therapy and potentially may lead to the ineffectiveness of standard treatment regimens. In this context, rational use of antibiotics based on modern diagnostic methods and an individualised approach to each patient becomes especially important.

Description of the sample. To conduct a more detailed analysis of the clinical manifestations of middle ear otitis in children, a study was carried out aimed at examining its etiological structure depending on the age category of patients. It was found that the nature of the disease course, the form of otitis, and the type of pathogen vary significantly across different age groups. Etiological verification was performed based on the results of video endoscopic examination and laboratory diagnostic methods. Consolidated data on the distribution of cases of secretory, purulent, and viral otitis by age groups are presented in Table 1.

Table 1. Distribution of otitis media aetiology by age groups

Age group	Total patients (n)	Secretory otitis	Purulent otitis	Virus otitis
Infancy (up to 12 months)	28	11 (39.3%)	9 (32.1%)	8 (28.6%)
Early childhood (1-3 years)	19	8 (42.1%)	6 (31.6%)	5 (26.3%)
First childhood (4-7 years)	13	4 (30.8%)	6 (46.2%)	3 (23.1%)
Second childhood (8-11 years)	7	2 (28.6%)	3 (42.9%)	2 (28.6%)
Adolescence (13+ years)	1	1 (100%)	0 (0%)	0 (0%)
Total	68	26 (38.2%)	24 (35.3%)	18 (26.4%)

Source: created by the authors based on the results of the study

Analysis of the obtained data demonstrates variability in the etiological structure of middle ear otitis depending on the age of the patients. In younger age groups (infant and early childhood), viral aetiology predominates, whereas in patients of older age categories, the bacterial nature of the disease is more frequently detected. The secretory form of otitis dominates in all age groups, indicating its high prevalence regardless of age. These results emphasise the necessity of a differentiated approach to the diagnosis and treatment of middle ear otitis, taking into account age-related characteristics and the etiological factor.

The duration from the onset of the disease to seeking medical help ranged from 1 to 6 days, with 42 patients (61.8%) seeking help on the 2nd or 3rd day after the onset of symptoms. Ear pain and the sensation of ear fullness were the main symptoms observed in 42 (61.7%) of the examined patients, regardless of age group. The obtained results regarding the duration from the onset of symptoms to seeking medical help demonstrate an important clinical

trend. Most patients (61.8%) sought medical help on the 2nd-3rd day after the onset of the disease, which may indicate moderate parental vigilance and a gradual increase in clinical symptoms to a level that causes concern. Although such an approach is not delayed, it creates a risk of losing valuable time for early diagnosis, especially in young children, in whom inflammatory processes tend to progress rapidly and can cause intracranial complications.

It should be noted that only 6 patients (8.8%) sought medical help on the first day after symptom onset, indicating limited parental awareness or underestimation of the severity of otitis media at an early stage. The largest share was patients – 42 persons (61.8%) – who sought help on the 2nd-3rd day after symptom onset, which is an optimal period for starting treatment and achieving effective conservative therapy. At the same time, 20 patients (29.4%) sought help only on the 4th-6th day of the disease, which is undesirable because it increases the risk of complications, prolonged course, and reduced treatment effectiveness.

These data highlight the need for active educational work with parents regarding the importance of timely medical consultation at the first signs of upper respiratory tract infections, especially in the presence of symptoms such as ear pain, hearing loss, fever, irritability, refusal to eat, or sleep disturbances. Explaining the possible consequences of delaying medical intervention, with emphasis on the risks of purulent otitis, auditory system damage, and potential complications, should become an essential part of the daily practice of paediatricians, otolaryngologists, and family physicians.

Clinical picture. In patients with secretory otitis media, the dominant complaints were a sensation of ear fullness and hearing impairment, in the absence of pain. The leading clinical symptom of acute external otitis (AEO) is ear pain, which can be particularly intense. An important

differential sign from acute middle ear otitis (MEO) is the worsening of pain when pressing on the auricle or tragus in the case of AEO. Symptoms usually develop progressively over two days. Often, a small amount of whitish discharge is observed, as well as swelling and erythema of the skin of the external auditory canal. This corresponds to the findings in the study by A. Jamal *et al.* [14].

An increase in body temperature to 38°C and higher, against the background of an upper respiratory tract infection, was observed in 58 patients (85.3% of the total), of which 52 (89.7%) were aged 1 to 5 years, and 6 (10.3%) were aged 6 to 12 years. The distribution of febrile response by aetiology is presented in Table 2, providing greater clarity regarding the correlation between fever and the underlying cause of otitis media in different age groups.

Table 2. Distribution of temperature response by types of otitis media

Temperature response	Secretory otitis (n = 26)	Bacterial (purulent) otitis (n = 24)	Viral (bullous) otitis (n = 18)
Subfebrile (37.1-38.0 °C)	22 (84.6%)	6 (25.0%)	0 (0%)
Febrile (38.1-39.0 °C)	4 (15.4%)	13 (54.2%)	6 (33.3%)
High febrile (> 39.0 °C)	0 (0%)	5 (20.8%)	2 (11.1%)
No temperature elevation	0 (0%)	0 (0%)	10 (55.6%)
Total	26 (100%)	24 (100%)	18 (100%)

Source: created by the authors based on the results of the study

A subfebrile temperature (37.1-38.0°C) was detected in 28 patients (48.3% of all cases with elevated temperature), of which 22 (78.6%) had viral otitis and 6(21.4%) had bacterial otitis. The identification of these aetiological factors was based on the clinical presentation, objective endoscopic findings, bacteriological analysis, and laboratory investigations. This temperature response was most characteristic of young children: 8 patients (28.6%) in the infant group (up to 12 months), 13 patients (46.4%) in the early childhood group (1-3 years), 4 patients (14.3%) in the first childhood group (4-7 years), and 3 patients (10.7%) in the second childhood group (8-12 years). Clinically, these children exhibited mild irritability, occasional otalgia, and minor disturbances of sleep. In most cases (82.1%), symptomatic treatment without the use of antibiotics proved effective.

A febrile temperature (38.1-39.0°C) was recorded in 23 patients (39.7% of all cases with elevated temperature), of which 10 (43.5%) had viral otitis and 13 (56.5%) had bacterial otitis. The distribution by age groups was as follows: 9 patients (39.1%) in the infant group, 8 patients (34.8%) in the early childhood group, 4 patients (17.4%) in the first childhood group, and 2 patients (8.7%) in the second childhood group. The clinical picture was dominated by moderate or severe ear pain (91.3% of cases) and sleep disturbances (87.0% of cases).

A high-grade febrile temperature (> 39.0°C) was observed in 7 patients (12.0% of all cases with elevated temperature), of which 2 (28.6%) had viral otitis and 5 (71.4%) had bacterial otitis. The distribution by age groups was as follows: 2 patients (28.6%) in the infant group, 3 patients (42.8%) in the early childhood group, 1 patient (14.3%) in the first childhood group, and 1 patient (14.3%) in the

second childhood group. All children with high fever presented with marked anorexia and pronounced asthenia.

The analysis of parental complaints and psychoemotional background as part of the anamnesis for high temperature revealed. In children, the clinical picture of otitis was accompanied by asthenovegetative symptoms such as irritability, crying, refusal to eat, sleep disturbances, and constant fatigue. Among 68 patients, 65 (95.6%) were found to exhibit these symptoms. In infants (under 12 months), typical signs included frequent touching or rubbing of the ear, as well as inconsolable crying, which worried the parents. During anamnesis collection, when asked about pain in the right or left ear, parents often described the situation indirectly: "I don't know if it hurts, she keeps touching her right ear and cries, so I think it does, but we're not sure. And she cries". In children aged 1 to 3 years, parents often elaborated on the asthenovegetative symptoms, noting signs of restlessness, persistent crying, sleep disturbances, reduced appetite, and increased irritability (17 out of 19 patients, 89.5%).

In older children (from 4 to 13 years), more specific complaints such as ear pain, a sensation of fullness, and hearing loss were reported (20 out of 21 patients, 95.2%). Asthenovegetative symptoms and manifestations in the studied group were also similar, including feelings of fatigue, difficulty concentrating, and thinking. According to parental reports, 47 patients (69.1%) experienced either temporary or permanent hearing loss. Of them, 18 patients had a viral aetiology. Discharge from the ear, which was purulent due to perforation of the eardrum, experienced in 24 patients (32.29% of the total), of which 24 (100%) had bacterial aetiology, representing 100% of all bacterial pathology. Moreover, a direct proportional relationship

between asthenia and elevated temperature was observed. In 100% of patients with a temperature exceeding 38.5°C, asthenovegetative symptoms such as lethargy and hypodynamia were noted.

Aspects of diagnosing specific forms of otitis media

Accurate and timely diagnosis is crucial for prescribing appropriate treatment. In the case of AEO, the diagnosis is established based on physical examination. For the verification of middle ear otitis with effusion, a detailed medical history combined with a thorough clinical examination is required. The presence of signs of inflammation and fluid in the middle ear, identified through anamnesis, indicates MEO. To assess the mobility of the tympanic membrane, pneumatic otoscopy is applied [14]. The identification of etiological factors and forms of otitis was based on clinical data, objective findings from endoscopic examination, bacteriological studies, and laboratory tests. According to the results of the otoscopic evaluations, 68 patients with various forms of otitis media showed characteristic morphological changes in the eardrum, which allowed for differential diagnosis between different forms of the disease. Among the examined patients, were identified 3 main forms of otitis media: secretory otitis

media, acute purulent otitis media, and viral (bullous) otitis media. According to the results of laboratory blood tests including C-reactive protein (CRP) levels, it was found that in all observed groups, there was an increase in this indicator; however, in acute purulent otitis, the levels were significantly higher, which corresponds to the study by N.R. Tejani *et al.* [16]. In their study, children with bacterial acute otitis media had significantly higher CRP concentrations (mean 1.58 ± 3.16 mg/dL) compared to those with non-bacterial forms (mean 0.64 ± 1.24 mg/dL). Moreover, elevated CRP levels above 2.0 mg/dL were found in 22% of bacterial AOM cases, whereas only 6% of non-bacterial cases reached this threshold, suggesting a strong association between CRP elevation and bacterial aetiology.

In 26 patients from the secretory otitis group, pronounced changes in the nasopharynx during endoscopy were observed, including an increase in adenoid vegetations, the dripping of mucopurulent secretion along the back wall of the pharynx, and hyperaemia of the mucosa at the level of the nasopharyngeal vault. It should be noted that secretory otitis media does not always indicate a specific aetiology and can be a result viral, bacterial, or combined upper respiratory tract infections. The data are presented in Table 3.

Table 3. Etiological characteristics of different forms of otitis media in the study population

Type of otitis	Number of patients	Percentage of patients	Aetiology
Secretory otitis	26	38.2	Viral
Acute purulent otitis	24	35.3	Bacterial
Bullous otitis	18	26.4	Viral

Source: created by the authors based on the results of the study

Secretory otitis (Fig. 1), diagnosed in 26 patients (38.2%), is characterised by a milky appearance of the tympanic membrane, most prominently in the area of the handle of the malleus and the light reflex. In 17 cases, retraction Figure 1b of the eardrum was observed, indicating impaired ventilation of the middle ear and a decrease in pressure in the tympanic cavity. In this form of otitis media, the integrity of the eardrum is preserved, and fluid accumulation (Fig. 1a) is present in the middle ear in 9 patients, without clear signs of acute ear inflammation. Secretory otitis media is characterised by the presence of effusion in the middle ear and may last up to 12 weeks following an episode of acute otitis media, regardless of the primary aetiology.

In acute purulent otitis (Fig. 2), which was identified in 24 patients (35.3%), there is pronounced hyperaemia of the tympanic membrane, accompanied by its bulging (2 patients, Fig. 2d), indicating the presence of purulent exudate in the middle ear cavity. The light reflex in such cases is absent, flattened, or appears as a weak flash. A characteristic feature of acute purulent otitis was the perforation of the tympanic membrane (21 patients, Fig. 2a, b, c) with the presence of purulent discharge in the external auditory canal. This form of otitis had a

bacterial aetiology and was accompanied by febrile or high-grade febrile temperature.



Figure 1. Secretory otitis

Notes: a – fluid accumulation behind the intact tympanic membrane in secretory otitis media (milky appearance); b – retraction of the tympanic membrane indicating impaired middle ear ventilation

Source: created by the authors based on the results of the study

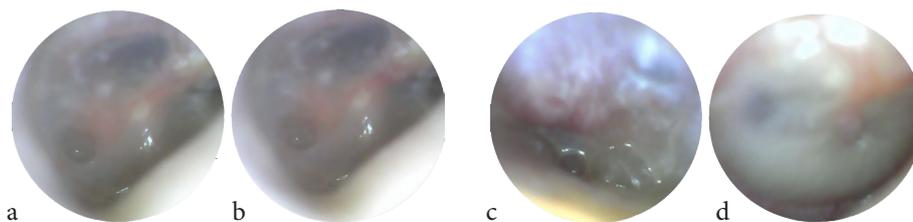


Figure 2. Perforated acute purulent otitis media: Visible perforation with inflammatory signs

Notes: a – tympanic membrane perforations with purulent discharge in acute purulent otitis media; b – tympanic membrane perforations with purulent discharge in acute purulent otitis media; c – angular perforation of the tympanic membrane with purulent discharge in acute purulent otitis media; d – bulging and hyperaemic tympanic membrane indicating purulent exudate in the middle ear

Source: created by the authors based on the results of the study

Viral (Bullous) otitis (Fig. 3), which was identified in 18 patients (26.4%), was characterised by the formation of typical bullae on the surface of the eardrum, filled with serous or haemorrhagic contents. This form of the disease is associated with damage to the endothelium and nerve fibres and had a viral aetiology. Patients with bullous otitis

complained of intense, pulsating pain in the ear due to the involvement of nerve endings in the inflammatory process. Clearly visualised during otoscopy, these bullae are a pathognomonic sign of this form of otitis and were observed in the form of a single (Fig. 3a, c, d) and multiple bullae (Fig. 3b).

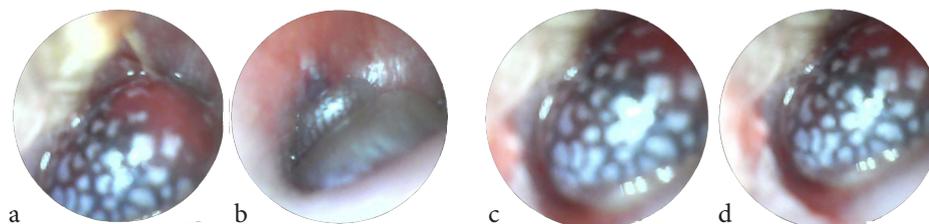


Figure 3. Bullous otitis media: characteristic bullae on the tympanic membrane

Notes: a – single bullae on the tympanic membrane filled with haemorrhagic fluid in viral (bullous) otitis; b – multiple bullae visible on the tympanic membrane in viral (bullous) otitis; c – single bullae on the tympanic membrane filled with serous fluid in viral (bullous) otitis; d – single bullae on the tympanic membrane filled with haemorrhagic fluid in viral (bullous) otitis

Source: created by the authors based on the results of the study

These observations during otoscopic examination not only allowed for the diagnosis of different forms of middle ear otitis but also provided the opportunity to assess the degree of the inflammatory process and select appropriate personalised treatment strategies for each patient individually. In particular, the presence of haemorrhagic bullae (Fig. 3a, d) was associated with a more intense inflammatory response and higher levels of discomfort reported by the patients. The differentiation between serous and haemorrhagic content (c vs d) also contributed to distinguishing viral aetiologies and guided the decision-making process regarding the need for symptomatic versus antimicrobial therapy.

Treatment. Treatment of otitis media requires a comprehensive approach that considers the patient's age, clinical picture, and potential complications. Effective therapy aims to combat the infection, reduce inflammation in the upper respiratory tract, relieve pain, and prevent possible complications. The main method of treating bacterial otitis media is the use of antibacterial therapy. All patients with a bacterial aetiology of the disease and purulent discharge in the external auditory canal underwent microbiological testing to determine sensitivity and prevent antibiotic

resistance. In this study, bacterial aetiology was identified in 35.3% (24 out of 68) of patients. In 100% of these cases, amoxicillin was prescribed, as the bacterial flora was sensitive to this drug. The dosage was based on the child's body weight. Alternative antibiotics, such as macrolides, were not used, which may indicate the absence of allergic reactions to penicillins in the studied groups. The use of antibiotics is justified when the clinical picture indicates a bacterial infection, for example, in the presence of high fever, purulent ear discharge, or severe ear pain. First-line drugs in such cases are antibiotics from the penicillin group, particularly amoxicillin, as confirmed by the research of G. Castelli Gattinara *et al.* [7], who also recommend amoxicillin as a first-line drug in their Italian intersocietal consensus.

If the disease is accompanied by an acute clinical picture or there is a risk of developing antibiotic-resistant bacterial strains, the physician may prescribe amoxicillin in combination with clavulanic acid (amoxicillin-clavulanate). This combination is effective even against bacteria that produce beta-lactamases, making them resistant to regular penicillins. In cases where the patient has an allergic reaction to penicillins, an alternative is the prescription

of antibiotics from the macrolide group, such as azithromycin or clarithromycin. Macrolides are the drugs of choice for diseases caused by atypical pathogens such as *Mycoplasma pneumoniae* or *Chlamydia pneumoniae*, as noted by J.O. Klein [17]. Although this therapeutic option was noted for completeness, no cases of atypical bacterial infections were found among the study participants; thus, this recommendation remained theoretical in the context of this study. Decongestants were prescribed in 55 out of 68 cases (80.9%) in the form of nasal drops or sprays according to paediatric dosage. These medications are an important part of otitis therapy, as decongestants improve the patency of the Eustachian tube in cases with a tendency toward bacterial processes. This helps normalise middle ear pressure and reduce nasopharyngeal mucosal swelling. Preparations based on xylometazoline or oxymetazoline quickly relieve nasal congestion, which promotes better drainage of exudate from the middle ear cavity, aligning with the recommendations of T. Hayashi *et al.* [13] regarding the importance of Eustachian tube patency. The use of decongestants should be limited to 5-7 days to avoid the development of medication-induced rhinitis. Subsequently, nasal irrigation is recommended. Nasal irrigation – irrigation therapy (with saline solutions) – was used in only 12 cases (17.6%). It is also worth noting the use of topical corticosteroids to reduce local inflammation. In the current study, mometasone was used in 100% of cases.

Analgesics, particularly non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen, may be used alone or in combination to achieve effective pain control in patients with otitis media. As noted by J.L.H. de Sévaux *et al.* [18], ibuprofen and paracetamol are the most widely used drugs in children. This is also confirmed by the results of the current study, where ibuprofen was prescribed in 94% of cases and paracetamol – in 87%. In patients with secretory otitis (38.2% of cases), analgesics were not used, unlike cases of acute purulent otitis (35.3%) and bullous otitis (26.4%), where analgesics were the main component of therapy. A similar approach is described in the study by Y. Bondarenko *et al.* [19], who also reported combined use of ibuprofen with paracetamol in 12.5% of cases – mainly in cases of severe pain (Visual Analogue Scale (VAS) > 5) or hyperthermia, which corresponds to observations regarding the need for enhanced analgesic therapy in severe cases. Specifically, authors note that in 13 children there was a decrease in intervals between fever peaks when monotherapy with ibuprofen or paracetamol proved insufficiently effective. In such cases, doctors resorted to alternating antipyretics – a strategy allowed by current clinical guidelines as an exceptional measure in cases of resistant hyperthermia. The alternating scheme involved administering paracetamol at a dose of 10-15 mg/kg, followed 4 hours later by ibuprofen at 5-10 mg/kg, with strict adherence to the maximum allowable daily doses. This approach is based on pharmacokinetic characteristics: ibuprofen is usually administered every 8 hours, and paracetamol every 4 hours, which allows for alternation. Combined

therapy was not prescribed for more than 3 days. However, the authors emphasise that this strategy has limited application due to the risk of overdose, potential masking of progressive disease symptoms, and possible toxic load on the liver and kidneys. Moreover, there is currently insufficient evidence for the superiority of alternating antipyretics over monotherapy in terms of efficacy and safety, as noted by other researchers [19].

In cases of mild pain (VAS ≤ 5), clinical guidelines recommend the use of local analgesics based on phenazone and lidocaine as first-line treatment. According to NICE guidelines, phenazone 40 mg/g in combination with lidocaine 10 mg/g is recommended as ear drops – 4 drops 2-3 times a day for up to 7 days [20]. This combination should be used only when immediate oral antibiotics are not prescribed and there is no perforation of the tympanic membrane or otorrhoea. At the same time, due to the outpatient format of this study and limited availability of local medications, only systemic symptomatic therapy was used. Ibuprofen was used mainly due to its combined analgesic and anti-inflammatory action, whereas paracetamol was used as an antipyretic. A.S. Lieberthal *et al.* [21] also noted that ibuprofen may have advantages in pain control due to its anti-inflammatory component, especially in cases of mild to moderate pain. Despite clear recommendations for the use of analgesics in acute otitis media in children, as noted by J.L.H. de Sévaux *et al.* [18], existing data on the effectiveness of paracetamol or NSAIDs – both as monotherapy and in combination – remain limited. The authors noted that data comparing the efficacy of ibuprofen with paracetamol, as well as their combination, are contradictory, which complicates the formation of definitive clinical conclusions.

In the presented study, local antiseptic drops were not used in cases of viral or secretory otitis. However, as noted by J. Buyten *et al.* [22], in cases of bacterial origin, drops based on ciprofloxacin or ofloxacin may be appropriate. Such treatment should be conducted under medical supervision, taking into account the risks associated with tympanic membrane perforation. In cases of severe course or presence of purulent effusion before perforation, surgical intervention may be appropriate. R.E. El Feghaly *et al.* [11] emphasised the effectiveness of paracentesis (myringotomy) for draining the middle ear cavity, which helps reduce pain and prevent complications. In patients with chronic effusion accumulation or frequent relapses, tympanostomy is recommended, which provides long-term drainage. The obtained data are practically significant for choosing a rational treatment approach. In younger age groups, a cautious approach to antibiotic prescription is appropriate, as in the vast majority of cases otitis has a viral aetiology and may be self-limiting with symptomatic treatment, adequate monitoring, and observation of the child's condition. For such patients, the use of analgesics and anti-inflammatory drugs, nasal decongestants, and evaluation of treatment effectiveness within 48-72 hours before considering the need for antibacterial therapy is recommended.

In contrast, in older children, especially adolescents, clinicians should maintain heightened vigilance regarding the bacterial nature of otitis, especially when symptoms such as persistent fever, otorrhoea, severe ear pain, signs of intoxication, hearing loss, or lack of improvement during symptomatic therapy are present. In such cases, early prescription of antibiotics is justified, and the choice of drug should be based on clinical guidelines, where amoxicillin is the first-line drug considering local antibiotic resistance patterns. In paediatric practice, it is important to timely identify clinical prognostic factors indicating the risk of complicated otitis. Key factors that should alert the physician include the child's age – especially the first three years of life, when the likelihood of recurrences increases. Also significant is the presence of frequent episodes of otitis in the history, indicating a chronic predisposition to the disease. Other alarming signs include high body temperature, otorrhoea, hearing loss, and general signs of intoxication, such as drowsiness, refusal to eat, sleep disturbances, and decreased activity [21]. Modern clinical guidelines emphasise the advisability of outpatient treatment of uncomplicated cases of otitis media in children, especially with probable viral aetiology. In such cases, the main method is symptomatic treatment, including the use of antipyretics and analgesics, nasal cavity sanitation, adequate hydration, and monitoring of the child's general condition. A mandatory follow-up examination within 48 hours is required to assess disease progression and identify possible bacterial complications [15]. Empirical prescription of antibiotics without clear objective indications should be avoided, as it contributes to the development of antibiotic resistance, complications, and microbiome disruption. This was demonstrated in the study by P.A. Knupp-Pereira *et al.* [23].

Indications for antibacterial therapy include the presence of pronounced clinical symptoms, particularly in children under 2 years of age combined with severe symptoms, purulent ear discharge as a sign of tympanic membrane perforation, febrile or high temperature, severe general condition, signs of systemic intoxication, lack of improvement following 48-72 hours of symptomatic treatment. In such cases, amoxicillin remains the drug of choice with proven efficacy against the main bacterial pathogens of otitis. Prevention of otitis media plays an important role in reducing morbidity and preventing intracranial complications. One of the key directions is effective control of upper respiratory tract infections – timely treatment of rhinitis, pharyngitis, and adenoiditis reduces the risk of infection spreading to the ear cavity. An important preventive measure is vaccination against pneumococcus and influenza, as these pathogens often cause or complicate the course of otitis. It is also necessary to eliminate modifiable risk factors: passive smoking, which negatively affects the mucous membrane of the respiratory tract; nutritional disorders that weaken immunity; and adenoids, which create conditions for chronic inflammation. Thus, the modern approach to the treatment of otitis media in children

involves a differentiated strategy depending on the patient's age, clinical picture, and disease severity. A balanced combination of symptomatic therapy with rational use of antibacterial drugs is a priority, allowing optimal treatment outcomes while minimising the risk of antibiotic resistance and side effects. It is especially important to pay attention to foci of chronic infection at the level of the upper respiratory tract, especially at the level of the nasopharynx and the Pirogov-Waldeyer lymphoepithelial ring.

Conclusions

The conducted study revealed a clear relationship between age and the aetiology of middle ear otitis in children, which has significant clinical implications for differentiated approach to diagnosis and management. In younger age groups, particularly among infants (up to 1-year-old), 67.9% of otitis cases were a viral origin. In early childhood (1-3 years), viral aetiology was found in 63.2% of cases, and in preschoolers (3-6 years) – in 53.8%. This trend indicates a high frequency of virus-associated forms of otitis in children under 7 years, often occurring against the background of acute respiratory viral infections, including adenoviral or rhinoviral infections, and owing to the functional and anatomical characteristics of the auditory (Eustachian) tube in infants.

Meanwhile, in older age groups, such as middle childhood (7-12 years) and adolescence (13-17 years), the proportion of bacterial otitis cases increases significantly. Specifically, in middle childhood, bacterial aetiology accounted for 57.1% of cases, and in adolescence – 100%. This trend may be related to a more mature immune system, a lower frequency of otitis association with viral infections, and an increased frequency of complicated courses of upper respiratory infections in this age group.

A connection was also found between the type of temperature response and the aetiology of the disease. Subfebrile temperature (37.1-38.0°C) is more often associated with viral processes (64.7% of cases), while febrile (38.1-39.0°C) and high fever temperatures (> 39.0°C) are characteristic of bacterial infections (54.2% and 20.8%, respectively). This supports the use of temperature as a readily available and simple clinical marker for the preliminary assessment of disease aetiology and the necessity for antibiotic therapy.

The use of video endoscopy made it possible to differentiate three main clinical-morphological forms of middle ear otitis: secretory otitis (38.2% of cases), acute purulent otitis (35.3%, bacterial aetiology), and bullous otitis (26.4%, predominantly viral origin). The obtained morphological changes in the tympanic membrane were typical for each form, highlighting the diagnostic value of video endoscopy and the need for its broader adoption in routine paediatric practice, especially in cases of ineffective therapy or recurrent episodes of otitis.

Thus, the results of the study emphasise the need for an individualised approach to diagnosing and treating middle ear otitis in children, taking into account age, clinical symptoms, temperature response, otoscopy results, and video endoscopy data. This approach not only helps improve

treatment outcomes and reduce the risk of complications but also minimises the inappropriate use of antibiotics, which is important in the context of growing antibiotic resistance. Among the most important treatment recommendations confirmed by the study results are the prescription of amoxicillin as the first-line drug in confirmed bacterial aetiology, refraining from antibacterial therapy in cases of viral otitis without signs of a severe course, the use of symptomatic agents (antipyretics, analgesics, vasoconstrictive drugs), and the evaluation of treatment effectiveness after 48-72 hours with subsequent adjustment of the strategy if necessary. It is also important to emphasise the widespread implementation of video endoscopy as an effective tool for differentiating forms of otitis.

Considering the obtained results, a promising direction for further research is the development and clinical testing of unified diagnostic algorithms using video

endoscopy for the early detection of various forms of otitis media, especially in young children, where the clinical picture may be nonspecific. Special attention should be given to studying the effectiveness of stepwise antibiotic therapy depending on the form of otitis and the age of the child, as well as evaluating the role of combined use of systemic and local anti-inflammatory agents in reducing symptoms and preventing complications.

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Conflict of Interest

None.

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Особливості клінічного перебігу та діагностики середнього отиту у дітей на тлі ГРВІ

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Анотація. Гострий середній отит залишається одним із найпоширеніших інфекційних захворювань у педіатричній практиці, причому зростаюча стурбованість щодо антибіотикорезистентності зумовлює потребу у точній діагностиці та терапевтичному підході. Метою цього дослідження було встановлення специфічних вікових етіологічних закономірностей та розробка доказових критеріїв для диференційної діагностики отиту у дітей із гострими респіраторними інфекціями верхніх дихальних шляхів. У проспективне спостережене дослідження було включено 68 пацієнтів віком від 1 до 13 років. Результати продемонстрували чітку вікову залежність етіології: вірусні причини переважали у молодших дітей (67,9 % серед немовлят, 63,2 % у ранньому дитинстві, 53,8 % у першому дитинстві), тоді як бактеріальні інфекції були більш поширені у старших дітей (57,1 % у другому дитинстві та 100 % у підлітків). Температурні показники мали тісний зв'язок з етіологією: субфебрильна температура (37,1–38,0 °C) зазвичай асоціювалася з вірусними інфекціями (64,7 % випадків), тоді як фебрильна (38,1–39,0 °C) і висока фебрильна температура (> 39,0 °C) були характерними для бактеріальних інфекцій (відповідно, 54,2 % та 20,8 %). Відеоендоскопія дозволила чітко диференціювати три основні клініко-морфологічні форми: секреторний отит (38,2 %, переважно вірусний), гострий гнійний отит (35,3 %, бактеріальний) та бульбозний отит (26,4 %, переважно вірусний). Ключовими клінічними предикторами ускладненого перебігу захворювання були: вік до трьох років, рецидивуючий анамнез отитів, висока температура тіла, оторея, зниження слуху та ознаки системної інтоксикації. Стратегії лікування акцентували увагу на раціональному застосуванні антибіотиків, при цьому амоксицилін виступав препаратом першої лінії при бактеріальній етіології, а при вірусному генезі – на симптоматичній терапії. Дослідження запропонувало індивідуалізований діагностичний алгоритм, який ґрунтується на віці пацієнта, температурному профілі та ендоскопічній картині, що дозволяє клініцистам оптимізувати лікувальні рішення та зменшити необґрунтоване призначення антибіотиків. Практична цінність роботи полягає у наданні доказових інструментів для педіатрів та отоларингологів з метою підвищення точності діагностики, покращення результатів лікування та сприяння антимікробній відповідальності в менеджменті середнього отиту у дітей

Ключові слова: диференціальна діагностика; вірусна етіологія; бактеріальна інфекція; відеоендоскопія; вікові особливості; температурні особливості; антимікробна резистентність



Modification of the physical therapy programme to factor in cognitive impairment in patients with Parkinson's disease

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Abstract. Parkinson's disease is a chronic progressive disease accompanied by motor and cognitive impairment, which considerably complicates the rehabilitation process and reduces the quality of life of patients. The purpose of this study was to evaluate the effectiveness of a modified physical therapy programme adapted to the cognitive status of patients. The study involved 10 patients who were divided into two equal groups: the experimental group ($n = 5$), which underwent an adapted programme with multisensory stimulation, cognitive motor exercises and slow learning, and the control group ($n = 5$), which received standard physical therapy. Tests were used for objective assessment: Timed Up and Go (TUG), UPDRS (motor part), Berg Balance Scale (BBS), PDQ-39 and SF-36. As a result, patients in the experimental group demonstrated positive dynamics in all indicators. Specifically, the time in the TUG test decreased from 16.8 ± 0.7 s to 13.2 ± 0.5 s, the UPDRS score decreased from 42.5 ± 2.1 pts to 35.4 ± 1.9 pts, the BBS balance score increased from 38.5 ± 1.5 pts to 41.8 ± 1.3 pts, while the PDQ-39 quality of life index improved from $59.3\% \pm 3.4\%$ to $48.7\% \pm 3.1\%$. The results obtained reflect the expediency of individualising rehabilitation programmes based on the cognitive profile of patients. The addition of cognitive tasks to physical therapy not only improved motor function but also helped to reduce cognitive deficits and improved overall quality of life. The practical value of this study lies in the possibility of implementing a modified physical therapy programme in clinical practice, particularly for multidisciplinary teams working in the field of neurorehabilitation, physical therapists, rehabilitation therapists, and neurologists. The proposed approach can be an effective tool for increasing the functional independence of patients with Parkinson's disease

Keywords: rehabilitation; quality of life; multisensory stimulation; motor symptoms; non-motor symptoms; cognitive dysfunction

Introduction

As the number of patients with Parkinson's disease (PD) and profound cognitive impairment increases, conventional physical therapy programmes are becoming less effective. Cognitive deficits, such as decreased executive function, memory, and attention, complicate exercise learning, reduce motivation, and increase the risk of falls. According to systematic reviews, between 40% and 60% of

patients with PD experience cognitive impairment during the course of their disease [1]. These changes often begin with slow thinking (bradyphrenia), difficulty concentrating, impaired executive functions (planning, problem solving), and are followed by episodes of forgetfulness that progress to severe memory impairment. Such symptoms substantially impede the daily functioning of patients,

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reduce their ability to self-care, complicate interaction with society, and reduce their motivation to take part in rehabilitation programmes. For this reason, current clinical guidelines increasingly emphasise the need to integrate a cognitive element into physical therapy to ensure a comprehensive approach to treatment and improve the quality of life of these patients.

Accumulated evidence suggests that exercise can not only improve motor function but also maintain cognitive health. A meta-analysis by R. Kim *et al.* [2] found that physical activity has a significantly positive effect on both global cognition and executive functions. These findings were confirmed in studies where exercise was combined with cognitive tasks. J.H. Zhou *et al.* [3] conducted a randomised controlled trial that demonstrated that the integration of cognitive components into exercise markedly improves executive function. The researchers found a decrease in dual-task cost and an increase in cognitive stability of the intervention participants. This suggests that combined programmes can reduce the effects of cognitive load during physical activity.

Numerous researchers emphasise that cognitive-motor programmes, especially in the dual-task format, positively influence executive functions, attention, and walking stability in patients with PD. A considerable amount of data obtained in the meta-analysis by H. Johansson *et al.* [4] demonstrated a stable improvement in both cognitive functions (primarily executive) and balance when using motor-cognitive training. It was emphasised that dual tasks not only improved functional efficiency but also provided a generalised effect on everyday activity. Particular attention should be paid to the issue of individualising the intensity and complexity of tasks according to the patient's cognitive profile. Y. Zheng *et al.* [5] reached analogous conclusions, addressing in their brief review the effectiveness of dual-load approaches in patients with moderate PD. The researchers emphasised the ability to improve not only cognitive function but also gait dynamics, which is critical for reducing the risk of falls. It was also noted that the ease of implementation of the dual-task approach made it attractive for use in outpatient settings. In their meta-analysis, H. García-López *et al.* [6] focused on reducing the risk of falls, which is a direct consequence of improving spatial attention and the ability to switch between tasks. The study showed that cognitive-motor interventions not only improve certain functional indicators but also develop self-regulation strategies in patients. The researchers addressed the need to standardise methods for assessing the effectiveness of such interventions.

A separate area of research focuses on alternative forms of rehabilitation, including the implementation of boxing programmes. In a systematic review, N. Chrysgis *et al.* [7] analysed 11 studies using boxing exercises (e.g., Rock Steady Boxing), which showed statistically significant improvements in balance, walking speed, strength, cognitive function, and psychoemotional state. Separately, the effects of motivational and social nature were noted,

which positively influenced the duration and sustainability of participation in the programmes. Analogously, A. Ferrusola-Pastrana *et al.* [8] proved in their prospective study that multimodal interventions – namely, those that combine aerobics, balance, and strength elements – effectively improve cognitive functioning, especially in patients with early signs of cognitive deficit.

Y. Xiao *et al.* [9] showed that motor-cognitive training provides a sustained improvement in both motor and cognitive functions, with an effect that lasts for at least two months after the intervention. The researchers noted an increase in neuroplasticity, which is the theoretical basis for the stability of the results achieved. At the same time, the researchers noted the need for longer-term follow-up studies.

Particular attention is drawn to studies where physical interventions were combined with the latest technologies, such as virtual reality, interactive interfaces, gamified exercises, or audio-visual cues. For instance, J. Rodríguez-Manzilla *et al.* [10] and J. Yu *et al.* [11] emphasised that VR allows integrating cognitive stimulation into a safe environment that simulates real life situations. The researchers noted that virtual reality helps to reduce apathy, increase motivation, and improve flexibility of thinking.

The analysis shows that the integration of cognitive tasks (dual-task, VR, audio/visual cues) into physical therapy systematically improves both motor and cognitive performance in patients with PD. However, most studies have short-term interventions (up to 12 weeks), are limited by sample size, or focus only on concrete cognitive domains. Additionally, the issue of adapting the intensity and format of training depending on the cognitive status of patients has not been resolved. Based on the identified gaps, the purpose of the present study was to evaluate the effectiveness of a modified physical therapy programme that would optimally accommodate the cognitive status of patients with PD, contributing to the improvement of their physical performance and overall quality of life.

Materials and Methods

The study was conducted at the Opora Kinesiotherapy Centre in Kyiv and the Department of Human Safety and Health of the National Technical University of Ukraine “Igor Sikorsky Kyiv Polytechnic Institute” from January to December 2024. Two groups of 10 people (5 women and 5 men) were formed. The average age of women was 64.8 years ($m = 0.64$), and that of men was 65 years. Experimental group received a modified physical therapy programme. Control group received a standard physical therapy programme without adaptation. Inclusion criteria were diagnosis of Parkinson's disease according to the criteria of the International Parkinson's and Movement Disorders Society (MDS), stage 2-3 on the Hoehn and Yahr scale, as well as the presence of mild or moderate cognitive impairment on the Montreal Cognitive Assessment (MoCA) scale within 18-25 points [12]. Exclusion criteria were severe dementia with a MoCA score of under 18, concomitant severe

somatic or mental illness, and refusal to take part in the study. The study was conducted in strict accordance with the Declaration of Helsinki [13] and following the European Commission's Ethics and Data Protection Guidelines [14]. All participants were informed about the potential risks that may arise from the presentation of their data in a scientific study, as well as about ensuring anonymity and confidentiality of information, and then signed a consent form to take part in the study.

The study methods included clinical neurological examination, assessment of cognitive status using the MoCA scale, assessment of quality of life using the SF-36 questionnaire [15], functional tests of balance and mobility,

such as the Timed Up and Go tests and the 6-minute walk test, and statistical analysis, including t-test for dependent and independent samples with a significance level of $p < 0.05$. The physical therapy programme for Parkinson's disease included a variety of exercises aimed at improving the patient's physical and psychological state (Table 1). This modified physical therapy programme for Parkinson's disease was designed to address the specific physical and psychological aspects of the disease. The programme was adapted individually to the patient's stage of the disease and physical capabilities. It was recommended to work under the supervision of a doctor, especially at the beginning of therapy.

Table 1. Exercises aimed at improving the patient's physical and psychological condition

Type of exercise	Purpose/effect	Examples of exercises
Warm-up and mobilisation of joints	Helps improve blood circulation and reduce muscle stiffness	Light circular movements of the arms, shoulders, ankles, head tilting back and forth and to the sides, stretching the neck, back, and hips.
Walking training	Prevention of "freezing" and development of stability	Walking with wide steps with an emphasis on arm movements, turning on the spot, crossing obstacles, walking to rhythmic music or a metronome.
Balance and stability exercises	Reducing the risk of falls	Standing on one leg (with or without support), transferring body weight, sitting down to a chair and standing up without hands.
Strength training exercises	Preservation of muscle strength and endurance	Squats against the wall, exercises with rubber expander, light exercises with dumbbells (0.5-2 kg).
Relaxation and breathing exercises	Stress relief and improved body control	Deep diaphragmatic breathing, progressive muscle relaxation.
Coordination exercises	Development of motor coordination	Throwing and catching the ball, changing the direction of movement on command, drawing shapes in the air with hands and feet.

Source: created by the authors of this study

The purpose of the initial examination of the study participants was to comprehensively determine the physical, motor, cognitive, and psychoemotional state of patients with Parkinson's disease. For this, patient history was taken, and the stage of the disease was determined according to the Hoehn and Yahr scale, which provided detailed data on the symptoms and course of the disease. Functional testing of patients included the following methods:

- Timed Up and Go (TUG) [16] – to assess the risk of falls;
- UPDRS (part III – motorics) [17] – to assess motor symptoms;
- Berg Balance Scale (BBS) [18] – to assess balance and control over body position;
- PDQ-39 (Parkinson's Disease Questionnaire) [19] and SF-36 (Short Form Health Survey) [15] – to assess the quality of life of patients, including physical and psycho-emotional well-being.

The cognitive status of patients was assessed using the Montreal Cognitive Assessment (MoCA) test [12], which helped to identify cognitive impairment and its severity. Based on the results obtained, a personalised physical therapy programme was developed, which accommodated the physical condition, level of motor deficit, the presence of cognitive impairment, and individual needs of patients.

The rehabilitation programme included:

1. Training in walking, balance, coordination, as well as strength and breathing exercises.

2. Modification of the intensity of physical activity according to the level of physical fitness and fatigue of patients.

3. Teaching compensation strategies, including techniques to overcome freezing.

4. Psycho-emotional support using relaxation and stress management techniques.

5. Involvement of relatives in the rehabilitation process to improve the effectiveness of the programme and social integration of patients.

Upon completion of the physical therapy programme, patients were re-evaluated using the same methods and tests: TUG, UPDRS (part III), BBS, PDQ-39, SF-36. The SF-36 and BBS were assessed three times (before treatment, 30 days after the start of rehabilitation activities, and 90 days after the completion of rehabilitation), which allowed tracking the dynamics of health changes throughout the rehabilitation process. This helped to compare the results before and after the therapeutic intervention, evaluate the effectiveness of the programme, and determine the degree of improvement in the physical, motor, and cognitive state of patients.

Results and Discussion

The study analysed the effectiveness of a modified physical therapy programme adapted to the cognitive state of patients with Parkinson's disease. Its features and differences from the standard programme conventionally used in treatment are presented in Table 2. The principal difference is the addition of a cognitive load in the therapy sessions.

This required the corresponding adaptation of rehabilitation interventions to activate executive functions, reduce

the burden on short-term memory, and improve cognitive-motor integration.

Table 2. Comparison of a standard and modified physical therapy programme for patients with Parkinson's disease

Element	Standard programme	Modified programme
Training structure	30-40 minutes, 3 times a week	40-45 minutes, 3-4 times a week
Physical activity	Exercises for balance, coordination, gait	Same exercises + cognitive tasks
Cognitive load	None	Double task (walking + counting, memorisation, etc.)
Types of cognitive tasks	-	Arithmetic on the move (counting in reverse), attention and memory tasks
Training method	Direct instructions	Slow learning strategy with multisensory stimulation
Response to cognitive profile	Not considered	Tasks are adapted according to the results of the MoCA test
Expected outcomes	Improved physical performance	Improved physical performance + cognitive function + improved quality of life

Source: compiled by the authors of this study

The following cognitive tasks were integrated into the modified programme:

- arithmetic exercises while moving (e.g., counting in reverse while walking);
- exercises to memorise words, symbols, or objects;
- spatial orientation with simultaneous physical activity;
- following instructions with a delayed response (executive function training).

The focus was on how cognitive impairment affects the choice of rehabilitation tools and methods, as well as the outcomes of therapy. Patients in the experimental group had an average MoCA score of 20-25 points, which

corresponds to mild to moderate cognitive impairment. The results showed that such cognitive-motor integration contributed not only to the improvement of physical indicators (TUG, UPDRS, BBS), but also to a decrease in the level of cognitive deficit. Patients demonstrated improvements in the domains of quality of life related to memory, communication, social interaction, and emotional stability as early as day 30 of the study (Table 3). Thus, the cognitive profile plays a key role in choosing the structure and intensity of a rehabilitation programme. Its consideration can improve the efficacy of the intervention, ensure better functioning in everyday life, and stabilise the psycho-emotional state of patients with Parkinson's disease.

Table 3. Mean SF-36 results before and after physical therapy

Group	Average age	SF-36 before (average)	SF-36 after 30 days	SF-36 after 90 days
Experimental (modified)	68.3 years	42.5 ± 6.1	60.8 ± 5.3	70.2 ± 4.7
Control (standard)	69.1 years	43.0 ± 5.9	51.2 ± 5.7	56.7 ± 5.1

Source: compiled by the authors of this study based on the conducted experiment

The table demonstrates that patients in the experimental group showed a substantial improvement in their general condition after 30 days of rehabilitation, as evidenced by an increase in the average SF-36 score by an average of 17 points. Such dynamics indicates the positive influence of an individualised approach to physical therapy, accounting for the specific features of the cognitive status of patients. In 90 days after the start of therapy, the SF-36 score reached an even greater level, adding more than 9 points, reflecting the continuation of positive dynamics. This suggests that the effect of the modified rehabilitation programme is not only maintained but also enhanced over time. Indicators of physical functioning, vitality, and social adaptation improved significantly. Patients also reported a reduction in anxiety, improved mood, and increased motivation to perform daily tasks. The control group, which received standard treatment, also showed some improvement, but it was less pronounced. The SF-36 score increased by 8.2 points after 30 days and by another 5.5 points after 90 days. The relative improvement shows that basic physical therapy has a positive effect, but its efficacy is inferior to the modified

approach. Statistical analysis of changes in SF-36 scores was performed using a paired t-test for matched samples. In the intervention group, a statistically significant improvement was found between all three measurement points ($p < 0.01$). In the control group, the changes were also significant, but less significant ($p < 0.05$), and the increase between 30 and 90 days tended to be statistically significant. The difference between the groups in the final SF-36 score (after 90 days) was 13.5 points in favour of the experimental group, which is a clinically significant indicator in terms of rehabilitation effectiveness. Apart from the quantitative data, it is also worth noting some of the qualitative aspects recorded during the study:

1. Patients in the experimental group demonstrated better emotional engagement in the rehabilitation process, were more active and motivated.

2. Many of the patients reported improved sleep, reduced fatigue and anxiety.

3. There was greater adherence to physical therapy, which is presumably a result of the personalised approach and the integration of cognitive stimulation into the exercises.

To evaluate the effectiveness of the modified physical therapy programme in patients with Parkinson's disease, the study compared the average scores of functional tests before and after the rehabilitation course. Table 4 demonstrates changes in key parameters such as mobility, balance,

and risk of falls measured using standardised scales (TUG, BBS, UPDRS-III, etc.). The analysis of the results allows assessing the dynamics of the physical condition of patients in the experimental group and confirming the effectiveness of the proposed approach to therapy.

Table 4. Average results of functional tests for balance and mobility of the experimental group before and after physical therapy

No.	Indicator	Normative value / Description	Result before rehabilitation	Result after rehabilitation
1	Timed Up and Go (TUG) (seconds)	<10 seconds – normal for healthy individuals; >14 seconds – increased risk of falling	16.8 ± 0.7 s	13.2 ± 0.5 s
2	UPDRS (part III - motorics) (points)	0 – no symptoms; the greater the score, the worse the condition	42.5 ± 2.1 pts	35.4 ± 1.9 pts
3	Berg Balance Scale (BBS) (points)	56 points – excellent balance; <45 points – high risk of falling	38.5 ± 1.5 pts	41.8 ± 1.3 pts
4	PDQ-39 (life quality index) (%)	0% – best quality of life, 100% – worst quality of life	59.3% ± 3.4%	48.7% ± 3.1%
5	MoCA (Montreal Cognitive Assessment)	<26 points – cognitive impairment; maximum – 30 points	22.1 ± 1.2 pts	25.3 ± 1.1 pts

Source: compiled by the authors of this study

All indicators show positive dynamics after completing a modified rehabilitation programme. The reduction in TUG time and UPDRS scores reflects an improvement in motor function and mobility. An increase in BBS reflects improved balance and reduced risk of falls. A significant decrease in the PDQ-39 index and an increase in MoCA scores reflect an improvement in the quality of life and cognitive status of patients.

The results showed the benefits of a modified rehabilitation programme that accommodates the cognitive status of patients. This approach not only improved physical performance but also positively influenced the overall psycho-emotional well-being and social activity. Consideration of cognitive impairment in treatment planning allows creating a more effective model for managing patients with Parkinson's disease that meets the principles of personalised medicine. Thus, the study results confirmed the high effectiveness of individualised physical therapy adapted to the cognitive state of patients.

The findings of the present study confirmed that the adaptation of physical therapy programmes to the cognitive status of patients with Parkinson's disease can markedly improve functional performance and quality of life. These data are consistent with the findings presented by G. Abbruzzese *et al.* [20], who proved the effectiveness of using cognitive-oriented strategies in physical rehabilitation, particularly through the involvement of executive functions during motor learning. This approach contributed to the improvement of both motor and cognitive functions. I. Litvan *et al.* [21] also emphasised the significance of integrating cognitive tasks into the process of physical therapy in Parkinson's disease. The researchers noted that patients who took part in multicomponent rehabilitation programmes showed improvements not only in motor activity but also in cognitive domains such as attention and memory. The findings of the present study confirmed these findings: patients in the intervention group who performed

cognitive exercises during motor activity showed greater scores on the MoCA tests compared to the control group receiving standard therapy.

M. Avenali *et al.* [22] obtained comparable findings, focusing on the long-term effectiveness of physical therapy in patients with PD who have mild cognitive deficits. During the six-month follow-up period, statistically significant improvements in attention, information processing speed, and spatial orientation were recorded. Thus, physical interventions may have a preventive function against further cognitive deterioration. This is consistent with the current data on improvements in attention and orientation in the experimental group. According to a review by F. da Silva *et al.* [23], the most pronounced cognitive improvement in PD is observed when using combined aerobic and cognitive programmes. The researchers emphasised that the most efficacious protocols include tasks for attention, memory, and flexibility of thinking, which confirms the effectiveness of the multicomponent rehabilitation employed in the present study.

The current study demonstrated a significant improvement in balance, gait stability, and overall quality of life in the experimental group. D. Ferrazzoli *et al.* [24] obtained analogous findings, investigating the effect of multisensory stimulation in combination with motor training on patients with PD. The researchers noted that the combination of physical and cognitive activity has a synergistic effect, which is manifested in more pronounced functional improvements.

In their review, Z. Li *et al.* [25] confirmed that dual-task training markedly improves gait quality, balance and cognitive performance, emphasising the role of these programmes in increasing functional autonomy. The researchers noted that reducing the cognitive load during gait contributes to more effective postural control. In this context, it is recommended to adapt training to the individual motor and cognitive characteristics of the patient. H. Gaßner *et*

al. [26] showed that even conventional physiotherapy and treadmill training improve dual-task walking ability, but according to the present study, supplementing the programme with cognitive modules enhances this effect. Notably, in both studies, the researchers concluded that without the cognitive element, improvements may be limited in time.

In contrast to conventional physical therapy, which is mainly focused on overcoming motor symptoms, modern approaches – both in the present study and in A. Petrelli *et al.* [27] – have demonstrated the benefits of integrating cognitive components. The researchers noted that a decrease in cognitive reserve can negatively affect the effectiveness of rehabilitation, and therefore individualising programmes based on the cognitive profile is a key success factor. The present study confirmed this hypothesis: patients with severe cognitive impairment who underwent an adapted programme showed marked improvement in both motor and cognitive areas.

Thus, the findings are in line with current trends in rehabilitation medicine and confirm the findings of earlier studies. At the same time, in contrast to a series of studies where cognitive exercises were considered as an auxiliary element, in the modified programme they became an integral part of therapy, which probably provided a more stable clinical effect. This suggests the feasibility of introducing such programmes into clinical practice to improve the quality of life of patients and optimise rehabilitation outcomes.

Conclusions

The evaluation of the effectiveness of a modified physical therapy programme adapted to the cognitive status of patients with Parkinson's disease showed that the use of an individualised programme that included cognitive components enabled a substantial improvement in the physical condition of patients, a reduction in cognitive deficit, and an increase in their quality of life. The findings revealed that patients who took part in the modified programme showed a more pronounced improvement in all key indicators compared to the control group. Specifically, an improvement in motor function (reduced UPDRS III scores) was observed, as well as reduced TUG test time, improved BBS scores, a pronounced increase in quality-of-life domains (SF-36), and a decrease in symptom severity according to the PDQ-39 questionnaire. Additionally, patients in the experimental group showed an improvement in cognitive function, which further emphasises the comprehensive therapeutic effect of the adapted programme. The study found that the integration of cognitive components

into the physical therapy programme creates an added positive effect, which lies not only in improving physical performance but also in reducing cognitive impairment. The following cognitive elements were used in the study: performing arithmetic tasks in motion (counting backwards), exercises to memorise visual and verbal stimuli during physical activity, spatial orientation with simultaneous motor activity, and the use of delayed response instructions to train executive functions and control attention. These cognitive-motor exercises were aimed at stimulating short-term memory, concentration, information processing speed, and flexibility of thinking. As a result, patients in the experimental group demonstrated not only an improvement in physical parameters (TUG, UPDRS, BBS), but also positive dynamics in the subjective PDQ-39 quality of life scale, particularly in the domains of memory, emotional state, communication, and social interaction. The PDQ-39 index decreased from $59.3\% \pm 3.4\%$ to $48.7\% \pm 3.1\%$, which reflects an improvement in cognitive functioning and psycho-emotional adaptation of patients. Thus, cognitive integration in physical therapy was effective in improving both motor and higher mental functions.

Thus, the findings of the presented study reflect the feasibility of a tailored approach to the rehabilitation of patients with Parkinson's disease, particularly the value of accommodating the cognitive status. Conceptually, the findings emphasised the significance of an interdisciplinary approach in the rehabilitation of Parkinson's patients. They demonstrated that the combination of physical therapy with cognitive tasks can become an indispensable element of standard rehabilitation interventions for this category of patients. The use of cognitive training methods not only improves physical condition but also helps to reduce psycho-emotional difficulties, contributing to an increase in overall quality of life. Promising areas for further research include a detailed investigation of the optimal formats of cognitive motor training, adaptation of rehabilitation programmes depending on the severity of cognitive impairment, and long-term follow-up monitoring of the outcomes achieved.

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Conflict of Interest

None.

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Модифікація програми фізичної терапії з урахуванням когнітивних порушень у пацієнтів із хворобою Паркінсона

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Анотація. Хвороба Паркінсона є хронічним прогресуючим захворюванням, що супроводжується руховими та когнітивними порушеннями, які значно ускладнюють процес реабілітації та знижують якість життя пацієнтів. Метою даного дослідження було оцінити ефективність модифікованої програми фізичної терапії, адаптованої з урахуванням когнітивного статусу хворих. У дослідженні взяли участь 10 пацієнтів, які були розподілені на дві рівні групи: основну ($n = 5$), що проходила адаптовану програму з мультисенсорною стимуляцією, когнітивно-моторними вправами та уповільненим навчанням, і контрольну ($n = 5$), яка отримувала стандартну фізичну терапію. Для об'єктивної оцінки використовували тести: Timed Up and Go (TUG), UPDRS (моторна частина), Berg Balance Scale (BBS), PDQ-39 та SF-36. У результаті пацієнти основної групи продемонстрували позитивну динаміку за всіма показниками. Зокрема, час у тесті TUG зменшився з $16,8 \pm 0,7$ с до $13,2 \pm 0,5$ с, бал за UPDRS знизився з $42,5 \pm 2,1$ до $35,4 \pm 1,9$, показники рівноваги за BBS зросли з $38,5 \pm 1,5$ до $41,8 \pm 1,3$, а індекс якості життя за PDQ-39 покращився з $59,3 \pm 3,4$ % до $48,7 \pm 3,1$ %. Отримані результати свідчать про доцільність індивідуалізації реабілітаційних програм із врахуванням когнітивного профілю пацієнтів. Додавання когнітивних завдань до фізичної терапії не лише покращує моторні функції, а й сприяє зниженню когнітивного дефіциту та підвищенню загальної якості життя. Практична цінність дослідження полягає в можливості впровадження модифікованої програми фізичної терапії в клінічну практику, зокрема для мультидисциплінарних команд, що працюють у сфері нейрореабілітації, фізичних терапевтів, реабілітологів та лікарів-неврологів. Запропонований підхід може стати ефективним інструментом для підвищення функціональної незалежності пацієнтів з хворобою Паркінсона

Ключові слова: реабілітація; якість життя; мультисенсорна стимуляція; моторні симптоми; немоторні симптоми; когнітивна дисфункція



Modern strategies for lipid-lowering therapy in patients with ischaemic heart failure and concomitant metabolic pathology

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Abstract. Given the increasing prevalence of cardiovascular diseases and their complications, the study of effective approaches to lipid-lowering therapy, especially in patients with comorbid conditions, is a highly relevant task in modern cardiology. The aim of this study was to analyse modern therapeutic strategies for lowering low-density lipoprotein cholesterol (LDL-C) in patients with chronic heart failure (CHF) due to ischaemic heart disease (IHD), with concomitant obesity and type 2 diabetes mellitus. We also evaluated their effectiveness and safety, taking into account the latest clinical data. The study included 225 patients with ischaemic CHF, who were divided into four groups according to the presence of metabolic disorders. The effectiveness of lipid-lowering therapy with rosuvastatin (20-40 mg) and ezetimibe was assessed. Rosuvastatin monotherapy at a dose of 20 mg enabled only partial achievement of target LDL-C levels (< 1.4 mmol/L): these were reached by 44% of patients in the first group, 56% in the second, 58% in the third, and 66% in the fourth. Some patients independently discontinued the medication. Further escalation of therapy (increasing the dose of rosuvastatin or adding ezetimibe) significantly improved lipid profile parameters. Combined therapy with rosuvastatin 20 mg and ezetimibe 10 mg proved to be highly effective in patients at extreme risk, allowing them to achieve target LDL-C levels (< 1.0 mmol/L) in 95.5% of cases. Achieving target low-density lipoprotein cholesterol levels in patients with chronic heart failure and ischaemic heart disease, especially in the presence of concomitant type 2 diabetes mellitus and obesity, is a complex task. Statin monotherapy is often insufficiently effective, which requires the use of combined hypolipidaemic therapy. The value of this work lies in confirming the need for an individualised approach to the treatment of dyslipidaemia and the importance of increasing patient adherence to the prescribed therapy to achieve optimal results

Keywords: chronic heart failure; ischaemic heart disease; type 2 diabetes mellitus; obesity; rosuvastatin; ezetimibe; low-density lipoprotein cholesterol

Introduction

Chronic heart failure (CHF) remains one of the leading causes of morbidity and mortality worldwide, significantly impairing patients' quality of life and imposing a substantial burden on healthcare systems. Studying effective therapeutic strategies for patients with ischaemic heart disease (IHD)-related CHF and concomitant metabolic disorders, such as obesity and type 2 diabetes mellitus, is of particular relevance. According to studies by K. Nakamura *et al.* [1] and S.S. Jankauskas *et al.* [2], this patient group exhibits a more complex clinical course and an increased risk of adverse

outcomes, which necessitates the urgent need for optimising their treatment, particularly in correcting dyslipidaemia.

Modern medical science is actively investigating the impact of dyslipidaemia on the progression of cardiovascular diseases, especially in patients with comorbid conditions [3, 4]. The accumulation of low-density lipoprotein cholesterol (LDL-C) in arterial walls, according to findings by J. Yu *et al.* [5] and E. Raschi *et al.* [6], is a key pathogenic factor in the development of atherosclerosis, which is the primary cause of IHD and a factor that worsens the

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course of CHF. Recent studies emphasise the importance of aggressive LDL-C control in this population. For example, a review by Y.H. Mak *et al.* [7] showed that achieving target LDL-C levels significantly reduces the risk of cardiovascular events in patients with CHF and IHD, even in the presence of diabetes mellitus. They highlight the need for intensive hypolipidaemic therapy, which often requires combined approaches. A study by K. Wróbel-Nowicka *et al.* [8] focused on the role of inflammation and oxidative stress, exacerbated by obesity and diabetes, in worsening dyslipidaemia and the progression of CHF. The authors concluded that standard statin monotherapy might be insufficient to achieve target levels in patients with significant metabolic disturbances.

Ukrainian researchers were also actively involved in studying this problem. A study by M. Shved *et al.* [9] examined the features of the lipid profile in patients with ischaemic CHF against the background of metabolic syndrome. The authors found that the combination of CHF, IHD, and type 2 diabetes mellitus (DM)/obesity leads to more pronounced dyslipidaemic shifts, requiring earlier and more intensive intervention. The work of O.A. Koval *et al.* [10] confirmed the effectiveness of using high-dose statins in patients with IHD and CHF, but at the same time pointed out a significant percentage of patients who do not achieve target LDL-C levels, which indicates the need for additional lipid-lowering drugs. International guidelines, such as the ESC Guidelines on cardiovascular disease prevention in clinical practice [11], also emphasise the importance of an individualised approach to LDL-C reduction, especially in patients with very high and extreme cardiovascular risk, which includes patients with CHF, IHD, and concomitant metabolic pathology. The guidelines recommend using combinations of statins with ezetimibe and/or PCSK9 inhibitors if target levels are not reached with maximum doses of statins. The study by G. Iannuzzo *et al.* [12] investigated the effect of various hypolipidaemic strategies on myocardial functional status in patients with CHF. The authors found that intensive LDL-C reduction not only improves the lipid profile but can also positively affect echocardiography parameters, especially in obese patients.

Despite significant advances in understanding the pathogenesis and treatment of dyslipidaemia, aspects of the long-term effectiveness and safety of combined hypolipidaemic strategies in the subgroup of patients with ischaemic CHF, complicated by concomitant metabolic disorders, remain understudied. Specifically, their impact on treatment adherence and clinical outcomes in a real-world clinical setting is not well-documented. In addition, there is a lack of data on the optimal sequence and timing of adding different classes of lipid-lowering drugs in these complex clinical scenarios, which justifies the need for further research. The aim of this study was to analyse modern therapeutic strategies aimed at lowering low-density lipoprotein cholesterol levels in patients with chronic heart failure due to ischaemic heart disease with

concomitant obesity and type 2 diabetes mellitus, and to evaluate their effectiveness and safety based on the latest clinical research.

Materials and Methods

The study covered 225 patients with CHF caused by IHD who were treated in the cardiology department of Kharkiv City Council Clinical Hospital No. 27 between 2021 and 2023. Depending on the presence of metabolic disorders, the participants were divided into four groups. The first group consisted of 75 patients with CHF and IHD who also had type 2 diabetes mellitus and obesity. The second group included 50 patients with CHF against the background of IHD, accompanied by type 2 diabetes mellitus. The third group consisted of 50 patients with CHF and IHD and concomitant obesity. The fourth group, the comparison group, consisted of 50 patients with ischaemic CHF without any metabolic disorders. All groups of subjects were comparable in terms of age and gender.

The patients were examined using clinical, laboratory and instrumental methods in accordance with the recommendations of the European Society of Cardiology (ESC) [11], the American Diabetes Association (ADA) [13] and the International Diabetes Federation (IDF) [14]. Laboratory analyses and instrumental studies were performed at the municipal non-profit enterprise “City Clinical Hospital No. 27” of the Kharkiv City Council and the Central Research Laboratory of the Kharkiv National Medical University. The diagnosis of ischaemic heart disease was verified according to the standards of the ESC [11], the European Society of Cardiology [15], and the unified clinical protocol “Stable Ischemic Heart Disease” [16], approved by Order of the Ministry of Health of Ukraine No. 2857 [17].

The diagnosis of chronic heart failure was established according to the classification of the Ukrainian Association of Cardiology [18], and the functional class was determined according to the Criteria Committee of the New York Heart Association [19]. The diagnosis of type 2 diabetes mellitus was based on the criteria of the unified clinical protocol for primary and specialised medical care “Type 2 diabetes in adults” [20]. All patients included in the study had confirmed cardiovascular disease, which, according to current international and national clinical guidelines, automatically classified this cohort of patients as a group at very high cardiovascular risk.

Biochemical analysis was used to assess the lipid profile of patients in heparinised blood serum. Total cholesterol (TC) and high-density lipoprotein cholesterol (HDL-C) were determined by the peroxidase method using “Cholesterol Liquicolor” reagents (Human, Germany). The amount of triglycerides (TG) was determined by an enzymatic-colorimetric method using the “Triglycerides 105 GPO” kit (Human, Germany). Based on the data obtained, the atherogenicity coefficient (AC) was calculated using the formula: $AC = (TC - HDL - C) / HDL - C$. The level of VLDL-C was calculated using the following ratio: $VLDL - C = TG / 2.2 \times 0.45$ (mmol/L). The concentration of low-density

lipoproteins (LDL) was determined using the Friedewald formula: $LDL-C = TC - (VLDL-C + HDL-C)$ (mmol/L).

The licensed software STATISTICA® for Windows 6.0 (StatSoft Inc.) was used for statistical analysis of the obtained data. Quantitative data were presented as mean (M) and standard deviation (SD). To compare groups based on quantitative indicators, the distribution of which did not contradict the normal distribution, Student's t-test was used. Differences were considered statistically significant at a probability of error of less than 0.05 ($p < 0.05$). For each study group, the absolute (n) and relative (%) frequencies of qualitative indicators were calculated. To assess statistically significant differences in achieving target levels of low-density lipoprotein cholesterol (LDL-C) between the study groups, Pearson's χ^2 test was performed at each stage of therapy.

The study was approved by the Ethics and Bioethics Committee of Kharkiv National Medical University (protocol No. 2 of 3 February 2020). All participants were informed about the risks associated with the study and the publication of data, and were guaranteed confidentiality of

data. They then provided written informed consent to participate. The study was conducted in accordance with the ethical principles of the Declaration of Helsinki "Ethical principles for medical research involving human participants" [21] and the Universal Declaration on Bioethics and Human Rights (UNESCO) [22].

Results and Discussion

In accordance with the study design, the assessment of patients' lipid profile indicators was carried out in several consecutive stages, which made it possible to track changes in the lipid profile and the effectiveness of the prescribed therapy step by step. At the first stage, in the hospital, a baseline lipid profile was determined for 100% of the included patients, which became the starting point for further therapeutic interventions and evaluation of their effectiveness. The data obtained at this stage on the initial levels of low-density lipoprotein cholesterol in the study groups are presented in Table 1, providing a visual representation of the patients' baseline condition prior to the initiation of active lipid-lowering therapy.

Table 1. Initial levels of low-density lipoprotein cholesterol in the study groups of patients

Parameter, measurement units	Patients with CHF			
	IHD + type 2 DM + obesity (n = 75)	IHD + type 2 DM (n = 50)	IHD + obesity (n = 50)	IHD without metabolic pathology (n = 50)
mmol/L	4.68 ± 0.05	2.74 ± 0.04	2.94 ± 0.06	2.35 ± 0.04

Source: developed by the author based on own research

The status of patients with very high cardiovascular risk necessitated aggressive and targeted treatment to prevent further cardiovascular events. In accordance with treatment standards, a detailed discussion was held with all patients regarding the importance of lifestyle modification, which included recommendations on diet, increased physical activity, and cessation of harmful habits. Simultaneously, patients were prescribed a starting dose of hypolipidaemic therapy with rosuvastatin at 20 mg per day. After 8 weeks, the patients' lipid profiles were examined to assess whether they had achieved the target LDL-C levels (< 1.4 mmol/L). Among the patients studied, 33 individuals (44%) in the first group, 28 individuals (56%) in the second group, 29 individuals (58%) in the third group, and 33 individuals (66%) in the fourth group reached the target LDL-C levels. The data is presented in Figure 1. It should be noted that among the patients examined, 9 individuals in the first group, 7 in the second group, 6 in the third group, and 7 in the fourth group independently discontinued taking rosuvastatin.

Given that the target LDL-C levels were not achieved, a group of extreme-risk patients was identified among the participants. This group included 8 patients from the first group, 5 from the second group, 6 from the third group and 3 from the fourth group. These patients were prescribed 10 mg of ezetimibe in addition to their existing 20 mg rosuvastatin therapy. The remaining patients had their rosuvastatin dose increased to 40 mg per day. The next stage involved evaluating the lipid profile parameters

after another 8 weeks. In the extreme-risk group, target LDL-C levels (< 1.0 mmol/L) were achieved by 21 patients, representing 95.5% of the group. In one patient (4.5%), the target LDL-C level was not reached, and therapy with a combination of rosuvastatin and a PCSK9 inhibitor was recommended. However, the outcome of this prescribed therapy could not be evaluated because the patient declined the proposed regimen due to financial reasons. Among the patients who took rosuvastatin at a dose of 40 mg, the following percentages achieved the target LDL-C levels: 5 individuals (31.25%) in the first group, 4 individuals (25%) in the second group, 6 individuals (35.29%) in the third group, and 8 individuals (34.78%) in the fourth group. This is shown in Figure 2.

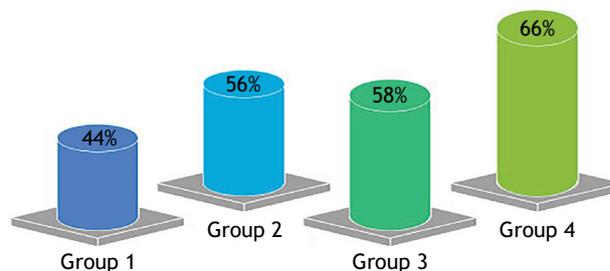


Figure 1. Achievement of target LDL-C levels in patient groups after the first stage of therapy

Notes: therapy with rosuvastatin 40 mg

Source: developed by the author based on own research

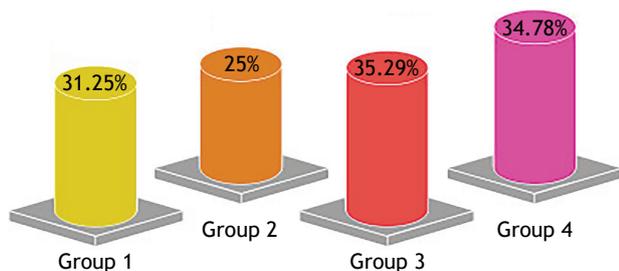


Figure 2. Achievement of target LDL-C levels in patient groups after the second stage of therapy

Notes: therapy with rosuvastatin 40 mg

Source: developed by the author based on own research

Individuals who had achieved the target LDL-C levels were recommended to take rosuvastatin at a daily dose of 40 mg for an extended period. Other patients were given ezetimibe at a daily dose of 10 mg in addition to lipid-lowering therapy. As a result of the selected regimen, target LDL-C levels were achieved in patients in all groups, except for those who voluntarily refused to take combination drugs (5 patients in total). To assess statistically significant differences in achieving target low-density lipoprotein cholesterol (LDL-C) levels between the study groups, Pearson's χ^2 test was performed at each stage of therapy. At the first stage, when using monotherapy with rosuvastatin at a dose of 20 mg, $\chi^2 = 6.29$; $p = 0.098$. This indicates a tendency towards statistically significant differences between the groups, although the p-value obtained did not reach the generally accepted level of significance ($p < 0.05$). It is possible that the influence of comorbid conditions, in particular type 2 diabetes mellitus and obesity, partially reduces the effectiveness of basic statin therapy. In the second stage, after increasing the dose of rosuvastatin to 40 mg, a further increase in differentiation between the groups was observed ($\chi^2 = 7.63$; $p = 0.054$). This result is close to the threshold of statistical significance, which may indicate the insufficient universality of this approach in patients with severe metabolic disorders. In the third stage, when using combination therapy with rosuvastatin 20 mg + ezetimibe 10 mg in patients at extreme risk, the values obtained were $\chi^2 = 6.63$; $p = 0.084$. Despite high clinical efficacy, the statistical difference between the groups remained insignificant, which may be explained by the almost universal achievement of the therapeutic goal in all groups. The data obtained indicate the high efficacy of combined lipid-lowering therapy regardless of the presence of comorbid pathology.

The results of the statistical analysis clearly emphasise the need for a personalised approach to the choice of lipid-lowering strategy in patients with cardiovascular disease and concomitant metabolic disorders. Initial monotherapy with rosuvastatin at a moderate dose showed limited effectiveness in achieving target LDL-C levels, especially in patients with comorbid conditions such as type 2 diabetes mellitus and obesity, indicating a more complex pathogenesis of dyslipidaemia in this category of patients. At the same time, the use of combined lipid-lowering therapy has

shown significantly higher clinical efficacy and is potentially capable of neutralising the negative impact of metabolic disorders on achieving the LDL-C target levels recommended by international guidelines, which opens up prospects for improving the long-term prognosis of such patients.

The results of the study demonstrated the difficulty of achieving target LDL-C levels in patients with CHF against the background of IHD with comorbid metabolic disorders, such as type 2 diabetes mellitus and obesity. This is confirmed by many other studies conducted in different countries [23, 24]. As the presented experiment showed, in the first stage, monotherapy with rosuvastatin at a dose of 20 mg allowed achieving target LDL-C levels only in a relatively small proportion of patients in all groups (44%, 56%, 58% and 66%, respectively). These results indicate that a significant proportion of very high-risk patients require more intensive lipid-lowering therapy to achieve the recommended targets. The relatively higher percentage of target levels achieved in the group of patients without metabolic disorders (group 4) highlights the negative impact of comorbidity on the effectiveness of standard statin therapy, which is likely related to more pronounced dyslipidaemia and insulin resistance in patients with type 2 diabetes and obesity. The data obtained are consistent with current recommendations and confirm the conclusions of the authors, who emphasise the need to intensify lipid-lowering therapy in patients with very high cardiovascular risk. In particular, the results of the current study, demonstrating the limited effectiveness of initial monotherapy with rosuvastatin in patients with ischaemic heart disease complicated by type 2 diabetes and obesity, fully correlate with the findings of J. Gu *et al.* [25], who argue that only the use of combined strategies, including high-dose statins with ezetimibe and/or PCSK9 inhibitors, allows aggressive LDL-C target levels to be achieved in such complex patient categories.

It is important to note the significant proportion of patients who independently discontinued taking rosuvastatin (6 to 9 individuals in each group). Low adherence to treatment is a serious problem in clinical practice and can significantly limit the effectiveness of any therapy, especially in patients with chronic diseases requiring long-term medication. The data presented in this study do not conflict with E. Danielson *et al.* [26] and D. Berardinelli *et al.* [27], who associate low adherence with a lack of knowledge about the disease and its risks, leading to delays in seeking help and insufficient participation in treatment. Patients need more information and support from healthcare professionals, as awareness of the threat of the disease can motivate patients to adhere to treatment, but sustained adherence requires ongoing interaction and support.

Further escalation of lipid-lowering therapy by increasing the dose of rosuvastatin to 40 mg or adding ezetimibe led to improved lipid profile parameters. In the extreme risk group, the combination of 20 mg rosuvastatin and 10 mg ezetimibe was highly effective, allowing the vast majority of patients (95.5%) to achieve target LDL-C levels (< 1.0 mmol/L). This highlights the importance of

combination therapy in achieving sustained treatment goals in patients at highest risk, which is supported by the findings of other researchers. According to a meta-analysis by Y.M. Ah *et al.* [28], statin therapy in combination with ezetimibe is more effective in lowering LDL-C than high-intensity statin monotherapy. In addition, combination therapy is often associated with better safety and tolerability, indicating the advantage of this approach for achieving target LDL-C levels. The effectiveness of combination therapy in the context of comorbidities was also confirmed in a study by M. Orel & L. Martynyuk [29].

However, in patients who only had their rosuvastatin dose increased to 40 mg, the percentage of achieving target LDL-C levels remained insufficient (31.25%, 25%, 35.29% and 34.78% in the respective groups). This indicates that in many patients with CHF against the background of IHD and metabolic disorders, high-dose statin monotherapy may be insufficient to achieve the recommended goals, and the addition of drugs with a different mechanism of action, such as ezetimibe, is required, which is also considered by M. Leosdottir *et al.* [30]. In addition to recognising ezetimibe as an effective component of lipid-lowering therapy, researchers also emphasise a significant reduction in the risk of future cardiovascular events.

The successful achievement of LDL-C target levels after adding ezetimibe to rosuvastatin in most patients who did not achieve their goals on monotherapy or moderate doses of statins confirms the synergistic effect of combined lipid-lowering therapy. However, the refusal of even a single to escalate to PCSK9 inhibitors due to financial constraints highlights the importance of the economic accessibility of modern, highly effective drugs.

Conclusions

The study was aimed at analysing current therapeutic strategies for lowering low-density lipoprotein cholesterol levels in patients with chronic heart failure against a background of ischaemic heart disease with concomitant obesity and type 2 diabetes mellitus, as well as to evaluate their efficacy and safety based on the latest clinical data. The objective of the study was successfully achieved through a systematic analysis of the impact of various lipid-lowering approaches in a complex cohort of patients. During the study, 225 patients with chronic heart failure of ischemic origin were examined and divided into four groups according to the presence of metabolic disorders, which allowed a detailed evaluation of the impact of comorbidity on the lipid profile and response to therapy. In the first stage, initial monotherapy with rosuvastatin at a dose of 20 mg was not effective enough, achieving target low-density lipoprotein cholesterol levels (< 1.4 mmol/L) in only 44-66% of patients depending on the group, with

the worst results observed in the group with multiple metabolic disorders. This highlighted the difficulty of achieving target levels in this category of patients and the impact of comorbidities on the effectiveness of standard therapy. In subsequent stages, therapy was escalated, including increasing the dose of rosuvastatin to 40 mg or adding ezetimibe. It is important to note that in the extreme risk group, the combination of 20 mg rosuvastatin and 10 mg ezetimibe demonstrated exceptional efficacy, allowing aggressive target levels of low-density lipoprotein cholesterol (< 1.0 mmol/L) to be achieved in 95.5% of patients. However, a significant proportion of patients were found to have discontinued rosuvastatin on their own, indicating a problem with low treatment adherence.

The results obtained convincingly demonstrate that achieving strict LDL cholesterol targets in patients with chronic heart failure of ischaemic origin, especially in the presence of comorbid type 2 diabetes mellitus and obesity, is an ambitious but achievable only with the use of intensified, namely combined, lipid-lowering strategies. Statin monotherapy, even at high doses, is often insufficient for this group of patients, confirming the need for a multimodal approach. The high efficacy of the combination of rosuvastatin and ezetimibe in achieving aggressive treatment goals in patients at highest risk underscores its key role in modern cardiology practice. These findings are consistent with recent international guidelines and meta-analyses, which indicate the superiority of combination therapy over high-intensity statin monotherapy in achieving target low-density lipoprotein cholesterol levels and improving cardiovascular outcomes. An important aspect that requires further attention is the problem of low patient adherence to prescribed therapy, which can negate the effectiveness of the most modern treatment approaches. Given the results obtained, promising areas for further research should include studying the long-term efficacy and safety of various combinations of lipid-lowering drugs in patients with CHF and metabolic disorders, as well as the development and implementation of effective strategies to increase patient adherence to treatment. Particular attention should be paid to studying the impact of the economic accessibility of drugs on compliance and further clinical outcomes.

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Conflict of Interest

None.

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Сучасні стратегії гіполіпідемічної терапії у хворих з серцевою недостатністю ішемічного генезу з супутньою метаболічною патологією

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Анотація. З огляду на зростаючу поширеність серцево-судинних захворювань та їх ускладнень, вивчення ефективних підходів до ліпідознижуючої терапії, особливо у пацієнтів із коморбідними станами, є вкрай актуальним завданням сучасної кардіології. Метою роботи було проаналізувати сучасні терапевтичні стратегії, спрямовані на зниження рівня холестерину ліпопротеїнів низької щільності (ХС ЛПНЩ) у пацієнтів з хронічною серцевою недостатністю (ХСН) на тлі ішемічної хвороби серця (ІХС) з супутнім ожирінням та цукровим діабетом 2 типу, а також оцінити їх ефективність та безпеку з урахуванням останніх клінічних даних. Дослідження включило 225 пацієнтів з ХСН ішемічного генезу, яких розділили на чотири групи відповідно до наявності метаболічних порушень, та оцінювали ефективність ліпідознижуючої терапії розувастатином (20–40 мг) та езетимібом. Монотерапія розувастатином у дозі 20 мг дозволила досягти цільових рівнів ХС ЛПНЩ (<1,4 ммоль/л) лише у 44 % пацієнтів 1 групи, 56 % – 2 групи, 58 % – 3 групи та 66 % – 4 групи, причому частина пацієнтів самостійно припинила прийом препарату. Подальша ескалація терапії (збільшення дози розувастатину або додавання езетимібу) значно покращила показники ліпідного профілю, а комбінована терапія розувастатином 20 мг та езетимібом 10 мг виявилася високоефективною у пацієнтів групи екстремального ризику, дозволивши досягти цільових рівнів ХС ЛПНЩ (< 1,0 ммоль/л) у 95,5 % випадків. Досягнення цільових рівнів холестерину ліпопротеїдів низької щільності у пацієнтів з хронічною серцевою недостатністю та ішемічною хворобою серця, особливо за наявності супутнього цукрового діабету 2 типу та ожиріння, є складним завданням, де монотерапія статинами часто є недостатньо ефективною, що потребує застосування комбінованої гіполіпідемічної терапії. Цінність роботи полягає в підтвердженні необхідності індивідуалізованого підходу до лікування дисліпідемії та важливості підвищення прихильності пацієнтів до призначеної терапії для досягнення оптимальних результатів

Ключові слова: хронічна серцева недостатність; ішемічна хвороба серця; цукровий діабет 2 типу; ожиріння; розувастатин; езетиміб; холестерин ліпопротеїдів низької щільності

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