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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/2.2×0.45 (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 fours 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 fours 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 fours 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 fours group. This is shown in Figure 2.

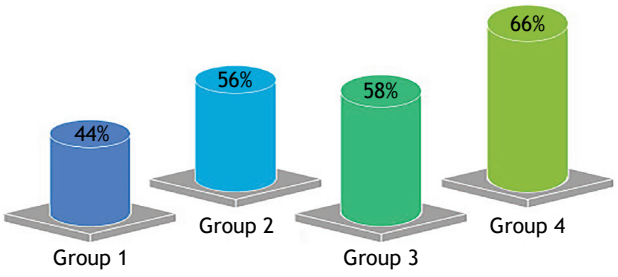

Figure 1. Achievement of target LDL-C levels in patient groups after the first stage of therapy

Notes: therapy with rosuvastatin 40 mg

Source: developed by the author based on own research

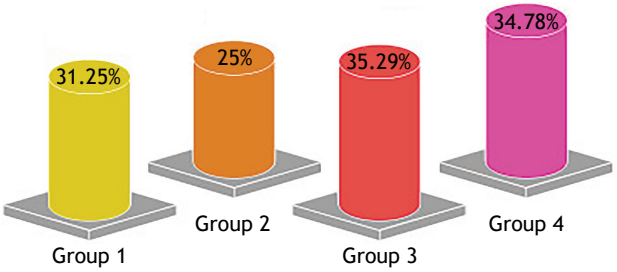

Figure 2. Achievement of target LDL-C levels in patient groups after the second stage of therapy
Notes: therapy with rosuvastatin 40 mg
Source: developed by the author based on own research

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